Clinical trial results:
Combined Phase 2b/3, Double-Blind, Randomized, Placebo-Controlled Studies Evaluating the Efficacy and Safety of Filgotinib in the Induction and Maintenance of Remission in Subjects with Moderately to Severely Active Ulcerative Colitis

Summary

EudraCT number	2016-001392-78
Trial protocol	HU GB BE SE AT PT GR SK IS ES BG DE NL HR NO IT
Global end of trial date	31 March 2020

Results information

Result version number	v1 (current)
This version publication date	08 April 2021
First version publication date	08 April 2021

Trial information

Trial identification

Sponsor protocol code	GS-US-418-3898

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02914522
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Gilead Sciences
Sponsor organisation address	333 Lakeside Drive, Foster City, CA, United States, 94404
Public contact	Gilead Clinical Study Information Center, Gilead Sciences, GileadClinicalTrials@gilead.com
Scientific contact	Gilead Clinical Study Information Center, Gilead Sciences, GileadClinicalTrials@gilead.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	31 March 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 March 2020
Global end of trial reached?	Yes
Global end of trial date	31 March 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy of filgotinib as compared with placebo in establishing endoscopy/bleeding/stool frequency (EBS) remission at Week 10 and Week 58.

Protection of trial subjects:

The protocol and consent/assent forms were submitted by each investigator to a duly constituted Independent Ethics Committee (IEC) or Institutional Review Board (IRB) for review and approval before study initiation. All revisions to the consent/assent forms (if applicable) after initial IEC/IRB approval were submitted by the investigator to the IEC/IRB for review and approval before implementation in accordance with regulatory requirements.

This study was conducted in accordance with recognized international scientific and ethical standards, including but not limited to the International Conference on Harmonization guideline for Good Clinical Practice (ICH GCP) and the original principles embodied in the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 November 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	Netherlands: 4
Country: Number of subjects enrolled	Norway: 6
Country: Number of subjects enrolled	Poland: 188
Country: Number of subjects enrolled	Portugal: 2
Country: Number of subjects enrolled	Slovakia: 4
Country: Number of subjects enrolled	Spain: 8
Country: Number of subjects enrolled	Sweden: 6
Country: Number of subjects enrolled	United Kingdom: 40
Country: Number of subjects enrolled	Croatia: 6
Country: Number of subjects enrolled	Austria: 7
Country: Number of subjects enrolled	Belgium: 36
Country: Number of subjects enrolled	Bulgaria: 5
Country: Number of subjects enrolled	Czechia: 17
Country: Number of subjects enrolled	France: 80
Country: Number of subjects enrolled	Germany: 70
Country: Number of subjects enrolled	Greece: 5

Country: Number of subjects enrolled	Hungary: 28
Country: Number of subjects enrolled	Ireland: 2
Country: Number of subjects enrolled	United States: 181
Country: Number of subjects enrolled	India: 145
Country: Number of subjects enrolled	Japan: 109
Country: Number of subjects enrolled	Ukraine: 106
Country: Number of subjects enrolled	Russian Federation: 59
Country: Number of subjects enrolled	Italy: 57
Country: Number of subjects enrolled	Korea, Republic of: 33
Country: Number of subjects enrolled	Australia: 31
Country: Number of subjects enrolled	Romania: 19
Country: Number of subjects enrolled	Switzerland: 19
Country: Number of subjects enrolled	Canada: 17
Country: Number of subjects enrolled	Taiwan: 12
Country: Number of subjects enrolled	Israel: 11
Country: Number of subjects enrolled	New Zealand: 10
Country: Number of subjects enrolled	South Africa: 8
Country: Number of subjects enrolled	Georgia: 4
Country: Number of subjects enrolled	Hong Kong: 4
Country: Number of subjects enrolled	Serbia: 4
Country: Number of subjects enrolled	Argentina: 3
Country: Number of subjects enrolled	Malaysia: 3
Country: Number of subjects enrolled	Mexico: 1
Country: Number of subjects enrolled	Singapore: 1
Worldwide total number of subjects	1351
EEA total number of subjects	550

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)	1262
From 65 to 84 years	89
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled at study sites in Australia, New Zealand, North America, South America, Asia and Europe. The first participant was screened on 14 November 2016. The last study visit occurred on 31 March 2020.

Pre-assignment

Screening details:

2040 participants were screened.

Period 1

Period 1 title	Induction Study: Up to Week 11
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 Study (Cohort A): Filgotinib 200 mg

Arm description:

Participants in Cohort A (biologic-naive) received filgotinib 200 milligrams (mg) and placebo-to-match (PTM) filgotinib 100 mg orally once daily for 10 weeks.

Arm type	Experimental
Investigational medicinal product name	Filgotinib
Investigational medicinal product code	
Other name	GS-6034, formerly GLPG0634
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

200 mg administered once daily for 10 weeks

Investigational medicinal product name	PTM filgotinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Placebo administered once daily for 10 weeks

Arm title	Induction Study (Cohort A): Filgotinib 100 mg

Arm description:

Participants in Cohort A (biologic-naive) received filgotinib 100 mg and PTM filgotinib 200 mg orally once daily for 10 weeks.

Arm type	Experimental
Investigational medicinal product name	Filgotinib
Investigational medicinal product code	
Other name	GS-6034, formerly GLPG0634
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

100 mg administered once daily for 10 weeks

Investigational medicinal product name	PTM filgotinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Placebo administered once daily for 10 weeks

Arm title	Induction Study (Cohort A): Placebo

Arm description:

Participants in Cohort A (biologic-naive) received PTM filgotinib 200 mg and PTM filgotinib 100 mg orally once daily for 10 weeks.

Arm type	Placebo
Investigational medicinal product name	PTM filgotinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Placebo administered once daily for 10 weeks

Arm title	Induction Study (Cohort B): Filgotinib 200 mg

Arm description:

Participants in Cohort B (biologic-experienced) received filgotinib 200 mg and PTM filgotinib 100 mg orally once daily for 10 weeks.

Arm type	Experimental
Investigational medicinal product name	Filgotinib
Investigational medicinal product code	
Other name	GS-6034, formerly GLPG0634
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

200 mg administered once daily for 10 weeks

Investigational medicinal product name	PTM filgotinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Placebo administered once daily for 10 weeks

Arm title	Induction Study (Cohort B): Filgotinib 100 mg

Arm description:

Participants in Cohort B (biologic-experienced) received filgotinib 100 mg and PTM filgotinib 200 mg orally once daily for 10 weeks.

Arm type	Experimental
Investigational medicinal product name	Filgotinib
Investigational medicinal product code	
Other name	GS-6034, formerly GLPG0634
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

100 mg administered once daily for 10 weeks

Investigational medicinal product name	PTM filgotinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Placebo administered once daily for 10 weeks

Arm title	Induction Study (Cohort B): Placebo

Arm description:

Participants in Cohort B (biologic-experienced) received PTM filgotinib 200 mg and PTM filgotinib 100 mg orally once daily for 10 weeks

Arm type	Placebo
Investigational medicinal product name	PTM filgotinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Placebo administered once daily for 10 weeks

Number of subjects in period 1[1]	Induction Study (Cohort A): Filgotinib 200 mg	Induction Study (Cohort A): Filgotinib 100 mg	Induction Study (Cohort A): Placebo
Started	245	277	137
Completed	235	256	127
Not completed	10	21	10
Protocol violation	-	2	1
Pregnancy	-	-	-
Adverse event	5	6	4
Non-compliance with study drug	1	-	-
Withdrew consent	4	11	4
Lost to follow-up	-	2	1
Investigator's discretion	-	-	-

Number of subjects in period 1[1]	Induction Study (Cohort B): Filgotinib 200 mg	Induction Study (Cohort B): Filgotinib 100 mg	Induction Study (Cohort B): Placebo
Started	262	285	142
Completed	234	262	127
Not completed	28	23	15
Protocol violation	3	4	2
Pregnancy	-	1	-
Adverse event	18	14	10
Non-compliance with study drug	-	-	-
Withdrew consent	6	3	3
Lost to follow-up	1	-	-

Investigator's discretion	-	1	-

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: 3 participants who were randomized but not treated were not included in the Safety Analysis Set.

Period 2

Period 2 title	Maintenance Study: Week 11 to Week 58
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Maintenance Study: FIL 200 mg From Induction FIL 200 mg

Arm description:

Participants in the Filgotinib 200 mg arm who completed the Induction Study and achieved either Endoscopy/Bleeding/Stool Frequency (EBS) remission or Mayo Clinic Score (MCS) response at Week 10 were re-randomized at Week 11 into the Maintenance Study to receive filgotinib 200 mg and PTM filgotinib 100 mg orally once daily for an additional 47 weeks (up to Week 58).

Arm type	Experimental
Investigational medicinal product name	Filgotinib
Investigational medicinal product code	
Other name	GS-6034, formerly GLPG0634
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

200 mg administered once daily up to 47 weeks

Investigational medicinal product name	PTM filgotinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Placebo administered once daily up to 47 weeks

Arm title	Maintenance Study: Placebo From Induction Filgotinib 200 mg

Arm description:

Participants in the Filgotinib 200 mg arm who completed the Induction Study and achieved either EBS remission or MCS response at Week 10 were re-randomized at Week 11 into the Maintenance Study to receive PTM filgotinib orally once daily for an additional 47 weeks (up to Week 58).

Arm type	Placebo
Investigational medicinal product name	PTM filgotinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Placebo administered once daily up to 47 weeks

Arm title	Maintenance Study: FIL 100 mg From Induction FIL 100 mg

Arm description:

Participants in the Filgotinib 100 mg arm who completed the Induction Study and achieved either EBS remission or MCS response at Week 10 were re-randomized at Week 11 into the Maintenance Study to receive filgotinib 100 mg and PTM filgotinib 200 mg orally once daily for an additional 47 weeks (up to Week 58).

Arm type	Experimental
Investigational medicinal product name	Filgotinib
Investigational medicinal product code	
Other name	GS-6034, formerly GLPG0634
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

100 mg administered once daily up to 47 weeks

Investigational medicinal product name	PTM filgotinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Placebo administered once daily up to 47 weeks

Arm title	Maintenance Study: Placebo From Induction Filgotinib 100 mg

Arm description:

Participants in the Filgotinib 100 mg arm who completed the Induction Study and achieved either EBS remission or MCS response at Week 10 were rerandomized at Week 11 into the Maintenance Study to receive PTM filgotinib orally once daily for an additional 47 weeks (up to Week 58).

Arm type	Placebo
Investigational medicinal product name	PTM filgotinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Placebo administered once daily up to 47 weeks

Arm title	Maintenance Study: Placebo From Induction Placebo

Arm description:

Participants in the Placebo arm who completed the Induction Study and achieved either EBS remission or MCS response at Week 10 were re-randomized at Week 11 into the Maintenance Study to receive PTM filgotinib orally once daily once daily for an additional 47 weeks (up to Week 58).

Arm type	Placebo
Investigational medicinal product name	PTM filgotinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Placebo administered once daily up to 47 weeks

Number of subjects in period 2[2]	Maintenance Study: FIL 200 mg From Induction FIL 200 mg	Maintenance Study: Placebo From Induction Filgotinib 200 mg	Maintenance Study: FIL 100 mg From Induction FIL 100 mg
Started	202	99	179
Completed	150	41	104
Not completed	52	58	75
Protocol-specified disease worsening	34	49	53
Protocol violation	5	5	3
Death	2	-	-
Pregnancy	-	-	1
Adverse event	7	2	10
Non-compliance with study drug	-	-	-
Withdrew consent	4	1	6
Investigator's discretion	-	1	2

Number of subjects in period 2[2]	Maintenance Study: Placebo From Induction Filgotinib 100 mg	Maintenance Study: Placebo From Induction Placebo
Started	91	93
Completed	42	64
Not completed	49	29
Protocol-specified disease worsening	39	21
Protocol violation	-	1
Death	-	-
Pregnancy	2	-
Adverse event	4	3
Non-compliance with study drug	1	-
Withdrew consent	3	4
Investigator's discretion	-	-

Notes:

[2] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Participants achieved either EBS remission/MCS response at Week 10 continued into Maintenance Study.

Baseline characteristics

Reporting groups	
Reporting group title	Induction Study (Cohort A): Filgotinib 200 mg
Reporting group description:	
Participants in Cohort A (biologic-naive) received filgotinib 200 milligrams (mg) and placebo-to-match (PTM) filgotinib 100 mg orally once daily for 10 weeks.	
Reporting group title	Induction Study (Cohort A): Filgotinib 100 mg
Reporting group description:	
Participants in Cohort A (biologic-naive) received filgotinib 100 mg and PTM filgotinib 200 mg orally once daily for 10 weeks.	
Reporting group title	Induction Study (Cohort A): Placebo
Reporting group description:	
Participants in Cohort A (biologic-naive) received PTM filgotinib 200 mg and PTM filgotinib 100 mg orally once daily for 10 weeks.	
Reporting group title	Induction Study (Cohort B): Filgotinib 200 mg
Reporting group description:	
Participants in Cohort B (biologic-experienced) received filgotinib 200 mg and PTM filgotinib 100 mg orally once daily for 10 weeks.	
Reporting group title	Induction Study (Cohort B): Filgotinib 100 mg
Reporting group description:	
Participants in Cohort B (biologic-experienced) received filgotinib 100 mg and PTM filgotinib 200 mg orally once daily for 10 weeks.	
Reporting group title	Induction Study (Cohort B): Placebo
Reporting group description:	
Participants in Cohort B (biologic-experienced) received PTM filgotinib 200 mg and PTM filgotinib 100 mg orally once daily for 10 weeks	

Reporting group values	Induction Study (Cohort A): Filgotinib 200 mg	Induction Study (Cohort A): Filgotinib 100 mg	Induction Study (Cohort A): Placebo
Number of subjects	245	277	137
Age categorical Units: Subjects			
<=18 years	0	0	0
Between 18 and 65 years	234	261	129
>=65 years	11	16	8
Gender categorical Units: Subjects			
Female	122	120	50
Male	123	157	87
Race			
Not Permitted = local regulators did not allow collection of race or ethnicity information.			
Units: Subjects			
American Indian or Alaska Native	1	0	0
Asian	77	79	38
Black or African American	2	3	1
White	165	192	95
Other	0	2	2
Not Permitted	0	1	1
Ethnicity Units: Subjects			

Not Hispanic or Latino	238	269	134
Hispanic or Latino	6	6	3
Not Permitted	1	2	0

Reporting group values	Induction Study (Cohort B): Filgotinib 200 mg	Induction Study (Cohort B): Filgotinib 100 mg	Induction Study (Cohort B): Placebo
Number of subjects	262	285	142
Age categorical Units: Subjects			
<=18 years	0	0	0
Between 18 and 65 years	243	264	128
>=65 years	19	21	14
Gender categorical Units: Subjects			
Female	114	99	56
Male	148	186	86
Race			
Not Permitted = local regulators did not allow collection of race or ethnicity information.			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	50	51	27
Black or African American	4	6	3
White	190	212	98
Other	0	0	1
Not Permitted	18	16	13
Ethnicity Units: Subjects			
Not Hispanic or Latino	249	273	134
Hispanic or Latino	8	8	4
Not Permitted	5	4	4

Reporting group values	Total		
Number of subjects	1348		
Age categorical Units: Subjects			
<=18 years	0		
Between 18 and 65 years	1259		
>=65 years	89		
Gender categorical Units: Subjects			
Female	561		
Male	787		
Race			
Not Permitted = local regulators did not allow collection of race or ethnicity information.			
Units: Subjects			
American Indian or Alaska Native	1		
Asian	322		
Black or African American	19		
White	952		
Other	5		
Not Permitted	49		

Ethnicity Units: Subjects			
Not Hispanic or Latino	1297		
Hispanic or Latino	35		
Not Permitted	16		

End points

End points reporting groups

Reporting group title	Induction Study (Cohort A): Filgotinib 200 mg
Reporting group description:	
Participants in Cohort A (biologic-naive) received filgotinib 200 milligrams (mg) and placebo-to-match (PTM) filgotinib 100 mg orally once daily for 10 weeks.	
Reporting group title	Induction Study (Cohort A): Filgotinib 100 mg
Reporting group description:	
Participants in Cohort A (biologic-naive) received filgotinib 100 mg and PTM filgotinib 200 mg orally once daily for 10 weeks.	
Reporting group title	Induction Study (Cohort A): Placebo
Reporting group description:	
Participants in Cohort A (biologic-naive) received PTM filgotinib 200 mg and PTM filgotinib 100 mg orally once daily for 10 weeks.	
Reporting group title	Induction Study (Cohort B): Filgotinib 200 mg
Reporting group description:	
Participants in Cohort B (biologic-experienced) received filgotinib 200 mg and PTM filgotinib 100 mg orally once daily for 10 weeks.	
Reporting group title	Induction Study (Cohort B): Filgotinib 100 mg
Reporting group description:	
Participants in Cohort B (biologic-experienced) received filgotinib 100 mg and PTM filgotinib 200 mg orally once daily for 10 weeks.	
Reporting group title	Induction Study (Cohort B): Placebo
Reporting group description:	
Participants in Cohort B (biologic-experienced) received PTM filgotinib 200 mg and PTM filgotinib 100 mg orally once daily for 10 weeks	
Reporting group title	Maintenance Study: FIL 200 mg From Induction FIL 200 mg
Reporting group description:	
Participants in the Filgotinib 200 mg arm who completed the Induction Study and achieved either Endoscopy/Bleeding/Stool Frequency (EBS) remission or Mayo Clinic Score (MCS) response at Week 10 were re-randomized at Week 11 into the Maintenance Study to receive filgotinib 200 mg and PTM filgotinib 100 mg orally once daily for an additional 47 weeks (up to Week 58).	
Reporting group title	Maintenance Study: Placebo From Induction Filgotinib 200 mg
Reporting group description:	
Participants in the Filgotinib 200 mg arm who completed the Induction Study and achieved either EBS remission or MCS response at Week 10 were re-randomized at Week 11 into the Maintenance Study to receive PTM filgotinib orally once daily for an additional 47 weeks (up to Week 58).	
Reporting group title	Maintenance Study: FIL 100 mg From Induction FIL 100 mg
Reporting group description:	
Participants in the Filgotinib 100 mg arm who completed the Induction Study and achieved either EBS remission or MCS response at Week 10 were re-randomized at Week 11 into the Maintenance Study to receive filgotinib 100 mg and PTM filgotinib 200 mg orally once daily for an additional 47 weeks (up to Week 58).	
Reporting group title	Maintenance Study: Placebo From Induction Filgotinib 100 mg
Reporting group description:	
Participants in the Filgotinib 100 mg arm who completed the Induction Study and achieved either EBS remission or MCS response at Week 10 were rerandomized at Week 11 into the Maintenance Study to receive PTM filgotinib orally once daily for an additional 47 weeks (up to Week 58).	
Reporting group title	Maintenance Study: Placebo From Induction Placebo
Reporting group description:	
Participants in the Placebo arm who completed the Induction Study and achieved either EBS remission or MCS response at Week 10 were re-randomized at Week 11 into the Maintenance Study to receive PTM filgotinib orally once daily once daily for an additional 47 weeks (up to Week 58).	

Subject analysis set title	Induction Study (Cohort A): Filgotinib 200 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants in Cohort A (biologic-naive) received filgotinib 200 mg and PTM filgotinib 100 mg orally once daily for 10 weeks.

Subject analysis set title	Induction Study (Cohort A): Filgotinib 100 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants in Cohort A (biologic-naive) received filgotinib 100 mg and PTM filgotinib 200 mg orally once daily for 10 weeks.

Subject analysis set title	Induction Study (Cohort A): Placebo
Subject analysis set type	Full analysis

Subject analysis set description:

Participants in Cohort A (biologic-naive) received PTM filgotinib 200 mg and PTM filgotinib 100 mg orally once daily for 10 weeks.

Subject analysis set title	Induction Study (Cohort B): Filgotinib 200 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants in Cohort B (biologic-experienced) received filgotinib 200 mg and PTM filgotinib 100 mg orally once daily for 10 weeks.

Subject analysis set title	Induction Study (Cohort B): Filgotinib 100 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants in Cohort B (biologic-experienced) received filgotinib 100 mg and PTM filgotinib 200 mg orally once daily for 10 weeks.

Subject analysis set title	Induction Study (Cohort B): Placebo
Subject analysis set type	Full analysis

Subject analysis set description:

Participants in Cohort B (biologic-experienced) received PTM filgotinib 200 mg and PTM filgotinib 100 mg orally once daily for 10 weeks.

Primary: Induction Study: Percentage of Participants Who Achieved EBS Remission at Week 10

End point title	Induction Study: Percentage of Participants Who Achieved EBS Remission at Week 10

End point description:

EBS remission was defined as an endoscopic subscore of 0 or 1; rectal bleeding subscore of 0; and at least a 1-point decrease in stool frequency from baseline to achieve a subscore of 0 or 1. Endoscopic subscore range: 0 to 3, where 0 = normal or inactive disease and 3 = severe disease (spontaneous bleeding, ulceration); rectal bleeding subscore range: 0 to 3, where 0 = no blood seen and 3 = blood alone passes; stool frequency subscore range: 0 to 3, where 0 = normal number of stools and 3 = at least 5 stools more than normal. Total score for EBS ranged from 0 to 9 (sum of all subscores), with higher scores indicating more severe disease. Full Analysis Set (FAS) for the Induction study (Cohorts A and B) included all randomised participants who took at least 1 dose of study drug in the corresponding Induction study.

End point type	Primary

End point timeframe:

Week 10

End point values	Induction Study (Cohort A): Filgotinib 200 mg	Induction Study (Cohort A): Filgotinib 100 mg	Induction Study (Cohort A): Placebo	Induction Study (Cohort B): Filgotinib 200 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	245	277	137	262
Units: percentage of participants				
number (confidence interval 95%)	26.1 (20.4 to 31.8)	19.1 (14.3 to 23.9)	15.3 (8.9 to 21.7)	11.5 (7.4 to 15.5)

End point values	Induction Study (Cohort B): Filgotinib 100 mg	Induction Study (Cohort B): Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	285	142		
Units: percentage of participants				
number (confidence interval 95%)	9.5 (5.9 to 13.0)	4.2 (0.6 to 7.9)		

Statistical analyses

Statistical analysis title	Induction Study (Cohort A): 200 mg vs Placebo
Comparison groups	Induction Study (Cohort A): Filgotinib 200 mg v Induction Study (Cohort A): Placebo
Number of subjects included in analysis	382
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0157 [1]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.1
upper limit	19.5

Notes:

[1] - Cochran-Mantel-Haenszel (CMH) test was stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and immunomodulators (Yes or No) at Day 1.

Statistical analysis title	Induction Study (Cohort A): 100 mg vs Placebo
Comparison groups	Induction Study (Cohort A): Filgotinib 100 mg v Induction Study (Cohort A): Placebo

Number of subjects included in analysis	414
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3379 [2]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	3.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.3
upper limit	12

Notes:

[2] - CMH test was stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and of immunomodulators (Yes or No) at Day 1.

Statistical analysis title	Induction Study (Cohort B): 200 mg vs Placebo
Comparison groups	Induction Study (Cohort B): Filgotinib 200 mg v Induction Study (Cohort B): Placebo
Number of subjects included in analysis	404
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0103 [3]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	7.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.6
upper limit	12.8

Notes:

[3] - CMH test is stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and of immunomodulators (Yes or No) at Day 1, and number of prior exposure to biologic agent (<=1, >1).

Statistical analysis title	Induction Study (Cohort B): 100 mg vs Placebo
Comparison groups	Induction Study (Cohort B): Filgotinib 100 mg v Induction Study (Cohort B): Placebo
Number of subjects included in analysis	427
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0645 [4]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	5.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	10.5

Notes:

[4] - CMH test is stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and of immunomodulators (Yes or No) at Day 1, and number of prior exposure to biologic agent (<=1, >1).

Primary: Maintenance Study: Percentage of Participants Who Achieved EBS Remission at Week 58

End point title	Maintenance Study: Percentage of Participants Who Achieved EBS Remission at Week 58

End point description:

EBS remission was defined as an endoscopic subscore of 0 or 1; rectal bleeding subscore of 0; and at least a 1-point decrease in stool frequency from baseline to achieve a subscore of 0 or 1. Endoscopic subscore range: 0 to 3, where 0 = normal or inactive disease and 3 = severe disease (spontaneous bleeding, ulceration); rectal bleeding subscore range: 0 to 3, where 0 = no blood seen and 3 = blood alone passes; stool frequency subscore range: 0 to 3, where 0 = normal number of stools and 3 = at least 5 stools more than normal. Total score for EBS ranged from 0 to 9 (sum of all subscores), with higher scores indicating more severe disease. Full Analysis Set for the Maintenance Study included all participants randomised to either the filgotinib 200 mg or filgotinib 100 mg treatment groups in the Induction Study (Cohorts A and B) who achieved EBS remission or MCS response at Week 10, were rerandomised, and took at least 1 dose of study drug in the Maintenance Study.

End point type	Primary

End point timeframe:

Week 58

End point values	Maintenance Study: FIL 200 mg From Induction FIL 200 mg	Maintenance Study: Placebo From Induction Filgotinib 200 mg	Maintenance Study: FIL 100 mg From Induction FIL 100 mg	Maintenance Study: Placebo From Induction Filgotinib 100 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	199	98	172	89
Units: percentage of participants				
number (confidence interval 95%)	37.2 (30.2 to 44.2)	11.2 (4.5 to 18.0)	23.8 (17.2 to 30.5)	13.5 (5.8 to 21.1)

Statistical analyses

Statistical analysis title	Maintenance Study: 200 mg vs Placebo
Comparison groups	Maintenance Study: FIL 200 mg From Induction FIL 200 mg v Maintenance Study: Placebo From Induction Filgotinib 200 mg
Number of subjects included in analysis	297
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [5]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	26
Confidence interval	
level	95 %
sides	2-sided
lower limit	16
upper limit	35.9

Notes:

[5] - CMH test was stratified by concomitant use of oral, systemic corticosteroids (Yes/No) and of immunomodulators (Yes/No) at maintenance baseline, and participation in Induction Study (Cohort A or B).

Statistical analysis title	Maintenance Study: 100 mg vs Placebo
Comparison groups	Maintenance Study: FIL 100 mg From Induction FIL 100 mg v Maintenance Study: Placebo From Induction Filgotinib 100 mg
Number of subjects included in analysis	261
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.042 [6]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	10.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	20.7

Notes:

[6] - CMH test was stratified by concomitant use of oral, systemic corticosteroids (Yes/No) and of immunomodulators (Yes/No) at maintenance baseline, and participation in Induction Study (Cohort A or B).

Secondary: Induction Study: Percentage of Participants Who Achieved MCS Remission at Week 10

End point title	Induction Study: Percentage of Participants Who Achieved MCS Remission at Week 10

End point description:

MCS remission was defined as having a MCS of 2 or less and no single subscore higher than 1. The MCS was composed of subscores from endoscopy (range: 0 to 3, where 0 = normal or inactive disease and 3 = severe disease [spontaneous bleeding, ulceration]), rectal bleeding (range: 0 to 3, where 0 = no blood seen and 3 = blood alone passes), stool frequency (range: 0 to 3, where 0 = normal number of stools and 3 = at least 5 stools more than normal), and physician's global assessment (PGA). The PGA acknowledged the participant's daily recollection of abdominal discomfort and general sense of wellbeing, and other observations, such as physical findings and the participant's performance status. The PGA score ranged from 0 to 3 with higher score indicating severe disease. Total score for MCS ranged from 0 to 12 (sum of all subscores), with higher scores indicating more severe disease. Participants in the Full Analysis Set for the Induction Study (Cohorts A and B) were analysed.

End point type	Secondary

End point timeframe:

Week 10

End point values	Induction Study (Cohort A): Filgotinib 200 mg	Induction Study (Cohort A): Filgotinib 100 mg	Induction Study (Cohort A): Placebo	Induction Study (Cohort B): Filgotinib 200 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	245	277	137	262
Units: percentage of participants				
number (confidence interval 95%)	24.5 (18.9 to 30.1)	17.0 (12.4 to 21.6)	12.4 (6.5 to 18.3)	9.5 (5.8 to 13.3)

End point values	Induction Study (Cohort B): Filgotinib 100 mg	Induction Study (Cohort B): Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	285	142		
Units: percentage of participants				
number (confidence interval 95%)	6.0 (3.0 to 8.9)	4.2 (0.6 to 7.9)		

Statistical analyses

Statistical analysis title	Induction Study (Cohort A): 200 mg vs Placebo
Comparison groups	Induction Study (Cohort A): Filgotinib 200 mg v Induction Study (Cohort A): Placebo
Number of subjects included in analysis	382
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0053 [7]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	12.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.8
upper limit	20.4

Notes:

[7] - CMH test is stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and of immunomodulators (Yes or No) at Day 1.

Statistical analysis title	Induction Study (Cohort A): 100 mg vs Placebo
Comparison groups	Induction Study (Cohort A): Filgotinib 100 mg v Induction Study (Cohort A): Placebo
Number of subjects included in analysis	414
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2295 [8]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	4.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.1
upper limit	12.2

Notes:

[8] - CMH test is stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and of immunomodulators (Yes or No) at Day 1.

Statistical analysis title	Induction Study (Cohort B): 200 mg vs Placebo
Comparison groups	Induction Study (Cohort B): Filgotinib 200 mg v Induction Study (Cohort B): Placebo
Number of subjects included in analysis	404
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0393 [9]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	5.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	10.7

Notes:

[9] - CMH test is stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and of immunomodulators (Yes or No) at Day 1, and number of prior exposure to biologic agent (<=1, >1).

Statistical analysis title	Induction Study (Cohort B): 100 mg vs Placebo
Comparison groups	Induction Study (Cohort B): Filgotinib 100 mg v Induction Study (Cohort B): Placebo
Number of subjects included in analysis	427
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5308 [10]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.1
upper limit	6.6

Notes:

[10] - CMH test is stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and of immunomodulators (Yes or No) at Day 1, and number of prior exposure to biologic agent (<=1, >1).

Secondary: Induction Study: Percentage of Participants Who Achieved an Endoscopic Subscore of 0 at Week 10

End point title	Induction Study: Percentage of Participants Who Achieved an Endoscopic Subscore of 0 at Week 10

End point description:

Endoscopic subscore range: 0 to 3, where 0 = normal or inactive disease and 3 = severe disease (spontaneous bleeding, ulceration). Participants in the Full Analysis Set for the Induction Study (Cohorts A and B) were analysed.

End point type	Secondary

End point timeframe:

Week 10

End point values	Induction Study (Cohort A): Filgotinib 200 mg	Induction Study (Cohort A): Filgotinib 100 mg	Induction Study (Cohort A): Placebo	Induction Study (Cohort B): Filgotinib 200 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	245	277	137	262
Units: percentage of participants				
number (confidence interval 95%)	12.2 (7.9 to 16.6)	5.8 (2.8 to 8.7)	3.6 (0.1 to 7.2)	3.4 (1.0 to 5.8)

End point values	Induction Study (Cohort B): Filgotinib 100 mg	Induction Study (Cohort B): Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	285	142		
Units: percentage of participants				
number (confidence interval 95%)	2.1 (0.3 to 3.9)	2.1 (0.0 to 4.8)		

Statistical analyses

Statistical analysis title	Induction Study (Cohort A): 200 mg vs Placebo
Comparison groups	Induction Study (Cohort A): Filgotinib 200 mg v Induction Study (Cohort A): Placebo
Number of subjects included in analysis	382
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0047 [11]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	8.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.9
upper limit	14.3

Notes:

[11] - CMH test is stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and of immunomodulators (Yes or No) at Day 1.

Statistical analysis title	Induction Study (Cohort A): 100 mg vs Placebo
Comparison groups	Induction Study (Cohort A): Filgotinib 100 mg v Induction Study (Cohort A): Placebo

Number of subjects included in analysis	414
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3495 [12]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	2.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.6
upper limit	6.8

Notes:

[12] - CMH test is stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and of immunomodulators (Yes or No) at Day 1.

Statistical analysis title	Induction Study (Cohort B): 200 mg vs Placebo
Comparison groups	Induction Study (Cohort B): Filgotinib 200 mg v Induction Study (Cohort B): Placebo
Number of subjects included in analysis	404
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4269 [13]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	5.1

Notes:

[13] - CMH test is stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and of immunomodulators (Yes or No) at Day 1, and number of prior exposure to biologic agent (<=1, >1).

Statistical analysis title	Induction Study (Cohort B): 100 mg vs Placebo
Comparison groups	Induction Study (Cohort B): Filgotinib 100 mg v Induction Study (Cohort B): Placebo
Number of subjects included in analysis	427
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9987 [14]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.4
upper limit	3.4

Notes:

[14] - CMH test is stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and of immunomodulators (Yes or No) at Day 1, and number of prior exposure to biologic agent (<=1, >1).

Secondary: Induction Study: Percentage of Participants Who Achieved Geboes Histologic Remission at Week 10

End point title	Induction Study: Percentage of Participants Who Achieved Geboes Histologic Remission at Week 10

End point description:

Geboes histologic remission assessed using Geboes histologic scores for evaluation of disease severity in UC and classifies histologic changes. Remission:Grade 0 of <= 0.3, Grade 1 of <= 1.1, Grade 2A of <= 2A.3, Grade 2B of 2B.0, Grade 3 of 3.0, Grade 4 of 4.0, and Grade 5 of 5.0. Possible scores are Grade 0: Architectural changes (0.0=No abnormality to 0.3=Severe diffuse or multifocal abnormalities); Grade 1:Chronic inflammatory infiltrate (1.0=No increase to 1.3=Marked increase); Grade 2A: Eosinophils in lamina propria (2A.0=No increase to 2A.3-=Marked increase; Grade 2B: Neutrophils in lamina propria (2B.0=No increase to 2B.3=Marked increase); Grade 3: Neutrophils in epithelium (3.0=None to 3.3=>50% crypts involved); Grade 4: Crypt destruction (4.0=none to 4.3=Unequivocal crypt destruction), and Grade 5: Erosions and ulcerations: (5.0=No erosion, ulceration or granulation to 5.4=Ulcer or granulation tissue).
Participants in FAS for Induction study (Cohorts A and B) were analysed.

End point type	Secondary

End point timeframe:

Week 10

End point values	Induction Study (Cohort A): Filgotinib 200 mg	Induction Study (Cohort A): Filgotinib 100 mg	Induction Study (Cohort A): Placebo	Induction Study (Cohort B): Filgotinib 200 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	245	277	137	262
Units: percentage of participants				
number (confidence interval 95%)	35.1 (28.9 to 41.3)	23.8 (18.6 to 29.0)	16.1 (9.5 to 22.6)	19.8 (14.8 to 24.9)

End point values	Induction Study (Cohort B): Filgotinib 100 mg	Induction Study (Cohort B): Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	285	142		
Units: percentage of participants				
number (confidence interval 95%)	13.7 (9.5 to 17.8)	8.5 (3.5 to 13.4)		

Statistical analyses

Statistical analysis title	Induction Study (Cohort A): 200 mg vs Placebo
Comparison groups	Induction Study (Cohort A): Filgotinib 200 mg v Induction Study (Cohort A): Placebo

Number of subjects included in analysis	382
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [15]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	19
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.9
upper limit	28.2

Notes:

[15] - CMH test is stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and of immunomodulators (Yes or No) at Day 1.

Statistical analysis title	Induction Study (Cohort A): 100 mg vs Placebo
Comparison groups	Induction Study (Cohort A): Filgotinib 100 mg v Induction Study (Cohort A): Placebo
Number of subjects included in analysis	414
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0672 [16]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	7.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	16.2

Notes:

[16] - CMH test is stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and of immunomodulators (Yes or No) at Day 1.

Statistical analysis title	Induction Study (Cohort B): 200 mg vs Placebo
Comparison groups	Induction Study (Cohort B): Filgotinib 200 mg v Induction Study (Cohort B): Placebo
Number of subjects included in analysis	404
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0019 [17]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	11.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.2
upper limit	18.6

Notes:

[17] - CMH test is stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and of immunomodulators (Yes or No) at Day 1, and number of prior exposure to biologic agent (<=1, >1).

Statistical analysis title	Induction Study (Cohort B): 100 mg vs Placebo
Comparison groups	Induction Study (Cohort B): Filgotinib 100 mg v Induction Study (Cohort B): Placebo
Number of subjects included in analysis	427
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1286 [18]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	5.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	11.8

Notes:

[18] - CMH test is stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and of immunomodulators (Yes or No) at Day 1, and number of prior exposure to biologic agent (<=1, >1).

Secondary: Induction Study: Percentage of Participants Who Achieved MCS Remission (Alternative Definition) at Week 10

End point title	Induction Study: Percentage of Participants Who Achieved MCS Remission (Alternative Definition) at Week 10

End point description:

MCS remission (alternative definition) was defined as having rectal bleeding, stool frequency, and PGA subscores of 0 and an endoscopic subscore of 0 or 1; overall MCS of ≤ 1. MCS possible subscores: rectal bleeding (range: 0 to 3, where 0 = no blood seen and 3 = blood alone passes), stool frequency (range: 0 to 3, where 0 = normal number of stools and 3 = at least 5 stools more than normal), PGA subscore (range: 0 to 3 with higher score indicating the severe disease), and an endoscopic subscore (range: 0 to 3, where 0 = normal or inactive disease and 3 = severe disease [spontaneous bleeding, ulceration]. Total score for MCS ranged from 0 to 12 (sum of all subscores), with higher scores indicating more severe disease. Participants in the Full Analysis Set for the Induction Study (Cohorts A and B) were analysed.

End point type	Secondary

End point timeframe:

Week 10

End point values	Induction Study (Cohort A): Filgotinib 200 mg	Induction Study (Cohort A): Filgotinib 100 mg	Induction Study (Cohort A): Placebo	Induction Study (Cohort B): Filgotinib 200 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	245	277	137	262
Units: percentage of participants				
number (confidence interval 95%)	12.2 (7.9 to 16.6)	8.7 (5.2 to 12.2)	4.4 (0.6 to 8.2)	3.8 (1.3 to 6.3)

End point values	Induction Study (Cohort B): Filgotinib 100 mg	Induction Study (Cohort B): Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	285	142		
Units: percentage of participants				
number (confidence interval 95%)	2.1 (0.3 to 3.9)	2.1 (0.0 to 4.8)		

Statistical analyses

Statistical analysis title	Induction Study (Cohort A): 200 mg vs Placebo
Comparison groups	Induction Study (Cohort A): Filgotinib 200 mg v Induction Study (Cohort A): Placebo
Number of subjects included in analysis	382
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0105 [19]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	7.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.9
upper limit	13.8

Notes:

[19] - CMH test is stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and of immunomodulators (Yes or No) at Day 1.

Statistical analysis title	Induction Study (Cohort A): 100 mg vs Placebo
Comparison groups	Induction Study (Cohort A): Filgotinib 100 mg v Induction Study (Cohort A): Placebo
Number of subjects included in analysis	414
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1062 [20]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	4.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	9.6

Notes:

[20] - CMH test is stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and of immunomodulators (Yes or No) at Day 1.

Statistical analysis title	Induction Study (Cohort B): 200 mg vs Placebo
Comparison groups	Induction Study (Cohort B): Filgotinib 200 mg v Induction Study (Cohort B): Placebo

Number of subjects included in analysis	404
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3084 [21]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.2
upper limit	5.6

Notes:

[21] - CMH test is stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and of immunomodulators (Yes or No) at Day 1, and number of prior exposure to biologic agent (<=1, >1).

Statistical analysis title	Induction Study (Cohort B): 100 mg vs Placebo
Comparison groups	Induction Study (Cohort B): Filgotinib 100 mg v Induction Study (Cohort B): Placebo
Number of subjects included in analysis	427
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9109 [22]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.4
upper limit	3.4

Notes:

[22] - CMH test is stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and of immunomodulators (Yes or No) at Day 1, and number of prior exposure to biologic agent (<=1, >1).

Secondary: Induction Study: Pharmacokinetic (PK) Parameter: Cmax of Filgotinib and Its Metabolite GS-829845

End point title	Induction Study: Pharmacokinetic (PK) Parameter: Cmax of Filgotinib and Its Metabolite GS-829845

End point description:

Cmax is defined as the maximum observed concentration of drug. PK Substudy Analysis Set included all randomised participants who took at least 1 dose of filgotinib, participated in the PK substudy, and had at least 1 nonmissing intensive concentration value for filgotinib and/or GS-829845 with available data were analyzed.

End point type	Secondary

End point timeframe:

Predose and at 0.5, 1, 2, 3, 4 and 6 hours postdose at a single visit between Week 2 and Week 10

End point values	Induction Study (Cohort A): Filgotinib 200 mg	Induction Study (Cohort A): Filgotinib 100 mg	Induction Study (Cohort B): Filgotinib 200 mg	Induction Study (Cohort B): Filgotinib 100 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	11	9	17
Units: nanograms per millilitre (ng/mL)				
arithmetic mean (standard deviation)				
Filgotinib (n= 4, 10, 9 ,17)	1746.3 (± 1244.05)	725.1 (± 313.36)	2283.3 (± 1012.03)	977.9 (± 403.51)
Metabolite GS-829845 (n= 4, 11, 9, 17)	3227.5 (± 1204.50)	1812.2 (± 701.46)	4373.3 (± 1121.58)	2002.9 (± 598.73)

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study: PK Parameter: Tmax of Filgotinib and Its Metabolite GS-829845

End point title	Induction Study: PK Parameter: Tmax of Filgotinib and Its Metabolite GS-829845

End point description:

Tmax is defined as the time to reach maximum observed concentration of drug. Participants in the PK Substudy Analysis Set with available data were analysed.

End point type	Secondary

End point timeframe:

Predose and at 0.5, 1, 2, 3, 4 and 6 hours postdose at a single visit between Week 2 and Week 10

End point values	Induction Study (Cohort A): Filgotinib 200 mg	Induction Study (Cohort A): Filgotinib 100 mg	Induction Study (Cohort B): Filgotinib 200 mg	Induction Study (Cohort B): Filgotinib 100 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	11	9	17
Units: hour (h)				
median (full range (min-max))				
Filgotinib (n= 4, 10, 9 ,17)	1.50 (0.75 to 2.00)	0.75 (0.50 to 3.00)	1.00 (0.50 to 2.25)	0.57 (0.42 to 3.00)
Metabolite GS-829845 (n= 4, 11, 9, 17)	3.76 (2.00 to 4.00)	3.00 (1.00 to 6.00)	3.02 (2.13 to 6.00)	3.00 (1.03 to 6.00)

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study: PK Parameter: AUCtau of Filgotinib and Its Metabolite GS-82984

End point title	Induction Study: PK Parameter: AUCtau of Filgotinib and Its

	Metabolite GS-82984

End point description:

AUCtau is defined as concentration of drug over time (the area under the concentration verses time curve over the dosing interval). Participants in the PK Substudy Analysis Set with available data were analysed.

End point type	Secondary

End point timeframe:

Predose and at 0.5, 1, 2, 3, 4 and 6 hours postdose at a single visit between Week 2 and Week 10

End point values	Induction Study (Cohort A): Filgotinib 200 mg	Induction Study (Cohort A): Filgotinib 100 mg	Induction Study (Cohort B): Filgotinib 200 mg	Induction Study (Cohort B): Filgotinib 100 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	11	9	17
Units: hour*nanograms per millilitre (h*ng/mL)				
arithmetic mean (standard deviation)				
Filgotinib (n= 4, 10, 8 ,15)	5501.3 (± 1956.39)	1909.3 (± 788.13)	6475.6 (± 1643.00)	2492.3 (± 852.52)
Metabolite GS-829845 (n= 4, 10, 7, 15)	57982.0 (± 17767.52)	31187.9 (± 11858.78)	80208.6 (± 25096.57)	36075.6 (± 13396.86)

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study: PK Parameter: AUClast of Filgotinib and Its Metabolite GS-82984

End point title	Induction Study: PK Parameter: AUClast of Filgotinib and Its Metabolite GS-82984

End point description:

AUClast is defined as the concentration of drug from time zero to the last observable concentration. Participants in the PK Substudy Analysis Set with available data were analysed.

End point type	Secondary

End point timeframe:

Predose and at 0.5, 1, 2, 3, 4 and 6 hours postdose at a single visit between Week 2 and Week 10

End point values	Induction Study (Cohort A): Filgotinib 200 mg	Induction Study (Cohort A): Filgotinib 100 mg	Induction Study (Cohort B): Filgotinib 200 mg	Induction Study (Cohort B): Filgotinib 100 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	11	9	17
Units: h*ng/mL				
arithmetic mean (standard deviation)				
Filgotinib (n= 4, 10, 9 ,17)	5537.3 (± 1900.93)	1881.9 (± 797.51)	6743.1 (± 1743.68)	2420.3 (± 837.26)

Metabolite GS-829845 (n= 4, 11, 9, 17)	60938.4 (± 6961.77)	30643.2 (± 12935.37)	79286.3 (± 27968.49)	34385.6 (± 15160.15)

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study: PK Parameter: Ctau of Filgotinib and Its Metabolite GS-82984

End point title	Induction Study: PK Parameter: Ctau of Filgotinib and Its Metabolite GS-82984

End point description:

Ctau is defined as the observed drug concentration at the end of the dosing interval. Participants in the PK Substudy Analysis Set with available data were analysed.

End point type	Secondary

End point timeframe:

Predose and at 0.5, 1, 2, 3, 4 and 6 hours postdose at a single visit between Week 2 and Week 8

End point values	Induction Study (Cohort A): Filgotinib 200 mg	Induction Study (Cohort A): Filgotinib 100 mg	Induction Study (Cohort B): Filgotinib 200 mg	Induction Study (Cohort B): Filgotinib 100 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	11	9	17
Units: ng/mL				
arithmetic mean (standard deviation)				
Filgotinib (n= 3, 8, 8 ,13)	12.0 (± 4.74)	4.5 (± 3.61)	36.6 (± 79.06)	4.1 (± 3.05)
Metabolite GS-829845 (n= 3, 10, 8, 15)	2050.0 (± 493.66)	934.8 (± 372.68)	2581.3 (± 777.07)	1062.8 (± 463.67)

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Percentage of Participants Who Achieved MCS Remission at Week 58

End point title	Maintenance Study: Percentage of Participants Who Achieved MCS Remission at Week 58

End point description:

MCS remission was defined as having a MCS of 2 or less and no single subscore higher than 1. The MCS was composed of subscores from endoscopy (range: 0 to 3, where 0 = normal or inactive disease and 3 = severe disease [spontaneous bleeding, ulceration]), rectal bleeding (range: 0 to 3, where 0 = no blood seen and 3 = blood alone passes), stool frequency (range: 0 to 3, where 0 = normal number of stools and 3 = at least 5 stools more than normal), and PGA. The PGA acknowledged the participant's daily recollection of abdominal discomfort and general sense of wellbeing, and other observations, such as physical findings and the participant's performance status. The PGA score ranged from 0 to 3 with higher score indicating the severe disease. Total score for MCS ranged from 0 to 12 (sum of all

subscores), with higher scores indicating more severe disease. Participants in the Full Analysis Set for the Maintenance Study were analysed.

End point type	Secondary
End point timeframe:	
Week 58	

End point values	Maintenance Study: FIL 200 mg From Induction FIL 200 mg	Maintenance Study: Placebo From Induction Filgotinib 200 mg	Maintenance Study: FIL 100 mg From Induction FIL 100 mg	Maintenance Study: Placebo From Induction Filgotinib 100 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	199	98	172	89
Units: percentage of participants				
number (confidence interval 95%)	34.7 (27.8 to 41.5)	9.2 (3.0 to 15.4)	22.7 (16.1 to 29.2)	13.5 (5.8 to 21.1)

Statistical analyses

Statistical analysis title	Maintenance Study: 200 mg vs Placebo
Comparison groups	Maintenance Study: FIL 200 mg From Induction FIL 200 mg v Maintenance Study: Placebo From Induction Filgotinib 200 mg
Number of subjects included in analysis	297
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [23]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	25.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	16
upper limit	35

Notes:

[23] - CMH test is stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and of immunomodulators (Yes or No) at Maintenance baseline, and participation in Cohort A or B.

Statistical analysis title	Maintenance Study: 100 mg vs Placebo
Comparison groups	Maintenance Study: FIL 100 mg From Induction FIL 100 mg v Maintenance Study: Placebo From Induction Filgotinib 100 mg
Number of subjects included in analysis	261
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0658 [24]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	9.2

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	19.5

Notes:

[24] - CMH test is stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and of immunomodulators (Yes or No) at Maintenance baseline, and participation in Cohort A or B.

Secondary: Maintenance Study: Percentage of Participants Who Achieved Sustained EBS Remission at Week 58

End point title	Maintenance Study: Percentage of Participants Who Achieved Sustained EBS Remission at Week 58

End point description:

Sustained EBS remission was defined as having achieved EBS remission at both Weeks 10 and 58. Participants in the Full Analysis Set for the Maintenance Study were analysed.

End point type	Secondary

End point timeframe:

Week 58

End point values	Maintenance Study: FIL 200 mg From Induction FIL 200 mg	Maintenance Study: Placebo From Induction Filgotinib 200 mg	Maintenance Study: FIL 100 mg From Induction FIL 100 mg	Maintenance Study: Placebo From Induction Filgotinib 100 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	199	98	172	89
Units: percentage of participants				
number (confidence interval 95%)	18.1 (12.5 to 23.7)	5.1 (0.2 to 10.0)	8.7 (4.2 to 13.2)	7.9 (1.7 to 14.0)

Statistical analyses

Statistical analysis title	Maintenance Study: Filgotinib 200 mg vs Placebo
Comparison groups	Maintenance Study: FIL 200 mg From Induction FIL 200 mg v Maintenance Study: Placebo From Induction Filgotinib 200 mg
Number of subjects included in analysis	297
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0024 [25]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	13
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.3
upper limit	20.6

Notes:

[25] - CMH test is stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and of immunomodulators (Yes or No) at Maintenance baseline, and participation in Cohort A or B.

Statistical analysis title	Maintenance Study: 100 mg vs Placebo
Comparison groups	Maintenance Study: FIL 100 mg From Induction FIL 100 mg v Maintenance Study: Placebo From Induction Filgotinib 100 mg
Number of subjects included in analysis	261
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7951 [26]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7
upper limit	8.7

Notes:

[26] - CMH test is stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and of immunomodulators (Yes or No) at Maintenance baseline, and participation in Cohort A or B.

Secondary: Maintenance Study: Percentage of Participants Who Achieved 6-Month Corticosteroid-Free EBS Remission at Week 58

End point title	Maintenance Study: Percentage of Participants Who Achieved 6-Month Corticosteroid-Free EBS Remission at Week 58

End point description:

Six-month corticosteroid-free EBS remission at Week 58 was defined as achieving EBS remission with no corticosteroid use for the indication of ulcerative colitis for at least 6 months prior to Week 58. Participants in the Full Analysis Set who were on corticosteroids at Maintenance Study baseline were analysed.

End point type	Secondary

End point timeframe:

Week 58

End point values	Maintenance Study: FIL 200 mg From Induction FIL 200 mg	Maintenance Study: Placebo From Induction Filgotinib 200 mg	Maintenance Study: FIL 100 mg From Induction FIL 100 mg	Maintenance Study: Placebo From Induction Filgotinib 100 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	92	47	81	37
Units: percentage of participants				
number (confidence interval 95%)	27.2 (17.5 to 36.8)	6.4 (0.0 to 14.4)	13.6 (5.5 to 21.7)	5.4 (0.0 to 14.0)

Statistical analyses

Statistical analysis title	Maintenance Study: 200 mg vs Placebo
Comparison groups	Maintenance Study: FIL 200 mg From Induction FIL 200 mg v Maintenance Study: Placebo From Induction Filgotinib 200 mg
Number of subjects included in analysis	139
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0055 [27]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	20.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.7
upper limit	33.9

Notes:

[27] - CMH test is stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and of immunomodulators (Yes or No) at Maintenance baseline, and participation in Cohort A or B.

Statistical analysis title	Maintenance Study: 100 mg vs Placebo
Comparison groups	Maintenance Study: FIL 100 mg From Induction FIL 100 mg v Maintenance Study: Placebo From Induction Filgotinib 100 mg
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1265 [28]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	8.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.2
upper limit	20.6

Notes:

[28] - CMH test is stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and of immunomodulators (Yes or No) at Maintenance baseline, and participation in Cohort A or B.

Secondary: Maintenance Study: Percentage of Participants Who Achieved Endoscopic Subscore of 0 at Weeks 58

End point title	Maintenance Study: Percentage of Participants Who Achieved Endoscopic Subscore of 0 at Weeks 58

End point description:

Endoscopic subscore range: 0 to 3, where 0 = normal or inactive disease and 3 = severe disease (spontaneous bleeding, ulceration). Participants in the Full Analysis Set for the Maintenance Study were analysed.

End point type	Secondary

End point timeframe:

Week 58

End point values	Maintenance Study: FIL 200 mg From Induction FIL 200 mg	Maintenance Study: Placebo From Induction Filgotinib 200 mg	Maintenance Study: FIL 100 mg From Induction FIL 100 mg	Maintenance Study: Placebo From Induction Filgotinib 100 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	199	98	172	89
Units: percentage of participants				
number (confidence interval 95%)	15.6 (10.3 to 20.9)	6.1 (0.9 to 11.4)	13.4 (8.0 to 18.7)	7.9 (1.7 to 14.0)

Statistical analyses

Statistical analysis title	Maintenance Study: 200 mg vs Placebo
Comparison groups	Maintenance Study: FIL 200 mg From Induction FIL 200 mg v Maintenance Study: Placebo From Induction Filgotinib 200 mg
Number of subjects included in analysis	297
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0157 [29]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	9.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.8
upper limit	17.1

Notes:

[29] - CMH test is stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and of immunomodulators (Yes or No) at Maintenance baseline, and participation in Cohort A or B.

Statistical analysis title	Maintenance Study: 100 mg vs Placebo
Comparison groups	Maintenance Study: FIL 100 mg From Induction FIL 100 mg v Maintenance Study: Placebo From Induction Filgotinib 100 mg
Number of subjects included in analysis	261
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1808 [30]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	5.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.9
upper limit	13.9

Notes:

[30] - CMH test is stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and of immunomodulators (Yes or No) at Maintenance baseline, and participation in Cohort A or B.

Secondary: Maintenance Study: Percentage of Participants Who Achieved Geboes

Histologic Remission at Week 58

End point title	Maintenance Study: Percentage of Participants Who Achieved Geboes Histologic Remission at Week 58

End point description:

Geboes histologic remission assessed using Geboes histologic scores for evaluation of disease severity in UC and classifies histologic changes. Remission:Grade 0 of <=0.3, Grade 1 of <= 1.1, Grade 2A of <= 2A.3, Grade 2B of 2B.0, Grade 3 of 3.0, Grade 4 of 4.0, and Grade 5 of 5.0. Possible scores are Grade 0: Architectural changes (0.0=No abnormality to 0.3=Severe diffuse or multifocal abnormalities); Grade 1:Chronic inflammatory infiltrate (1.0=No increase to 1.3=Marked increase); Grade 2A: Eosinophils in lamina propria (2A.0=No increase to 2A.3-=Marked increase; Grade 2B: Neutrophils in lamina propria (2B.0=No increase to 2B.3=Marked increase); Grade 3: Neutrophils in epithelium (3.0=None to 3.3=>50% crypts involved); Grade 4: Crypt destruction (4.0=none to 4.3=Unequivocal crypt destruction), and Grade 5: Erosions and ulcerations: (5.0=No erosion, ulceration or granulation to 5.4=Ulcer or granulation tissue). Participants in Full Analysis Set for the Maintenance Study were

End point type	Secondary

End point timeframe:

Week 58

End point values	Maintenance Study: FIL 200 mg From Induction FIL 200 mg	Maintenance Study: Placebo From Induction Filgotinib 200 mg	Maintenance Study: FIL 100 mg From Induction FIL 100 mg	Maintenance Study: Placebo From Induction Filgotinib 100 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	199	98	172	89
Units: percentage of participants				
number (confidence interval 95%)	38.2 (31.2 to 45.2)	13.3 (6.0 to 20.5)	27.9 (20.9 to 34.9)	18.0 (9.4 to 26.5)

Statistical analyses

Statistical analysis title	Maintenance Study: 200 mg vs Placebo
Comparison groups	Maintenance Study: FIL 200 mg From Induction FIL 200 mg v Maintenance Study: Placebo From Induction Filgotinib 200 mg
Number of subjects included in analysis	297
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [31]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	24.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	14.6
upper limit	35.2

Notes:

[31] - CMH test is stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and of immunomodulators (Yes or No) at Maintenance baseline, and participation in Cohort A or B.

Statistical analysis title	Maintenance Study: 100 mg vs Placebo

Comparison groups	Maintenance Study: FIL 100 mg From Induction FIL 100 mg v Maintenance Study: Placebo From Induction Filgotinib 100 mg
Number of subjects included in analysis	261
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0521 [32]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	9.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.3
upper limit	21.2

Notes:

[32] - CMH test is stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and of immunomodulators (Yes or No) at Maintenance baseline, and participation in Cohort A or B.

Secondary: Maintenance Study: Percentage of Participants Who Achieved MCS Remission (Alternative Definition) at Week 58

End point title	Maintenance Study: Percentage of Participants Who Achieved MCS Remission (Alternative Definition) at Week 58

End point description:

MCS remission (alternative definition) was defined as having rectal bleeding, stool frequency, and PGA assessment subscores of 0 and an endoscopic subscore of 0 or 1; overall MCS of ≤ 1. MCS possible subscores: rectal bleeding (range: 0 to 3, where 0 = no blood seen and 3 = blood alone passes), stool frequency (range: 0 to 3, where 0 = normal number of stools and 3 = at least 5 stools more than normal), PGA subscore (range: 0 to 3 with higher score indicating the severe disease), and an endoscopic subscore (range: 0 to 3, where 0 = normal or inactive disease and 3 = severe disease [spontaneous bleeding, ulceration]). Total score for MCS ranged from 0 to 12 (sum of all subscores), with higher scores indicating more severe disease. Participants in the Full Analysis Set for the Maintenance Study were analysed.

End point type	Secondary

End point timeframe:

Week 58

End point values	Maintenance Study: FIL 200 mg From Induction FIL 200 mg	Maintenance Study: Placebo From Induction Filgotinib 200 mg	Maintenance Study: FIL 100 mg From Induction FIL 100 mg	Maintenance Study: Placebo From Induction Filgotinib 100 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	199	98	172	89
Units: percentage of participants				
number (confidence interval 95%)	22.1 (16.1 to 28.1)	6.1 (0.9 to 11.4)	12.2 (7.0 to 17.4)	7.9 (1.7 to 14.0)

Statistical analyses

Statistical analysis title	Maintenance Study: 200 mg vs Placebo
Comparison groups	Maintenance Study: FIL 200 mg From Induction FIL 200 mg v Maintenance Study: Placebo From Induction Filgotinib 200 mg

Number of subjects included in analysis	297
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0005 [33]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	16
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.8
upper limit	24.2

Notes:

[33] - CMH test is stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and of immunomodulators (Yes or No) at Maintenance baseline, and participation in Cohort A or B.

Statistical analysis title	Maintenance Study: 100 mg vs Placebo
Comparison groups	Maintenance Study: FIL 100 mg From Induction FIL 100 mg v Maintenance Study: Placebo From Induction Filgotinib 100 mg
Number of subjects included in analysis	261
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2946 [34]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	4.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.9
upper limit	12.6

Notes:

[34] - CMH test is stratified by concomitant use of oral, systemic corticosteroids (Yes or No) and of immunomodulators (Yes or No) at Maintenance baseline, and participating in Cohort A or B.

Secondary: Maintenance Study: Plasma Concentration of Filgotinib and Its Metabolite GS-829845

End point title	Maintenance Study: Plasma Concentration of Filgotinib and Its Metabolite GS-829845

End point description:

Plasma concentration is defined as the measured drug concentration of filgotinib and its metabolite GS-829845. Lower limit of quantitation (LLOQ) was defined as 1 ng/mL for analyte filgotinib and 2 ng/mL for analyte GS-829845. PK Analysis Set included all participants in the Safety Analysis Set who who took at least 1 dose of filgotinib and had at least 1 nonmissing plasma concentration value for filgotinib and/or its metabolite GS-829845 with available data were analysed. -99999 signifies the value was below the limit of quantitation. Data was not collected for the Maintenance Study Placebo arms.

End point type	Secondary

End point timeframe:

Week 26 (any Time) and Week 58 (predose)

End point values	Maintenance Study: FIL 200 mg From Induction FIL 200 mg	Maintenance Study: FIL 100 mg From Induction FIL 100 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	173	136		
Units: ng/mL				
median (inter-quartile range (Q1-Q3))				
Filgotinib: Week 26 (n= 169, 127)	8.5 (5.0 to 25.8)	4.4 (2.5 to 14.0)		
Filgotinib: Week 58 (n= 44, 26)	3.9 (-99999 to 9.1)	4.1 (-99999 to 6.9)		
Metabolite GS-829845: Week 26 (n= 170, 130)	2495.0 (1940.0 to 3010.0)	1180.0 (852.0 to 1550.0)		
Metabolite GS-829845: Week 58 (n= 44, 26)	1930.0 (1320.0 to 2630.0)	973.5 (773.0 to 1350.0)		

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Induction Study: first dose date up to one day before the Maintenance first dose date or last dose date whichever is earlier (maximum 17 weeks) plus 30 days, Maintenance study: First dose to the last dose in the
Maintenance Study (maximum 51 weeks) plus

Adverse event reporting additional description:

Adverse Events: Safety Analysis Set for the study included all participants who took at least 1 dose of study
drug in either the Induction Study (Cohorts A and B) or the Maintenance Study. All-Cause Mortality: All Randomized Analysis Set included all participants who were randomized on Day 1 into each corresponding
study.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.1

Reporting groups

Reporting group title	Induction Study (Cohort A): Filgotinib 200 mg

Reporting group description:

Participants in Cohort A (biologic-naive) received filgotinib 200 mg and PTM filgotinib 100 mg orally once daily
for 10 weeks.

Reporting group title	Induction Study (Cohort A): Filgotinib 100 mg

Reporting group description:

Participants in Cohort A (biologic-naive) received filgotinib 100 mg and PTM filgotinib 200 mg orally once daily
for 10 weeks.

Reporting group title	Induction Study (Cohort A): Placebo

Reporting group description:

Participants in Cohort A (biologic-naive) received PTM filgotinib 200 mg and PTM filgotinib 100 mg orally once
daily for 10 weeks.

Reporting group title	Induction Study (Cohort B): Filgotinib 200 mg

Reporting group description:

Participants in Cohort B (biologic-experienced) received filgotinib 200 mg and PTM filgotinib 100 mg orally once
daily for 10 weeks.

Reporting group title	Induction Study (Cohort B): Filgotinib 100 mg

Reporting group description:

Participants in Cohort B (biologic-experienced) received filgotinib 100 mg and PTM filgotinib 200 mg orally once
daily for 10 weeks

Reporting group title	Induction Study (Cohort B): Placebo

Reporting group description:

Participants in Cohort B (biologic-experienced) received PTM filgotinib 200 mg and PTM filgotinib 100 mg orally
once daily for 10 weeks.

Reporting group title	Maintenance Study: FIL 200 mg From Induction FIL 200 mg

Reporting group description:

Participants in the Filgotinib 200 mg arm who completed the Induction Study and achieved either EBS remission or MCS response at Week 10 were re-randomized at Week 11 into the Maintenance Study to receive
filgotinib 200 mg and PTM filgotinib 100 mg orally once daily for an additional 47 weeks (up to Week 58).

Reporting group title	Maintenance Study: Placebo From Induction Filgotinib 200 mg
Reporting group description:	
Participants in the Filgotinib 200 mg arm who completed the Induction Study and achieved either EBS remission or MCS response at Week 10 were re-randomized at Week 11 into the Maintenance Study to receive PTM filgotinib orally once daily for an additional 47 weeks (up to Week 58).	

Reporting group title	Maintenance Study: FIL 100 mg From Induction FIL 100 mg
Reporting group description:	
Participants in the Filgotinib 100 mg arm who completed the Induction Study and achieved either EBS remission or MCS response at Week 10 were re-randomized at Week 11 into the Maintenance Study to receive filgotinib 100 mg and PTM filgotinib 200 mg orally once daily for an additional 47 weeks (up to Week 58).	

Reporting group title	Maintenance Study: Placebo From Induction Filgotinib 100 mg
Reporting group description:	
Participants in the Filgotinib 100 mg arm who completed the Induction Study and achieved either EBS remission or MCS response at Week 10 were rerandomized at Week 11 into the Maintenance Study to receive PTM filgotinib orally once daily for an additional 47 weeks (up to Week 58).	

Reporting group title	Maintenance Study: Placebo From Induction Placebo
Reporting group description:	
Participants in the Placebo arm who completed the Induction Study and achieved either EBS remission or MCS response at Week 10 were re-randomized at Week 11 into the Maintenance Study to receive PTM filgotinib orally once daily for an additional 47 weeks (up to Week 58).	

Serious adverse events	Induction Study (Cohort A): Filgotinib 200 mg	Induction Study (Cohort A): Filgotinib 100 mg	Induction Study (Cohort A): Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 245 (1.22%)	13 / 277 (4.69%)	4 / 137 (2.92%)
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 cancer			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Colon cancer			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Malignant melanoma			

subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Haemorrhagic infarction			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Hypertension			
subjects affected / exposed	0 / 245 (0.00%)	1 / 277 (0.36%)	0 / 137 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Ectopic pregnancy			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Pyrexia			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Non-cardiac chest pain			

subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Immune system disorders			
Type I hypersensitivity			
subjects affected / exposed	0 / 245 (0.00%)	1 / 277 (0.36%)	0 / 137 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst ruptured			
subjects affected / exposed	0 / 245 (0.00%)	1 / 277 (0.36%)	0 / 137 (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
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Atelectasis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Dyspnoea			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Haemoptysis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Pulmonary embolism			

subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Pulmonary mass			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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			
Femur fracture			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Meniscus injury			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Procedural intestinal perforation			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	1 / 137 (0.73%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 245 (0.00%)	1 / 277 (0.36%)	0 / 137 (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
Tendon rupture			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Coronary artery stenosis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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

Left ventricular failure			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Pericarditis			
subjects affected / exposed	1 / 245 (0.41%)	0 / 277 (0.00%)	0 / 137 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Headache			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Transient ischaemic attack			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 245 (0.00%)	1 / 277 (0.36%)	1 / 137 (0.73%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	0 / 245 (0.00%)	1 / 277 (0.36%)	0 / 137 (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
Pancytopenia			
subjects affected / exposed	0 / 245 (0.00%)	1 / 277 (0.36%)	0 / 137 (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

Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	0 / 245 (0.00%)	3 / 277 (1.08%)	3 / 137 (2.19%)
occurrences causally related to treatment / all	0 / 0	0 / 3	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Pancreatitis acute			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Vomiting			
subjects affected / exposed	0 / 245 (0.00%)	1 / 277 (0.36%)	0 / 137 (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
Anal fissure			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Appendiceal mucocoele			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Dental cyst			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Gastritis			

subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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 haemorrhage			
subjects affected / exposed	1 / 245 (0.41%)	0 / 277 (0.00%)	0 / 137 (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
Large intestinal haemorrhage			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Nausea			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Supernumerary teeth			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Cholelithiasis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Calculus urinary			

subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Nephrolithiasis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Renal colic			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Myalgia			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 245 (0.00%)	1 / 277 (0.36%)	0 / 137 (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
Gastroenteritis viral			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Cellulitis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	1 / 137 (0.73%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Sepsis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Acute hepatitis B			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Anal abscess			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Dengue fever			
subjects affected / exposed	1 / 245 (0.41%)	0 / 277 (0.00%)	0 / 137 (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
Diverticulitis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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			
subjects affected / exposed	0 / 245 (0.00%)	1 / 277 (0.36%)	0 / 137 (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
Osteomyelitis			

subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	1 / 137 (0.73%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paronychia			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Pneumonia			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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
Staphylococcal infection			
subjects affected / exposed	0 / 245 (0.00%)	0 / 277 (0.00%)	0 / 137 (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	Induction Study (Cohort B): Filgotinib 200 mg	Induction Study (Cohort B): Filgotinib 100 mg	Induction Study (Cohort B): Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	19 / 262 (7.25%)	15 / 285 (5.26%)	9 / 142 (6.34%)
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 cancer			
subjects affected / exposed	1 / 262 (0.38%)	0 / 285 (0.00%)	0 / 142 (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
Colon cancer			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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
Malignant melanoma			

subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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
Haemorrhagic infarction			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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
Hypertension			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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
Pregnancy, puerperium and perinatal conditions			
Ectopic pregnancy			
subjects affected / exposed	0 / 262 (0.00%)	1 / 285 (0.35%)	0 / 142 (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
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 262 (0.00%)	1 / 285 (0.35%)	0 / 142 (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
Pyrexia			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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
Non-cardiac chest pain			

subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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
Immune system disorders			
Type I hypersensitivity			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst ruptured			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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
Atelectasis			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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
Dyspnoea			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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
Haemoptysis			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	1 / 142 (0.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			

subjects affected / exposed	1 / 262 (0.38%)	0 / 285 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary mass			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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			
Femur fracture			
subjects affected / exposed	0 / 262 (0.00%)	1 / 285 (0.35%)	0 / 142 (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
Meniscus injury			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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
Procedural intestinal perforation			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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
Tendon rupture			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Coronary artery stenosis			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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

Left ventricular failure			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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
Pericarditis			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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			
Cerebrovascular accident			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	1 / 142 (0.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 262 (0.00%)	1 / 285 (0.35%)	0 / 142 (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
Transient ischaemic attack			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 262 (0.38%)	1 / 285 (0.35%)	0 / 142 (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
Iron deficiency anaemia			
subjects affected / exposed	1 / 262 (0.38%)	0 / 285 (0.00%)	0 / 142 (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
Pancytopenia			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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			
subjects affected / exposed	7 / 262 (2.67%)	5 / 285 (1.75%)	5 / 142 (3.52%)
occurrences causally related to treatment / all	1 / 7	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	1 / 262 (0.38%)	0 / 285 (0.00%)	0 / 142 (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
Pancreatitis acute			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	1 / 142 (0.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 262 (0.00%)	1 / 285 (0.35%)	0 / 142 (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
Anal fissure			
subjects affected / exposed	1 / 262 (0.38%)	0 / 285 (0.00%)	0 / 142 (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
Appendiceal mucocoele			
subjects affected / exposed	1 / 262 (0.38%)	0 / 285 (0.00%)	0 / 142 (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
Dental cyst			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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
Duodenal ulcer haemorrhage			
subjects affected / exposed	1 / 262 (0.38%)	0 / 285 (0.00%)	0 / 142 (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
Gastritis			

subjects affected / exposed	0 / 262 (0.00%)	1 / 285 (0.35%)	0 / 142 (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
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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 intestinal haemorrhage			
subjects affected / exposed	1 / 262 (0.38%)	0 / 285 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 262 (0.00%)	1 / 285 (0.35%)	0 / 142 (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
Supernumerary teeth			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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
Cholelithiasis			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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
Calculus urinary			

subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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
Nephrolithiasis			
subjects affected / exposed	1 / 262 (0.38%)	0 / 285 (0.00%)	0 / 142 (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
Renal colic			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	1 / 142 (0.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	2 / 262 (0.76%)	0 / 285 (0.00%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 262 (0.00%)	1 / 285 (0.35%)	0 / 142 (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
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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 viral			
subjects affected / exposed	1 / 262 (0.38%)	0 / 285 (0.00%)	1 / 142 (0.70%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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

Sepsis			
subjects affected / exposed	0 / 262 (0.00%)	2 / 285 (0.70%)	0 / 142 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute hepatitis B			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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
Anal abscess			
subjects affected / exposed	0 / 262 (0.00%)	1 / 285 (0.35%)	0 / 142 (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
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	1 / 142 (0.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	1 / 262 (0.38%)	0 / 285 (0.00%)	0 / 142 (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
Dengue fever			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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
Diverticulitis			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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
Osteomyelitis			

subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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
Paronychia			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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
Pneumonia			
subjects affected / exposed	0 / 262 (0.00%)	0 / 285 (0.00%)	0 / 142 (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
Staphylococcal infection			
subjects affected / exposed	0 / 262 (0.00%)	1 / 285 (0.35%)	0 / 142 (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

Serious adverse events	Maintenance Study: FIL 200 mg From Induction FIL 200 mg	Maintenance Study: Placebo From Induction Filgotinib 200 mg	Maintenance Study: FIL 100 mg From Induction FIL 100 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 202 (4.46%)	0 / 99 (0.00%)	8 / 179 (4.47%)
number of deaths (all causes)	2	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Colon cancer			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			

subjects affected / exposed	1 / 202 (0.50%)	0 / 99 (0.00%)	0 / 179 (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
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Haemorrhagic infarction			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Hypertension			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Pregnancy, puerperium and perinatal conditions			
Ectopic pregnancy			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	1 / 202 (0.50%)	0 / 99 (0.00%)	0 / 179 (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
Pyrexia			
subjects affected / exposed	1 / 202 (0.50%)	0 / 99 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			

subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Type I hypersensitivity			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst ruptured			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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	1 / 202 (0.50%)	0 / 99 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Atelectasis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Pulmonary embolism			

subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Pulmonary mass			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Femur fracture			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Meniscus injury			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Procedural intestinal perforation			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Tendon rupture			
subjects affected / exposed	1 / 202 (0.50%)	0 / 99 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Coronary artery stenosis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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

Left ventricular failure			
subjects affected / exposed	1 / 202 (0.50%)	0 / 99 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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			
Cerebrovascular accident			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Headache			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Transient ischaemic attack			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Iron deficiency anaemia			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Pancytopenia			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Anal fissure			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Appendiceal mucocoele			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Dental cyst			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Gastritis			

subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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 haemorrhage			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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 intestinal haemorrhage			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Nausea			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Supernumerary teeth			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Cholelithiasis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Calculus urinary			

subjects affected / exposed	1 / 202 (0.50%)	0 / 99 (0.00%)	0 / 179 (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
Nephrolithiasis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Renal colic			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Myalgia			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	1 / 202 (0.50%)	0 / 99 (0.00%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Cellulitis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Sepsis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Acute hepatitis B			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Anal abscess			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Dengue fever			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Diverticulitis			
subjects affected / exposed	1 / 202 (0.50%)	0 / 99 (0.00%)	0 / 179 (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
Gastroenteritis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Osteomyelitis			

subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Paronychia			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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
Staphylococcal infection			
subjects affected / exposed	0 / 202 (0.00%)	0 / 99 (0.00%)	0 / 179 (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 Study: Placebo From Induction Filgotinib 100 mg	Maintenance Study: Placebo From Induction Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 91 (7.69%)	4 / 93 (4.30%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant melanoma			

subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 91 (0.00%)	1 / 93 (1.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic infarction			
subjects affected / exposed	0 / 91 (0.00%)	1 / 93 (1.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Ectopic pregnancy			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			

subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Type I hypersensitivity			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Ovarian cyst ruptured			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atelectasis			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			

subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary mass			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Femur fracture			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus injury			
subjects affected / exposed	1 / 91 (1.10%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural intestinal perforation			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon rupture			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Coronary artery stenosis			
subjects affected / exposed	1 / 91 (1.10%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Left ventricular failure			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency anaemia			
subjects affected / exposed	1 / 91 (1.10%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	1 / 91 (1.10%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal fissure			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendiceal mucocoele			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dental cyst			
subjects affected / exposed	0 / 91 (0.00%)	1 / 93 (1.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			

subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal haemorrhage			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supernumerary teeth			
subjects affected / exposed	0 / 91 (0.00%)	1 / 93 (1.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	1 / 91 (1.10%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 91 (0.00%)	1 / 93 (1.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus urinary			

subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal colic			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myalgia			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			
subjects affected / exposed	1 / 91 (1.10%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Sepsis			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute hepatitis B			
subjects affected / exposed	1 / 91 (1.10%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal abscess			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dengue fever			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			

subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paronychia			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 91 (0.00%)	1 / 93 (1.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal infection			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Induction Study (Cohort A): Filgotinib 200 mg	Induction Study (Cohort A): Filgotinib 100 mg	Induction Study (Cohort A): Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	40 / 245 (16.33%)	43 / 277 (15.52%)	20 / 137 (14.60%)
Nervous system disorders			
Headache			
subjects affected / exposed	11 / 245 (4.49%)	12 / 277 (4.33%)	6 / 137 (4.38%)
occurrences (all)	11	14	8
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	6 / 245 (2.45%)	10 / 277 (3.61%)	4 / 137 (2.92%)
occurrences (all)	7	10	4
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	5 / 245 (2.04%)	1 / 277 (0.36%)	1 / 137 (0.73%)
occurrences (all)	5	1	1
Gastrointestinal disorders			

Colitis ulcerative			
subjects affected / exposed	6 / 245 (2.45%)	3 / 277 (1.08%)	5 / 137 (3.65%)
occurrences (all)	6	3	5
Abdominal pain			
subjects affected / exposed	3 / 245 (1.22%)	3 / 277 (1.08%)	3 / 137 (2.19%)
occurrences (all)	3	3	3
Nausea			
subjects affected / exposed	8 / 245 (3.27%)	3 / 277 (1.08%)	1 / 137 (0.73%)
occurrences (all)	8	3	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 245 (0.00%)	4 / 277 (1.44%)	2 / 137 (1.46%)
occurrences (all)	0	5	2
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	7 / 245 (2.86%)	9 / 277 (3.25%)	2 / 137 (1.46%)
occurrences (all)	7	9	2
Upper respiratory tract infection			
subjects affected / exposed	2 / 245 (0.82%)	2 / 277 (0.72%)	0 / 137 (0.00%)
occurrences (all)	3	2	0

Non-serious adverse events	Induction Study (Cohort B): Filgotinib 200 mg	Induction Study (Cohort B): Filgotinib 100 mg	Induction Study (Cohort B): Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	83 / 262 (31.68%)	77 / 285 (27.02%)	55 / 142 (38.73%)
Nervous system disorders			
Headache			
subjects affected / exposed	19 / 262 (7.25%)	10 / 285 (3.51%)	9 / 142 (6.34%)
occurrences (all)	21	13	13
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	12 / 262 (4.58%)	11 / 285 (3.86%)	10 / 142 (7.04%)
occurrences (all)	12	11	11
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	6 / 262 (2.29%)	3 / 285 (1.05%)	8 / 142 (5.63%)
occurrences (all)	6	4	8

Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	14 / 262 (5.34%)	11 / 285 (3.86%)	6 / 142 (4.23%)
occurrences (all)	14	11	6
Abdominal pain			
subjects affected / exposed	8 / 262 (3.05%)	7 / 285 (2.46%)	9 / 142 (6.34%)
occurrences (all)	9	7	9
Nausea			
subjects affected / exposed	7 / 262 (2.67%)	15 / 285 (5.26%)	6 / 142 (4.23%)
occurrences (all)	8	16	6
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	8 / 262 (3.05%)	10 / 285 (3.51%)	7 / 142 (4.93%)
occurrences (all)	8	11	8
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	20 / 262 (7.63%)	20 / 285 (7.02%)	11 / 142 (7.75%)
occurrences (all)	21	21	11
Upper respiratory tract infection			
subjects affected / exposed	13 / 262 (4.96%)	4 / 285 (1.40%)	5 / 142 (3.52%)
occurrences (all)	14	4	6

Non-serious adverse events	Maintenance Study: FIL 200 mg From Induction FIL 200 mg	Maintenance Study: Placebo From Induction Filgotinib 200 mg	Maintenance Study: FIL 100 mg From Induction FIL 100 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	67 / 202 (33.17%)	33 / 99 (33.33%)	53 / 179 (29.61%)
Nervous system disorders			
Headache			
subjects affected / exposed	7 / 202 (3.47%)	0 / 99 (0.00%)	10 / 179 (5.59%)
occurrences (all)	8	0	10
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 202 (1.98%)	0 / 99 (0.00%)	4 / 179 (2.23%)
occurrences (all)	4	0	4
General disorders and administration site conditions			
Pyrexia			

subjects affected / exposed	6 / 202 (2.97%)	1 / 99 (1.01%)	4 / 179 (2.23%)
occurrences (all)	7	1	4
Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	21 / 202 (10.40%)	18 / 99 (18.18%)	18 / 179 (10.06%)
occurrences (all)	23	18	18
Abdominal pain			
subjects affected / exposed	8 / 202 (3.96%)	6 / 99 (6.06%)	6 / 179 (3.35%)
occurrences (all)	8	9	7
Nausea			
subjects affected / exposed	5 / 202 (2.48%)	1 / 99 (1.01%)	4 / 179 (2.23%)
occurrences (all)	6	1	4
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	8 / 202 (3.96%)	7 / 99 (7.07%)	6 / 179 (3.35%)
occurrences (all)	9	7	6
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	22 / 202 (10.89%)	6 / 99 (6.06%)	12 / 179 (6.70%)
occurrences (all)	25	8	17
Upper respiratory tract infection			
subjects affected / exposed	11 / 202 (5.45%)	3 / 99 (3.03%)	6 / 179 (3.35%)
occurrences (all)	12	4	8

Non-serious adverse events	Maintenance Study: Placebo From Induction Filgotinib 100 mg	Maintenance Study: Placebo From Induction Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	33 / 91 (36.26%)	26 / 93 (27.96%)	
Nervous system disorders			
Headache			
subjects affected / exposed	5 / 91 (5.49%)	5 / 93 (5.38%)	
occurrences (all)	5	8	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 91 (1.10%)	0 / 93 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			

Pyrexia			
subjects affected / exposed	3 / 91 (3.30%)	1 / 93 (1.08%)	
occurrences (all)	3	1	
Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	16 / 91 (17.58%)	10 / 93 (10.75%)	
occurrences (all)	17	11	
Abdominal pain			
subjects affected / exposed	2 / 91 (2.20%)	4 / 93 (4.30%)	
occurrences (all)	2	4	
Nausea			
subjects affected / exposed	0 / 91 (0.00%)	2 / 93 (2.15%)	
occurrences (all)	0	3	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 91 (3.30%)	4 / 93 (4.30%)	
occurrences (all)	3	4	
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	6 / 91 (6.59%)	5 / 93 (5.38%)	
occurrences (all)	6	5	
Upper respiratory tract infection			
subjects affected / exposed	3 / 91 (3.30%)	3 / 93 (3.23%)	
occurrences (all)	3	3	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 September 2016	Amendment 1: • Updates were made in the text in response to US Food and Drug Administration (FDA) requests. • Updated Study Procedures Table and footnotes to reflect changes made to study visits assessments/procedures in the protocol. • Protocol GS-US-418-3899 title changed from open-label extension to long-term extension (LTE) study. • Sections were updated with emerging relevant nonclinical and clinical data. • A novel histologic endpoint was added to account for the evolution of understanding and thinking surrounding histologic healing. • Criteria for discontinuation for febrile neutropenia, anemia, and international normalized ratio (INR) value when considering hepatic laboratory changes were added to ensure subject safety. Additional text surrounding departure from the study clarified that pregnant subjects were to discontinue the study and that early termination (ET) and posttreatment visits were requested for subjects withdrawing. • An exclusion criterion of severe hepatic impairment defined by Child-Pugh Class C was added.
27 October 2016	Amendment 2: • Updates were made in the text in response to the Voluntary Harmonization Procedure (VHP) request to include MCS remission (alternative definition) as a secondary endpoint at Week 10 and Week 58. • Text was updated to clarify that lymphocyte-depleting therapies and natalizumab were prohibited concomitant medications for the duration of the study. • A rationale for the exclusion of potent P-glycoprotein (P-gp) inducers was added upon VHP request. • Additional Week 26 and Week 58 electrocardiogram (ECG) procedures were added upon VHP request. • Text was added to clarify that coagulation parameters should be tested in cases where either aspartate or alanine aminotransferase (AST/ALT) was > 3 * upper limit of normal (ULN), to enable compliance with subject discontinuation parameters based on AST/ALT and INR.

15 June 2017	Amendment 3: • Updates were made in the text in response to the South Korean Ministry of Food and Drug Safety request that the use of filgotinib 200 mg in males in Korea be limited to subjects who had failed 2 classes of biologic therapies (any TNF-α antagonist and vedolizumab). • Guidance from investigators regarding rate of steroid tapering was added to text and clarity was added regarding handling of subjects who exceed baseline steroid doses. • Sections were updated with emerging relevant clinical and pipeline data. • Text was updated to reflect that subjects were up to date on colorectal cancer surveillance processes prior to entering the screening period. • Text was added to clarify the type of colectomies that were excluded • Clarity around tuberculosis (TB) eligibility was added. • Instructions for recording the Normal Stool Count and ensuring eligibility prior to endoscopy were added.
05 March 2018	Amendment 4: • The number of sites was increased to ensure that a target number of subjects were enrolled in the study considering the accumulated enrollment rate. • Provided additional clarity on inclusion/exclusion criteria including those for hepatitis. • Provided additional flexibility for enhanced safety monitoring (with increased flexibility for data monitoring committee [DMC] meeting scheduling and suggested infectious workups for disease worsening).
02 April 2019	Amendment 5: • Removed plans for interim unblinded analysis for a prespecified sponsor's executive team review.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported