Clinical trial results:
Combined Phase 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 Crohn's Disease

Summary

EudraCT number	2016-001367-36
Trial protocol	HU BG AT CZ GB IS SE DE GR PT SK ES BE NL HR NO IT
Global end of trial date	11 November 2022

Results information

Result version number	v1 (current)
This version publication date	08 November 2023
First version publication date	08 November 2023

Trial information

Trial identification

Sponsor protocol code	GS-US-419-3895

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02914561
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Galapagos NV
Sponsor organisation address	Generaal De Wittelaan L11 A3, Mechelen, Belgium, 2800
Public contact	Galapagos Medical Information, Galapagos NV, medicalinfo@glpg.com
Scientific contact	Galapagos Medical Information, Galapagos NV, medicalinfo@glpg.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	11 November 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	11 November 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objectives of this study are to evaluate the safety and efficacy of filgotinib during induction and maintenance treatment of moderately to severely active Crohn's disease (CD) in participants who are biologic-naive and biologic-experienced.

Protection of trial subjects:

The study was performed in accordance with the ethical principles that have their origin in the "Declaration of Helsinki" and its amendments in force at the time of the study (2013 version). It was also carried out in conformity with the protocol, the International Council for Harmonization Guideline for Good Clinical Practice (ICH-GCP) E6 (R2), and local ethical and legal requirements. The investigator informed the subjects of the risks and benefits of the study. The subjects were informed that they could withdraw from the study at any time for any reason. Consent was obtained in writing prior to any study-related activities; the investigator retained a copy of the ICFs, which are available to the sponsor for inspection. The subjects were covered by the sponsor's insurance according to local legal requirements.

Background therapy: -
Evidence for comparator: -

Actual start date of recruitment	31 October 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	Serbia: 3
Country: Number of subjects enrolled	Romania: 9
Country: Number of subjects enrolled	Sri Lanka: 12
Country: Number of subjects enrolled	Japan: 61
Country: Number of subjects enrolled	Ukraine: 54
Country: Number of subjects enrolled	Switzerland: 13
Country: Number of subjects enrolled	India: 91
Country: Number of subjects enrolled	Hong Kong: 4
Country: Number of subjects enrolled	United States: 303
Country: Number of subjects enrolled	Malaysia: 8
Country: Number of subjects enrolled	Russian Federation: 24
Country: Number of subjects enrolled	Korea, Republic of: 18
Country: Number of subjects enrolled	New Zealand: 11
Country: Number of subjects enrolled	Canada: 37
Country: Number of subjects enrolled	Taiwan: 10

Country: Number of subjects enrolled	South Africa: 9
Country: Number of subjects enrolled	Georgia: 4
Country: Number of subjects enrolled	Israel: 29
Country: Number of subjects enrolled	Australia: 49
Country: Number of subjects enrolled	Singapore: 4
Country: Number of subjects enrolled	Austria: 3
Country: Number of subjects enrolled	Greece: 2
Country: Number of subjects enrolled	Netherlands: 36
Country: Number of subjects enrolled	Norway: 4
Country: Number of subjects enrolled	Poland: 125
Country: Number of subjects enrolled	Portugal: 9
Country: Number of subjects enrolled	Slovakia: 15
Country: Number of subjects enrolled	Spain: 27
Country: Number of subjects enrolled	Sweden: 2
Country: Number of subjects enrolled	United Kingdom: 33
Country: Number of subjects enrolled	Croatia: 4
Country: Number of subjects enrolled	Belgium: 62
Country: Number of subjects enrolled	Czechia: 28
Country: Number of subjects enrolled	France: 130
Country: Number of subjects enrolled	Germany: 83
Country: Number of subjects enrolled	Hungary: 16
Country: Number of subjects enrolled	Iceland: 1
Country: Number of subjects enrolled	Ireland: 7
Country: Number of subjects enrolled	Italy: 32
Worldwide total number of subjects	1372
EEA total number of subjects	595

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)	1313
From 65 to 84 years	59
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants with diagnosis of moderately to severely Active Crohn's disease (CD) were enrolled in the study. Participants who were biologic-naïve or biologic-experienced were enrolled in Cohort A and participants who were biologic-experienced were enrolled in Cohort B, respectively.

Pre-assignment

Screening details:

Participants who met protocol eligibility criteria were assigned to the respective Cohort and subsequently randomized in a blinded fashion in a 1:1:1 ratio to 1 of 3 treatments: filgotinib 200 milligram (mg), filgotinib 100 mg and placebo.

Period 1

Period 1 title	Induction study (Day 1 to Week 10)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Cohort A: Filgotinib 200 mg (Induction Study)

Arm description:

Biologic naïve and biologic experienced participants received filgotinib 200 mg with placebo-to-match (PTM) filgotinib 100 mg tablet orally once daily, for a period of 10 weeks.

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

Dosage and administration details:

Filgotinib film-coated tablets administered orally once daily.

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

Dosage and administration details:

Placebo administered orally once daily.

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

Arm description:

Biologic naïve and biologic experienced participants received filgotinib 100 mg with PTM filgotinib 200 mg tablet orally once daily, for a period of 10 weeks.

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

Dosage and administration details:	
Filgotinib film-coated tablets administered orally once daily.	
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Placebo administered orally once daily.	
Arm title	Cohort A: Placebo (Induction Study)
Arm description:	
Biologic naïve and biologic experienced participants received PTM filgotinib 200 mg and PTM filgotinib 100 mg tablet orally once daily, for a period of 10 weeks.	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Placebo administered orally once daily.	
Arm title	Cohort B: Filgotinib 200 mg (Induction Study)
Arm description:	
Biologic experienced participants received filgotinib 200 mg with PTM filgotinib 100 mg tablet orally once daily, for a period of 10 weeks.	
Arm type	Experimental
Investigational medicinal product name	Filgotinib
Investigational medicinal product code	GS-6034, GLPG0634
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Filgotinib film-coated tablets administered orally once daily.	
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Placebo administered orally once daily.	
Arm title	Cohort B: Filgotinib 100 mg (Induction Study)
Arm description:	
Biologic experienced participants received filgotinib 100 mg with PTM filgotinib 200 mg tablet orally once daily, for a period of 10 weeks.	
Arm type	Experimental
Investigational medicinal product name	Filgotinib
Investigational medicinal product code	GS-6034, GLPG0634
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Filgotinib film-coated tablets administered orally once daily.	

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

Dosage and administration details:

Placebo administered orally once daily.

Arm title	Cohort B: Placebo (Induction Study)

Arm description:

Biologic experienced participants received PTM filgotinib 200 mg with PTM filgotinib 100 mg tablet orally once daily, for a period of 10 weeks.

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

Dosage and administration details:

Placebo administered orally once daily.

Number of subjects in period 1	Cohort A: Filgotinib 200 mg (Induction Study)	Cohort A: Filgotinib 100 mg (Induction Study)	Cohort A: Placebo (Induction Study)
Started	223	245	239
Completed	204	213	212
Not completed	19	32	27
Consent withdrawn by subject	1	9	6
Physician decision	1	5	2
Non-Compliance with Study Drug	-	-	1
Adverse event, non-fatal	15	14	14
Randomized but not treated	1	-	2
Pregnancy	1	-	-
Lost to follow-up	-	-	1
Protocol deviation	-	4	1

Number of subjects in period 1	Cohort B: Filgotinib 200 mg (Induction Study)	Cohort B: Filgotinib 100 mg (Induction Study)	Cohort B: Placebo (Induction Study)
Started	204	230	231
Completed	177	183	192
Not completed	27	47	39
Consent withdrawn by subject	-	7	12
Physician decision	-	4	4
Non-Compliance with Study Drug	-	-	1
Adverse event, non-fatal	24	31	19
Randomized but not treated	2	2	2

Pregnancy	-	-	-
Lost to follow-up	-	-	-
Protocol deviation	1	3	1

Period 2

Period 2 title	Maintenance study (Weeks 11 to 58)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Filgotinib 200 mg to Filgotinib 200 mg (Maintenance Study)

Arm description:

Participants who received filgotinib 200 mg in induction study and who achieved either clinical remission by PRO2 or endoscopic response at Week 10 were re-randomized to the maintenance study and received filgotinib 200 mg and PTM filgotinib 100 mg tablet orally once daily, up to Week 58.

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

Dosage and administration details:

Filgotinib film-coated tablets administered orally once daily.

Arm title	Filgotinib 200 mg to Placebo (Maintenance Study)

Arm description:

Participants who received filgotinib 200 mg in induction study and who achieved either clinical remission by PRO2 or endoscopic response at Week 10 were re-randomized to the maintenance study and received PTM filgotinib 100 mg and PTM filgotinib 200 mg tablet orally once daily, up to Week 58.

Arm type	Placebo
Investigational medicinal product name	Filgotinib
Investigational medicinal product code	GS-6034, GLPG0634
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Filgotinib film-coated tablets administered orally once daily.

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

Dosage and administration details:

Placebo administered orally once daily.

Arm title	Filgotinib 100 mg to Filgotinib 100 mg (Maintenance Study)

Arm description:

Participants who received filgotinib 100 mg in induction study and who achieved either clinical remission by PRO2 or endoscopic response at Week 10 were re-randomized to the maintenance study and received filgotinib 100 mg and PTM filgotinib 200 mg tablet orally once daily, up to Week 58.

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

Dosage and administration details:

Filgotinib film-coated tablets administered orally once daily.

Arm title	Filgotinib 100 mg to Placebo (Maintenance Study)

Arm description:

Participants who received filgotinib 100 mg in induction study and who achieved either clinical remission by PRO2 or endoscopic response at Week 10 were re-randomized to the maintenance study and received PTM filgotinib 200 mg and PTM filgotinib 100 mg tablet orally once daily, up to Week 58.

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

Dosage and administration details:

Filgotinib film-coated tablets administered orally once daily.

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

Dosage and administration details:

Placebo administered orally once daily.

Arm title	Placebo to Placebo (Maintenance Study)

Arm description:

Participants who received placebo in induction study and who achieved either clinical remission by PRO2 or endoscopic response at Week 10 were re-randomized to the maintenance study and received PTM filgotinib 100 mg and PTM filgotinib 200 mg tablet orally once daily, up to Week 58.

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

Dosage and administration details:

Placebo administered orally once daily.

Number of subjects in period 2[1]	Filgotinib 200 mg to Filgotinib 200 mg (Maintenance Study)	Filgotinib 200 mg to Placebo (Maintenance Study)	Filgotinib 100 mg to Filgotinib 100 mg (Maintenance Study)
Started	118	56	105
Completed	64	21	45
Not completed	54	35	60
Consent withdrawn by subject	5	1	2
Physician decision	1	-	2
Non- Compliance with Study Drug	-	-	1
Adverse event, non-fatal	9	2	11
Randomized but not treated	-	-	1
Protocol- Specified Disease Worsening	31	32	40
Pregnancy	1	-	-
Lost to follow-up	3	-	1
Protocol deviation	4	-	2

Number of subjects in period 2[1]	Filgotinib 100 mg to Placebo (Maintenance Study)	Placebo to Placebo (Maintenance Study)
Started	56	146
Completed	26	74
Not completed	30	72
Consent withdrawn by subject	1	9
Physician decision	1	3
Non- Compliance with Study Drug	-	-
Adverse event, non-fatal	2	12
Randomized but not treated	1	1
Protocol- Specified Disease Worsening	25	43
Pregnancy	-	-
Lost to follow-up	-	-
Protocol deviation	-	4

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Not all participants who completed the induction study entered the maintenance study.

Baseline characteristics

Reporting groups	
Reporting group title	Cohort A: Filgotinib 200 mg (Induction Study)
Reporting group description:	
Biologic naïve and biologic experienced participants received filgotinib 200 mg with placebo-to-match (PTM) filgotinib 100 mg tablet orally once daily, for a period of 10 weeks.	
Reporting group title	Cohort A: Filgotinib 100 mg (Induction Study)
Reporting group description:	
Biologic naïve and biologic experienced participants received filgotinib 100 mg with PTM filgotinib 200 mg tablet orally once daily, for a period of 10 weeks.	
Reporting group title	Cohort A: Placebo (Induction Study)
Reporting group description:	
Biologic naïve and biologic experienced participants received PTM filgotinib 200 mg and PTM filgotinib 100 mg tablet orally once daily, for a period of 10 weeks.	
Reporting group title	Cohort B: Filgotinib 200 mg (Induction Study)
Reporting group description:	
Biologic experienced participants received filgotinib 200 mg with PTM filgotinib 100 mg tablet orally once daily, for a period of 10 weeks.	
Reporting group title	Cohort B: Filgotinib 100 mg (Induction Study)
Reporting group description:	
Biologic experienced participants received filgotinib 100 mg with PTM filgotinib 200 mg tablet orally once daily, for a period of 10 weeks.	
Reporting group title	Cohort B: Placebo (Induction Study)
Reporting group description:	
Biologic experienced participants received PTM filgotinib 200 mg with PTM filgotinib 100 mg tablet orally once daily, for a period of 10 weeks.	

Reporting group values	Cohort A: Filgotinib 200 mg (Induction Study)	Cohort A: Filgotinib 100 mg (Induction Study)	Cohort A: Placebo (Induction Study)
Number of subjects	223	245	239
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	213	233	229
From 65-84 years	10	12	10
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	39	39	39
standard deviation	± 13.8	± 14.1	± 14.0
Gender categorical Units: Subjects			
Female	110	106	130

Male	113	139	109

Ethnicity			
Not Permitted = local regulators did not allow collection of race or ethnicity information.			
Units: Subjects			
Hispanic or Latino	4	5	4
Not Hispanic or Latino	214	237	232
Not Permitted	5	3	3
Race			
Not Permitted = local regulators did not allow collection of race information.			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	45	52	44
Black or African American	3	6	4
Native Hawaiian or Other Pacific Islander	0	0	0
White	166	179	185
Other	2	3	2
Not Permitted	7	5	4

Reporting group values	Cohort B: Filgotinib 200 mg (Induction Study)	Cohort B: Filgotinib 100 mg (Induction Study)	Cohort B: Placebo (Induction Study)
Number of subjects	204	230	231
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	191	220	227
From 65-84 years	13	10	4
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	39	42	39
standard deviation	± 14.1	± 13.5	± 12.4
Gender categorical Units: Subjects			
Female	115	129	116
Male	89	101	115
Ethnicity			
Not Permitted = local regulators did not allow collection of race or ethnicity information.			
Units: Subjects			
Hispanic or Latino	2	8	4
Not Hispanic or Latino	193	217	220
Not Permitted	9	5	7
Race			

Not Permitted = local regulators did not allow collection of race information.			
Units: Subjects			
American Indian or Alaska Native	0	1	0
Asian	24	25	31
Black or African American	6	9	6
Native Hawaiian or Other Pacific Islander	0	1	2
White	158	182	178
Other	3	0	1
Not Permitted	13	12	13

Reporting group values	Total		
Number of subjects	1372		
Age categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	1313		
From 65-84 years	59		
85 years and over	0		
Age continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical			
Units: Subjects			
Female	706		
Male	666		
Ethnicity			
Not Permitted = local regulators did not allow collection of race or ethnicity information.			
Units: Subjects			
Hispanic or Latino	27		
Not Hispanic or Latino	1313		
Not Permitted	32		
Race			
Not Permitted = local regulators did not allow collection of race information.			
Units: Subjects			
American Indian or Alaska Native	1		
Asian	221		
Black or African American	34		
Native Hawaiian or Other Pacific Islander	3		
White	1048		
Other	11		
Not Permitted	54		

End points

End points reporting groups

Reporting group title	Cohort A: Filgotinib 200 mg (Induction Study)
Reporting group description:	
Biologic naïve and biologic experienced participants received filgotinib 200 mg with placebo-to-match (PTM) filgotinib 100 mg tablet orally once daily, for a period of 10 weeks.	
Reporting group title	Cohort A: Filgotinib 100 mg (Induction Study)
Reporting group description:	
Biologic naïve and biologic experienced participants received filgotinib 100 mg with PTM filgotinib 200 mg tablet orally once daily, for a period of 10 weeks.	
Reporting group title	Cohort A: Placebo (Induction Study)
Reporting group description:	
Biologic naïve and biologic experienced participants received PTM filgotinib 200 mg and PTM filgotinib 100 mg tablet orally once daily, for a period of 10 weeks.	
Reporting group title	Cohort B: Filgotinib 200 mg (Induction Study)
Reporting group description:	
Biologic experienced participants received filgotinib 200 mg with PTM filgotinib 100 mg tablet orally once daily, for a period of 10 weeks.	
Reporting group title	Cohort B: Filgotinib 100 mg (Induction Study)
Reporting group description:	
Biologic experienced participants received filgotinib 100 mg with PTM filgotinib 200 mg tablet orally once daily, for a period of 10 weeks.	
Reporting group title	Cohort B: Placebo (Induction Study)
Reporting group description:	
Biologic experienced participants received PTM filgotinib 200 mg with PTM filgotinib 100 mg tablet orally once daily, for a period of 10 weeks.	
Reporting group title	Filgotinib 200 mg to Filgotinib 200 mg (Maintenance Study)
Reporting group description:	
Participants who received filgotinib 200 mg in induction study and who achieved either clinical remission by PRO2 or endoscopic response at Week 10 were re-randomized to the maintenance study and received filgotinib 200 mg and PTM filgotinib 100 mg tablet orally once daily, up to Week 58.	
Reporting group title	Filgotinib 200 mg to Placebo (Maintenance Study)
Reporting group description:	
Participants who received filgotinib 200 mg in induction study and who achieved either clinical remission by PRO2 or endoscopic response at Week 10 were re-randomized to the maintenance study and received PTM filgotinib 100 mg and PTM filgotinib 200 mg tablet orally once daily, up to Week 58.	
Reporting group title	Filgotinib 100 mg to Filgotinib 100 mg (Maintenance Study)
Reporting group description:	
Participants who received filgotinib 100 mg in induction study and who achieved either clinical remission by PRO2 or endoscopic response at Week 10 were re-randomized to the maintenance study and received filgotinib 100 mg and PTM filgotinib 200 mg tablet orally once daily, up to Week 58.	
Reporting group title	Filgotinib 100 mg to Placebo (Maintenance Study)
Reporting group description:	
Participants who received filgotinib 100 mg in induction study and who achieved either clinical remission by PRO2 or endoscopic response at Week 10 were re-randomized to the maintenance study and received PTM filgotinib 200 mg and PTM filgotinib 100 mg tablet orally once daily, up to Week 58.	
Reporting group title	Placebo to Placebo (Maintenance Study)
Reporting group description:	
Participants who received placebo in induction study and who achieved either clinical remission by PRO2 or endoscopic response at Week 10 were re-randomized to the maintenance study and received PTM filgotinib 100 mg and PTM filgotinib 200 mg tablet orally once daily, up to Week 58.	
Subject analysis set title	Filgotinib 200 mg (Maintenance Study)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants who received filgotinib 200 mg in induction study and who achieved either clinical remission by PRO2 or endoscopic response at Week 10 were re-randomized to the maintenance study and received filgotinib 200 mg and PTM filgotinib 100 mg tablet orally once daily, up to Week 58.

Subject analysis set title	Filgotinib 100 mg (Maintenance Study)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants who received filgotinib 100 mg in induction study and who achieved either clinical remission by PRO2 or endoscopic response at Week 10 were re-randomized to the maintenance study and received filgotinib 100 mg and PTM filgotinib 200 mg tablet orally once daily, up to Week 58.

Primary: Induction Study: Percentage of Participants who Achieved Endoscopic Response at Week 10

End point title	Induction Study: Percentage of Participants who Achieved Endoscopic Response at Week 10

End point description:

The Simple Endoscopic Score for Crohn's Disease (SES-CD) assessed the degree of inflammation on the basis of 4 components: size of ulcers, ulcerated surface, affected surface, and presence of narrowing. Each of these components was scored on a scale of 0 to 3 (worst). In the SES-CD, each of these 4 components are assessed in the five segments: ileum, right colon, transverse colon, left colon, and rectum. The SES-CD was the sum of the individual scores of each of the components across the five segments. The range of SES-CD scores was 0 - 12 for each segment, and 0 - 60 for the overall SES-CD score, with larger scores indicating greater severity of disease. Endoscopic response was defined as ≥ 50% reduction from baseline in total SES-CD score. The Full Analysis Set (FAS) for each Induction Study (Cohorts A and B) included all randomized 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	Cohort A: Filgotinib 200 mg (Induction Study)	Cohort A: Filgotinib 100 mg (Induction Study)	Cohort A: Placebo (Induction Study)	Cohort B: Filgotinib 200 mg (Induction Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	222	245	237	202
Units: Percentage of participants				
number (confidence interval 95%)	23.9 (18.0 to 29.7)	20.8 (15.5 to 26.1)	18.1 (13.0 to 23.3)	11.9 (7.2 to 16.6)

End point values	Cohort B: Filgotinib 100 mg (Induction Study)	Cohort B: Placebo (Induction Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	228	229		
Units: Percentage of participants				
number (confidence interval 95%)	13.6 (8.9 to 18.3)	11.4 (7.0 to 15.7)		

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description:	
CMH test was stratified by concomitant use of oral, systemic corticosteroids (Yes/No) and of immunomodulators (Yes/No) at Day 1, and number of prior exposures to biologic agent (0, >=1).	
Comparison groups	Cohort A: Filgotinib 200 mg (Induction Study) v Cohort A: Placebo (Induction Study)
Number of subjects included in analysis	459
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1365
Method	Cochran-Mantel-Haenszel
Parameter estimate	Stratified Percentage Difference
Point estimate	5.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2
upper limit	12.9

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
CMH test was stratified by concomitant use of oral, systemic corticosteroids (Yes/No) and of immunomodulators (Yes/No) at Day 1, and number of prior exposures to biologic agent (0, >=1).	
Comparison groups	Cohort A: Filgotinib 100 mg (Induction Study) v Cohort A: Placebo (Induction Study)
Number of subjects included in analysis	482
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5103
Method	Cochran-Mantel-Haenszel
Parameter estimate	Stratified Percentage Difference
Point estimate	2.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	9.5

Statistical analysis title	Statistical Analysis 3
Statistical analysis description:	
CMH test was stratified by concomitant use of oral, systemic corticosteroids (Yes/No) and of immunomodulators (Yes/No) at Day 1, and number of prior exposures to biologic agent (<=1, >1).	
Comparison groups	Cohort B: Filgotinib 200 mg (Induction Study) v Cohort B: Placebo (Induction Study)

Number of subjects included in analysis	431
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9797
Method	Cochran-Mantel-Haenszel
Parameter estimate	Stratified Percentage Difference
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.7
upper limit	6.6

Statistical analysis title	Statistical Analysis 4
Statistical analysis description:	
CMH test was stratified by concomitant use of oral, systemic corticosteroids (Yes/No) and of immunomodulators (Yes/No) at Day 1, and number of prior exposures to biologic agent (<=1, >1).	
Comparison groups	Cohort B: Filgotinib 100 mg (Induction Study) v Cohort B: Placebo (Induction Study)
Number of subjects included in analysis	457
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4264
Method	Cochran-Mantel-Haenszel
Parameter estimate	Stratified Percentage Difference
Point estimate	2.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.9
upper limit	8.8

Primary: Induction Study: Percentage of Participants who Achieved Clinical Remission by PRO2 at Week 10

End point title	Induction Study: Percentage of Participants who Achieved Clinical Remission by PRO2 at Week 10
End point description:	
The PRO2 was a composite score based on 2 components of the CDAI, the number of liquid or soft stools/day for 7 days, stool frequency and abdominal pain (rated on a scale of 0-3) assessed for 7 days. Clinical Remission was defined as the average daily stool score ≤3 points AND average daily abdominal pain score ≤1 point. FAS for induction study was analyzed.	
End point type	Primary
End point timeframe:	
Week 10	

End point values	Cohort A: Filgotinib 200 mg (Induction Study)	Cohort A: Filgotinib 100 mg (Induction Study)	Cohort A: Placebo (Induction Study)	Cohort B: Filgotinib 200 mg (Induction Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	222	245	237	202
Units: Percentage of participants				
number (confidence interval 95%)	32.9 (26.5 to 39.3)	30.6 (24.6 to 36.6)	25.7 (20.0 to 31.5)	29.7 (23.2 to 36.3)

End point values	Cohort B: Filgotinib 100 mg (Induction Study)	Cohort B: Placebo (Induction Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	228	229		
Units: Percentage of participants				
number (confidence interval 95%)	18.9 (13.6 to 24.2)	17.9 (12.7 to 23.1)		

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description:	
CMH test was stratified by concomitant use of oral, systemic corticosteroids (Yes/No) and of immunomodulators (Yes/No) at Day 1, and number of prior exposures to biologic agent (0, >=1).	
Comparison groups	Cohort A: Filgotinib 200 mg (Induction Study) v Cohort A: Placebo (Induction Study)
Number of subjects included in analysis	459
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0963
Method	Cochran-Mantel-Haenszel
Parameter estimate	Stratified Percentage Difference
Point estimate	6.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	15.2

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
CMH test was stratified by concomitant use of oral, systemic corticosteroids (Yes/No) and of immunomodulators (Yes/No) at Day 1, and number of prior exposures to biologic agent (0, >=1).	
Comparison groups	Cohort A: Filgotinib 100 mg (Induction Study) v Cohort A: Placebo (Induction Study)

Number of subjects included in analysis	482
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.305
Method	Cochran-Mantel-Haenszel
Parameter estimate	Stratified Percentage Difference
Point estimate	4.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.9
upper limit	12.2

Statistical analysis title	Statistical Analysis 3
Statistical analysis description:	
CMH test was stratified by concomitant use of oral, systemic corticosteroids (Yes/No) and of immunomodulators (Yes/No) at Day 1, and number of prior exposures to biologic agent (<=1, >1).	
Comparison groups	Cohort B: Filgotinib 200 mg (Induction Study) v Cohort B: Placebo (Induction Study)
Number of subjects included in analysis	431
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0039
Method	Cochran-Mantel-Haenszel
Parameter estimate	Stratified Percentage Difference
Point estimate	11.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.7
upper limit	20.2

Statistical analysis title	Statistical Analysis 4
Statistical analysis description:	
CMH test was stratified by concomitant use of oral, systemic corticosteroids (Yes/No) and of immunomodulators (Yes/No) at Day 1, and number of prior exposures to biologic agent (<=1, >1).	
Comparison groups	Cohort B: Filgotinib 100 mg (Induction Study) v Cohort B: Placebo (Induction Study)
Number of subjects included in analysis	457
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7556
Method	Cochran-Mantel-Haenszel
Parameter estimate	Stratified Percentage Difference
Point estimate	1.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.2
upper limit	8.5

Primary: Maintenance Study: Percentage of Participants who Achieved Clinical Remission by PRO2 at Week 58

End point title	Maintenance Study: Percentage of Participants who Achieved Clinical Remission by PRO2 at Week 58

End point description:

The PRO2 was a composite score based on 2 components of the CDAI, the number of liquid or soft stools/day for 7 days, stool frequency and abdominal pain (rated on a scale of 0-3) assessed for 7 days. Clinical Remission was defined as the average daily stool score ≤3 points AND average daily abdominal pain score ≤1 point. The FAS for the Maintenance Study included all participants randomized to either the filgotinib 200 mg or filgotinib 100 mg treatment groups in the Induction studies who were re-randomized in the Maintenance Study and took at least 1 dose of study drug in the Maintenance Study and achieved clinical remission by PRO2 or endoscopic response at Week 10.

End point type	Primary

End point timeframe:

Week 58

End point values	Filgotinib 200 mg to Filgotinib 200 mg (Maintenance Study)	Filgotinib 200 mg to Placebo (Maintenance Study)	Filgotinib 100 mg to Filgotinib 100 mg (Maintenance Study)	Filgotinib 100 mg to Placebo (Maintenance Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	112	53	98	53
Units: Percentage of participants				
number (confidence interval 95%)	43.8 (34.1 to 53.4)	26.4 (13.6 to 39.2)	29.6 (20.0 to 39.1)	24.5 (12.0 to 37.1)

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

CMH test was stratified by concomitant use of immunomodulators (Yes/No), at Maintenance baseline, and history of exposure to a biologic agent (Yes/No).

Comparison groups	Filgotinib 200 mg to Filgotinib 200 mg (Maintenance Study) v Filgotinib 200 mg to Placebo (Maintenance Study)
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0382
Method	Cochran-Mantel-Haenszel
Parameter estimate	Stratified Percentage Difference
Point estimate	16.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	2
upper limit	31.6

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

CMH test was stratified by concomitant use of immunomodulators (Yes/No), at Maintenance baseline, and history of exposure to a biologic agent (Yes/No).

Comparison groups	Filgotinib 100 mg to Filgotinib 100 mg (Maintenance Study) v Filgotinib 100 mg to Placebo (Maintenance Study)
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4263
Method	Cochran-Mantel-Haenszel
Parameter estimate	Stratified Percentage Difference
Point estimate	5.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.5
upper limit	20

Primary: Maintenance Study: Percentage of Participants who Achieved Endoscopic Response at Week 58

End point title	Maintenance Study: Percentage of Participants who Achieved Endoscopic Response at Week 58

End point description:

The SES-CD assessed the degree of inflammation on the basis of 4 components: size of ulcers, ulcerated surface, affected surface, and presence of narrowing. Each of these components was scored on a scale of 0 to 3 (worst). In the SES-CD, each of these 4 components are assessed in the five segments: ileum, right colon, transverse colon, left colon, and rectum. The SES-CD was the sum of the individual scores of each of the components across the five segments. The range of SES-CD scores was 0 - 12 for each segment, and 0 - 60 for the overall SES-CD score, with larger scores indicating greater severity of disease. Endoscopic response was defined as ≥ 50% reduction from baseline in total SES-CD score. FAS for Maintenance study was analyzed.

End point type	Primary

End point timeframe:

Week 58

End point values	Filgotinib 200 mg to Filgotinib 200 mg (Maintenance Study)	Filgotinib 200 mg to Placebo (Maintenance Study)	Filgotinib 100 mg to Filgotinib 100 mg (Maintenance Study)	Filgotinib 100 mg to Placebo (Maintenance Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	112	53	98	53
Units: Percentage of participants				
number (confidence interval 95%)	30.4 (21.4 to 39.3)	9.4 (0.6 to 18.2)	18.4 (10.2 to 26.5)	13.2 (3.1 to 23.3)

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description:	
CMH test was stratified by concomitant use of immunomodulators (Yes/No), at Maintenance baseline, and history of exposure to a biologic agent (Yes/No).	
Comparison groups	Filgotinib 200 mg to Filgotinib 200 mg (Maintenance Study) v Filgotinib 200 mg to Placebo (Maintenance Study)
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0038
Method	Cochran-Mantel-Haenszel
Parameter estimate	Stratified Percentage Difference
Point estimate	20.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.2
upper limit	33.1

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
CMH test was stratified by concomitant use of immunomodulators (Yes/No), at Maintenance baseline, and history of exposure to a biologic agent (Yes/No).	
Comparison groups	Filgotinib 100 mg to Filgotinib 100 mg (Maintenance Study) v Filgotinib 100 mg to Placebo (Maintenance Study)
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3466
Method	Cochran-Mantel-Haenszel
Parameter estimate	Stratified Percentage Difference
Point estimate	5.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.6
upper limit	18.3

Secondary: Induction Study: Percentage of Participants Who Achieved Clinical Remission by Crohn's Disease Activity Index (CDAI) at Week 10

End point title	Induction Study: Percentage of Participants Who Achieved Clinical Remission by Crohn's Disease Activity Index (CDAI) at Week 10

End point description:

The CDAI system was a composite index of 8 disease activity variables: severity of abdominal pain, general well-being, very soft/liquid stool frequency, extra-intestinal symptoms, need for antidiarrheal drugs, presence of an abdominal mass, body weight and hematocrit. Participants reported information regarding symptoms using a diary. The sub scores of abdominal pains (0-3), general well-being (0-4), and number of very soft or liquid stools were then summed over the 7 days prior to each visit. Additionally, the remaining predictors were also noted and weighted to create the total CDAI score which ranged from 0-600 with a higher score indicating a worse outcome.
Clinical remission was defined as a CDAI of < 150 points. FAS for induction study was analyzed.

End point type	Secondary

End point timeframe:

Week 10

End point values	Cohort A: Filgotinib 200 mg (Induction Study)	Cohort A: Filgotinib 100 mg (Induction Study)	Cohort A: Placebo (Induction Study)	Cohort B: Filgotinib 200 mg (Induction Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	222	245	237	202
Units: Percentage of participants				
number (confidence interval 95%)	32.9 (26.5 to 39.3)	25.7 (20.0 to 31.4)	19.8 (14.5 to 25.1)	26.7 (20.4 to 33.1)

End point values	Cohort B: Filgotinib 100 mg (Induction Study)	Cohort B: Placebo (Induction Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	228	229		
Units: Percentage of participants				
number (confidence interval 95%)	16.7 (11.6 to 21.7)	14.8 (10.0 to 19.7)		

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description: Cochran-Mantel-Haenszel (CMH) test was stratified by concomitant use of oral, systemic corticosteroids (Yes/No) and of immunomodulators (Yes/No) at Day 1, and number of prior exposures to biologic agent (0, >=1).	
Comparison groups	Cohort A: Filgotinib 200 mg (Induction Study) v Cohort A: Placebo (Induction Study)
Number of subjects included in analysis	459
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0017
Method	Cochran-Mantel-Haenszel
Parameter estimate	Stratified Percentage Difference
Point estimate	12.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.7
upper limit	20.7

Statistical analysis title	Statistical Analysis 2
Statistical analysis description: Cochran-Mantel-Haenszel (CMH) test was stratified by concomitant use of oral, systemic corticosteroids (Yes/No) and of immunomodulators (Yes/No) at Day 1, and number of prior exposures to biologic agent (0, >=1).	
Comparison groups	Cohort A: Filgotinib 100 mg (Induction Study) v Cohort A: Placebo (Induction Study)
Number of subjects included in analysis	482
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.173
Method	Cochran-Mantel-Haenszel
Parameter estimate	Stratified Percentage Difference
Point estimate	5.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4
upper limit	12.7

Statistical analysis title	Statistical Analysis 3
Statistical analysis description: Cochran-Mantel-Haenszel (CMH) test was stratified by concomitant use of oral, systemic corticosteroids (Yes/No) and of immunomodulators (Yes/No) at Day 1, and number of prior exposures to biologic agent (<=1, >1).	
Comparison groups	Cohort B: Filgotinib 200 mg (Induction Study) v Cohort B: Placebo (Induction Study)

Number of subjects included in analysis	431
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0023
Method	Cochran-Mantel-Haenszel
Parameter estimate	Stratified Percentage Difference
Point estimate	12
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.1
upper limit	19.9

Statistical analysis title	Statistical Analysis 4

Statistical analysis description:

Cochran-Mantel-Haenszel (CMH) test was stratified by concomitant use of oral, systemic corticosteroids (Yes/No) and of immunomodulators (Yes/No) at Day 1, and number of prior exposures to biologic agent (<=1, >1).

Comparison groups	Cohort B: Filgotinib 100 mg (Induction Study) v Cohort B: Placebo (Induction Study)
Number of subjects included in analysis	457
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6038
Method	Cochran-Mantel-Haenszel
Parameter estimate	Stratified Percentage Difference
Point estimate	1.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.2
upper limit	8.7

Secondary: Induction Study: Percentage of Participants who Achieved both Clinical Remission by PRO2 and Endoscopic Response at Week 10

End point title	Induction Study: Percentage of Participants who Achieved both Clinical Remission by PRO2 and Endoscopic Response at Week 10

End point description:

The PRO2 was a composite score based on 2 components of the CDAI, the number of liquid or soft stools/day for 7 days, stool frequency and abdominal pain (rated on a scale of 0-3) assessed for 7 days. The SES-CD assessed the degree of inflammation on the basis of 4 components: size of ulcers, ulcerated surface, affected surface, and presence of narrowing. Each of these components was scored on a scale of 0 to 3 (worst). In the SES-CD, each of these 4 components are assessed in the five segments: ileum, right colon, transverse colon, left colon, and rectum. The SES-CD was the sum of the individual scores of each of the components across the five segments. The range of SES-CD scores was 0 - 12 for each segment, and 0 - 60 for the overall SES-CD score, with larger scores indicating greater severity of disease. Clinical remission by PRO2: liquid or very soft stool ≤3 and abdominal pain ≤1. Endoscopic response at least 50% reduction from Induction baseline in SES-CD.

End point type	Secondary

End point timeframe:
Week 10

End point values	Cohort A: Filgotinib 200 mg (Induction Study)	Cohort A: Filgotinib 100 mg (Induction Study)	Cohort A: Placebo (Induction Study)	Cohort B: Filgotinib 200 mg (Induction Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	222[1]	245[2]	237[3]	202[4]
Units: Percentage of participants				
number (confidence interval 95%)	13.5 (8.8 to 18.2)	9.8 (5.9 to 13.7)	6.8 (3.3 to 10.2)	4.5 (1.4 to 7.5)

Notes:
[1] - FAS for induction study was analyzed.
[2] - FAS for induction study was analyzed.
[3] - FAS for induction study was analyzed.
[4] - FAS for induction study was analyzed.

End point values	Cohort B: Filgotinib 100 mg (Induction Study)	Cohort B: Placebo (Induction Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	228[5]	229[6]		
Units: Percentage of participants				
number (confidence interval 95%)	3.9 (1.2 to 6.7)	3.9 (1.2 to 6.7)		

Notes:
[5] - FAS for induction study was analyzed.
[6] - FAS for induction study was analyzed.

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:
CMH test was stratified by concomitant use of oral, systemic corticosteroids (Yes/No) and of immunomodulators (Yes/No) at Day 1, and number of prior exposures to biologic agent (0, >=1).

Comparison groups	Cohort A: Filgotinib 200 mg (Induction Study) v Cohort A: Placebo (Induction Study)
Number of subjects included in analysis	459
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0152
Method	Cochran-Mantel-Haenszel
Parameter estimate	Stratified Percentage Difference
Point estimate	6.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	12.6

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
CMH test was stratified by concomitant use of oral, systemic corticosteroids (Yes/No) and of immunomodulators (Yes/No) at Day 1, and number of prior exposures to biologic agent (0, >=1).	
Comparison groups	Cohort A: Filgotinib 100 mg (Induction Study) v Cohort A: Placebo (Induction Study)
Number of subjects included in analysis	482
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2629
Method	Cochran-Mantel-Haenszel
Parameter estimate	Stratified Percentage Difference
Point estimate	2.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	8.1

Statistical analysis title	Statistical Analysis 3
Statistical analysis description:	
CMH test was stratified by concomitant use of oral, systemic corticosteroids (Yes/No) and of immunomodulators (Yes/No) at Day 1, and number of prior exposures to biologic agent (≤1, >1).	
Comparison groups	Cohort B: Filgotinib 200 mg (Induction Study) v Cohort B: Placebo (Induction Study)
Number of subjects included in analysis	431
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9023
Method	Cochran-Mantel-Haenszel
Parameter estimate	Stratified Percentage Difference
Point estimate	0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.4
upper limit	4.8

Statistical analysis title	Statistical Analysis 4
Statistical analysis description:	
CMH test was stratified by concomitant use of oral, systemic corticosteroids (Yes/No) and of immunomodulators (Yes/No) at Day 1, and number of prior exposures to biologic agent (≤1, >1).	
Comparison groups	Cohort B: Filgotinib 100 mg (Induction Study) v Cohort B: Placebo (Induction Study)

Number of subjects included in analysis	457
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9094
Method	Cochran-Mantel-Haenszel
Parameter estimate	Stratified Percentage Difference
Point estimate	0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4
upper limit	4.4

Secondary: Maintenance Study: Percentage of Participants who Achieved Clinical Remission by CDAI at Week 58

End point title	Maintenance Study: Percentage of Participants who Achieved Clinical Remission by CDAI at Week 58

End point description:

The CDAI system was a composite index of 8 disease activity variables: severity of abdominal pain, general well-being, very soft/liquid stool frequency, extra-intestinal symptoms, need for antidiarrheal drugs, presence of an abdominal mass, body weight and hematocrit. Participants reported information regarding symptoms using a diary. The sub scores of abdominal pain (0-3), general well-being (0-4), and number of very soft or liquid stools were then summed over the 7 days prior to each visit. Additionally, the remaining predictors were also noted and weighted to create the total CDAI score which ranged from 0-600 with a higher score indicating a worse outcome.
Clinical remission was defined as a CDAI of < 150 points. FAS for Maintenance study was analyzed.

End point type	Secondary

End point timeframe:

Week 58

End point values	Filgotinib 200 mg to Filgotinib 200 mg (Maintenance Study)	Filgotinib 200 mg to Placebo (Maintenance Study)	Filgotinib 100 mg to Filgotinib 100 mg (Maintenance Study)	Filgotinib 100 mg to Placebo (Maintenance Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	112	53	98	53
Units: Percentage of participants				
number (confidence interval 95%)	42.9 (33.2 to 52.5)	28.3 (15.2 to 41.4)	23.5 (14.6 to 32.4)	22.6 (10.4 to 34.9)

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

CMH test was stratified by concomitant use of immunomodulators (Yes/No) at Maintenance baseline, and history of exposure to a biologic agent (Yes/No).

Comparison groups	Filgotinib 200 mg to Filgotinib 200 mg (Maintenance Study) v

	Filgotinib 200 mg to Placebo (Maintenance Study)
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0839
Method	Cochran-Mantel-Haenszel
Parameter estimate	Stratified Percentage Difference
Point estimate	13.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	28.4

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
CMH test was stratified by concomitant use of immunomodulators (Yes/No) at Maintenance baseline, and history of exposure to a biologic agent (Yes/No).	
Comparison groups	Filgotinib 100 mg to Filgotinib 100 mg (Maintenance Study) v Filgotinib 100 mg to Placebo (Maintenance Study)
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8288
Method	Cochran-Mantel-Haenszel
Parameter estimate	Stratified Percentage Difference
Point estimate	1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.1
upper limit	15

Secondary: Maintenance Study: Percentage of Participants who Achieved Sustained Clinical Remission by PRO2 at Both Weeks 10 and 58

End point title	Maintenance Study: Percentage of Participants who Achieved Sustained Clinical Remission by PRO2 at Both Weeks 10 and 58
End point description:	
The PRO2 was a composite score based on 2 components of the CDAI, the number of liquid or soft stools/day for 7 days, stool frequency and abdominal pain (rated on a scale of 0-3) assessed for 7 days. Sustained Clinical Remission by PRO2: liquid or very soft stool ≤3 and abdominal pain ≤1 combined at both Week 10 and Week 58. The FAS for the Maintenance Study was analyzed.	
End point type	Secondary
End point timeframe:	
Weeks 10 and 58	

End point values	Filgotinib 200 mg to Filgotinib 200 mg (Maintenance Study)	Filgotinib 200 mg to Placebo (Maintenance Study)	Filgotinib 100 mg to Filgotinib 100 mg (Maintenance Study)	Filgotinib 100 mg to Placebo (Maintenance Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	112	53	98	53
Units: Percentage of participants				
number (confidence interval 95%)	41.1 (31.5 to 50.6)	20.8 (8.9 to 32.6)	25.5 (16.4 to 34.7)	24.5 (12.0 to 37.1)

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description:	
CMH test was stratified by concomitant use of immunomodulators (Yes/No), at Maintenance baseline, and history of exposure to a biologic agent (Yes/No).	
Comparison groups	Filgotinib 200 mg to Filgotinib 200 mg (Maintenance Study) v Filgotinib 200 mg to Placebo (Maintenance Study)
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0122
Method	Cochran-Mantel-Haenszel
Parameter estimate	Stratified Percentage Difference
Point estimate	19.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.7
upper limit	34

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
CMH test was stratified by concomitant use of immunomodulators (Yes/No), at Maintenance baseline, and history of exposure to a biologic agent (Yes/No).	
Comparison groups	Filgotinib 100 mg to Filgotinib 100 mg (Maintenance Study) v Filgotinib 100 mg to Placebo (Maintenance Study)
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7708
Method	Cochran-Mantel-Haenszel
Parameter estimate	Stratified Percentage Difference
Point estimate	2

Confidence interval	
level	95 %
sides	2-sided
lower limit	-12
upper limit	16.1

Secondary: Maintenance Study: Percentage of Participants who Achieved both Clinical Remission by PRO2 and Endoscopic Response at Week 58

End point title	Maintenance Study: Percentage of Participants who Achieved both Clinical Remission by PRO2 and Endoscopic Response at Week 58

End point description:

The PRO2 was a composite score based on 2 components of the CDAI, the number of liquid or soft stools/day for 7 days, stool frequency and abdominal pain (rated on a scale of 0-3) assessed for 7 days. The SES-CD assessed the degree of inflammation on the basis of 4 components: size of ulcers, ulcerated surface, affected surface, and presence of narrowing. Each of these components was scored on a scale of 0 to 3 (worst). In the SES-CD, each of these 4 components are assessed in the five segments: ileum, right colon, transverse colon, left colon, and rectum. The SES-CD was the sum of the individual scores of each of the components across the five segments. The range of SES-CD scores was 0 - 12 for each segment, and 0 - 60 for the overall SES-CD score, with larger scores indicating greater severity of disease. Clinical remission by PRO2: liquid or very soft stool ≤3 and abdominal pain ≤1. Endoscopic response at least 50% reduction from Induction baseline in SES-CD.

End point type	Secondary

End point timeframe:

Week 58

End point values	Filgotinib 200 mg to Filgotinib 200 mg (Maintenance Study)	Filgotinib 200 mg to Placebo (Maintenance Study)	Filgotinib 100 mg to Filgotinib 100 mg (Maintenance Study)	Filgotinib 100 mg to Placebo (Maintenance Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	112[7]	53[8]	98[9]	53[10]
Units: Percentage of participants				
number (confidence interval 95%)	25.0 (16.5 to 33.5)	5.7 (0.0 to 12.8)	13.3 (6.0 to 20.5)	9.4 (0.6 to 18.2)

Notes:

[7] - The FAS for Maintenance study was analyzed.

[8] - The FAS for Maintenance study was analyzed.

[9] - The FAS for Maintenance study was analyzed.

[10] - The FAS for Maintenance study was analyzed.

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

CMH test was stratified by concomitant use of immunomodulators (Yes/No) at Maintenance baseline, and history of exposure to a biologic agent (Yes/No).

Comparison groups	Filgotinib 200 mg to Filgotinib 200 mg (Maintenance Study) v Filgotinib 200 mg to Placebo (Maintenance Study)

Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0036
Method	Cochran-Mantel-Haenszel
Parameter estimate	Stratified Percentage Difference
Point estimate	19
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.7
upper limit	30.3

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

CMH test was stratified by concomitant use of immunomodulators (Yes/No) at Maintenance baseline, and history of exposure to a biologic agent (Yes/No).

Comparison groups	Filgotinib 100 mg to Filgotinib 100 mg (Maintenance Study) v Filgotinib 100 mg to Placebo (Maintenance Study)
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4179
Method	Cochran-Mantel-Haenszel
Parameter estimate	Stratified Percentage Difference
Point estimate	4.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.9
upper limit	15.6

Secondary: Maintenance Study: Percentage of Participants who Achieved 6 Month Corticosteroid-Free Remission by PRO2 at Week 58

End point title	Maintenance Study: Percentage of Participants who Achieved 6 Month Corticosteroid-Free Remission by PRO2 at Week 58

End point description:

The PRO2 was a composite score based on 2 components of the CDAI, the number of liquid or soft stools/day for 7 days, stool frequency and abdominal pain (rated on a scale of 0-3) assessed for 7 days. 6-month Corticosteroid-Free Clinical Remission by PRO2: liquid or very soft stool ≤3 and abdominal pain ≤1 with no corticosteroid use for at least 6 months prior to Week 58. The FAS for the Maintenance Study with available data was analyzed.

End point type	Secondary

End point timeframe:

Week 58

End point values	Filgotinib 200 mg to Filgotinib 200 mg (Maintenance Study)	Filgotinib 200 mg to Placebo (Maintenance Study)	Filgotinib 100 mg to Filgotinib 100 mg (Maintenance Study)	Filgotinib 100 mg to Placebo (Maintenance Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	25	41	25
Units: Percentage of participants				
number (confidence interval 95%)	32.0 (18.1 to 45.9)	20.0 (2.3 to 37.7)	7.3 (0.0 to 16.5)	12.0 (0.0 to 26.7)

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description:	
CMH test was stratified by concomitant use of immunomodulators (Yes/No) at Maintenance baseline, and history of exposure to a biologic agent (Yes/No).	
Comparison groups	Filgotinib 200 mg to Filgotinib 200 mg (Maintenance Study) v Filgotinib 200 mg to Placebo (Maintenance Study)
Number of subjects included in analysis	75
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2631
Method	Cochran-Mantel-Haenszel
Parameter estimate	Stratified Percentage Difference
Point estimate	12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.3
upper limit	32.3

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
CMH test was stratified by concomitant use of immunomodulators (Yes/No) at Maintenance baseline, and history of exposure to a biologic agent (Yes/No).	
Comparison groups	Filgotinib 100 mg to Filgotinib 100 mg (Maintenance Study) v Filgotinib 100 mg to Placebo (Maintenance Study)
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6444
Method	Cochran-Mantel-Haenszel
Parameter estimate	Stratified Percentage Difference
Point estimate	-3.4

Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.9
upper limit	14

Secondary: Induction Study: Pharmacokinetic Plasma Concentrations of Filgotinib at Week 4

End point title	Induction Study: Pharmacokinetic Plasma Concentrations of Filgotinib at Week 4[11]

End point description:

Plasma concentrations of filgotinib [nanogram/milliliters (ng/mL)]. Pharmacokinetic (PK) Analysis Set (included all randomized participants who took at least 1 dose of filgotinib and had at least 1 non-missing concentration value for filgotinib and/or its metabolite GS-829845reported by the PK laboratory) for Induction study was analyzed. .

End point type	Secondary

End point timeframe:

Week 4: 0.5, 1, 2, and 3 hrs. post dose

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No statistical analysis was planned for the endpoint.

End point values	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 (Induction Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	177	181	141	168
Units: nanogram per milliliter (ng/mL)				
arithmetic mean (standard deviation)	1170 (± 1270)	611 (± 634)	1140 (± 1070)	604 (± 634)

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study: Pharmacokinetic Plasma Concentrations of Filgotinib at Week 10

End point title	Induction Study: Pharmacokinetic Plasma Concentrations of Filgotinib at Week 10[12]

End point description:

Plasma concentrations of filgotinib (ng/mL). PK Analysis Set for Induction study was analyzed. .

End point type	Secondary

End point timeframe:

Week 10: Predose

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No statistical analysis was planned for the endpoint.

End point values	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 (Induction Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	183	180	136	135
Units: ng/mL				
arithmetic mean (standard deviation)	46.8 (± 180)	21.3 (± 79.5)	47.9 (± 215)	40.8 (± 139)

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study: Pharmacokinetic Plasma Concentrations of Filgotinib's Metabolite GS-829845 at Week 4

End point title	Induction Study: Pharmacokinetic Plasma Concentrations of Filgotinib's Metabolite GS-829845 at Week 4[13]

End point description:

Plasma concentrations of GS-829845 (ng/mL). PK Analysis Set for Induction study was analyzed.

End point type	Secondary

End point timeframe:

Week 4: 0.5, 1, 2, and 3 hrs. post dose

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No statistical analysis was planned for the endpoint.

End point values	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 (Induction Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	177	181	141	168
Units: ng/mL				
arithmetic mean (standard deviation)	3100 (± 1530)	1800 (± 936)	3140 (± 1450)	1870 (± 776)

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study: Pharmacokinetic Plasma Concentrations of Filgotinib's Metabolite GS-829845 at Week 10

End point title	Induction Study: Pharmacokinetic Plasma Concentrations of Filgotinib's Metabolite GS-829845 at Week 10[14]

End point description:

Plasma concentrations of GS-829845 (ng/mL). PK Analysis Set for Induction study was analyzed.

End point type	Secondary

End point timeframe:

Week 10: Predose

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No statistical analysis was planned for the endpoint.

End point values	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 (Induction Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	183	180	136	135
Units: ng/mL				
arithmetic mean (standard deviation)	2550 (± 1390)	1290 (± 801)	2640 (± 1470)	1480 (± 917)

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Pharmacokinetic Plasma Concentrations of Filgotinib at Week 26

End point title	Maintenance Study: Pharmacokinetic Plasma Concentrations of Filgotinib at Week 26

End point description:

Plasma concentrations of filgotinib (ng/mL). PK Analysis Set for Maintenance study was analyzed.

End point type	Secondary

End point timeframe:

Week 26: At any timepoint

End point values	Filgotinib 200 mg (Maintenance Study)	Filgotinib 100 mg (Maintenance Study)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	77	63		
Units: nanogram/milliliters				
arithmetic mean (standard deviation)	284 (± 623)	58.5 (± 150)		

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Pharmacokinetic Plasma Concentrations of Filgotinib at Week 58

End point title	Maintenance Study: Pharmacokinetic Plasma Concentrations of Filgotinib at Week 58

End point description:

Plasma concentrations of filgotinib (ng/mL). PK Analysis Set for Maintenance study was analyzed.

End point type	Secondary

End point timeframe:

Week 58: Pre-dose

End point values	Filgotinib 200 mg (Maintenance Study)	Filgotinib 100 mg (Maintenance Study)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	34	27		
Units: nanogram/milliliters				
arithmetic mean (standard deviation)	75.8 (± 238)	16.9 (± 55.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Pharmacokinetic Plasma Concentrations of Filgotinib's Metabolite GS-829845 at Week 26

End point title	Maintenance Study: Pharmacokinetic Plasma Concentrations of Filgotinib's Metabolite GS-829845 at Week 26

End point description:

Plasma concentrations of GS-829845 (ng/mL). PK Analysis Set for Maintenance study was analyzed.

End point type	Secondary

End point timeframe:

Week 26: At any timepoint

End point values	Filgotinib 200 mg (Maintenance Study)	Filgotinib 100 mg (Maintenance Study)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	77	63		
Units: nanogram/milliliters				
arithmetic mean (standard deviation)	3090 (± 1500)	1460 (± 814)		

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Pharmacokinetic Plasma Concentrations of Filgotinib's Metabolite GS-829845 at Week 58

End point title	Maintenance Study: Pharmacokinetic Plasma Concentrations of Filgotinib's Metabolite GS-829845 at Week 58

End point description:

Plasma concentrations of GS-829845 (ng/mL). PK Analysis Set for Maintenance study was analyzed.

End point type	Secondary

End point timeframe:

Week 58: Pre-dose

End point values	Filgotinib 200 mg (Maintenance Study)	Filgotinib 100 mg (Maintenance Study)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	34	27		
Units: nanogram/milliliters				
arithmetic mean (standard deviation)	2430 (± 1430)	1220 (± 551)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first dose up to Week 62

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.0

Reporting groups

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

Reporting group description:

Participants received treatment of filgotinib 100 mg with PTM 200 mg once daily up to Week 10 after first day of randomization.

Reporting group title	Cohort A: Placebo (Induction Study)

Reporting group description:

Participants received treatment of PTM filgotinib 200 mg with PTM filgotinib 100 mg once daily up to Week 10 after first day of randomization.

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

Reporting group description:

Participants received treatment of filgotinib 200 mg with PTM 100 mg once daily up to Week 10 after first day of randomization.

Reporting group title	Filgotinib 100 mg to Filgotinib 100 mg (Maintenance Study)

Reporting group description:

Participants who received filgotinib 100 mg in induction study and who achieved either clinical remission by PRO2 or endoscopic response at Week 10 were re-randomized to the maintenance study and received filgotinib 100 mg and PTM filgotinib 200 mg tablet orally once daily, up to Week 58.

Reporting group title	Filgotinib 100 mg to Placebo (Maintenance Study)

Reporting group description:

Participants who received filgotinib 100 mg in induction study and who achieved either clinical remission by PRO2 or endoscopic response at Week 10 were re-randomized to the maintenance study and received PTM filgotinib 200 mg and PTM filgotinib 100 mg tablet orally once daily, up to Week 58.

Reporting group title	Filgotinib 200 mg to Filgotinib 200 mg (Maintenance Study)

Reporting group description:

Participants who received filgotinib 200 mg in induction study and who achieved either clinical remission by PRO2 or endoscopic response at Week 10 were re-randomized to the maintenance study and received filgotinib 200 mg and PTM filgotinib 100 mg tablet orally once daily, up to Week 58.

Reporting group title	Filgotinib 200 mg to Placebo (Maintenance Study)

Reporting group description:

Participants who received filgotinib 200 mg in induction study and who achieved either clinical remission by PRO2 or endoscopic response at Week 10 were re-randomized to the maintenance study and received PTM filgotinib 100 mg and PTM filgotinib 200 mg tablet orally once daily, up to Week 58.

Reporting group title	Placebo to Placebo (Maintenance Study)

Reporting group description:

Participants who received placebo in induction study and who achieved either clinical remission by PRO2 or endoscopic response at Week 10 were re-randomized to the maintenance study and received PTM filgotinib 100 mg and PTM filgotinib 200 mg tablet orally once daily, up to Week 58.

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

Reporting group description:

Participants received treatment of filgotinib 200 mg with PTM 100 mg once daily up to Week 10 after first day of randomization.

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

Reporting group description:

Participants received treatment of filgotinib 100 mg with PTM 200 mg once daily up to Week 10 after first day of randomization.

Reporting group title	Cohort B: Placebo (Induction Study)

Reporting group description:

Participants received treatment of PTM filgotinib 200 mg with PTM filgotinib 100 mg once daily up to Week 10 after first day of randomization.

Serious adverse events	Cohort A: Filgotinib 100 mg (Induction Study)	Cohort A: Placebo (Induction Study)	Cohort A: Filgotinib 200 mg (Induction Study)
Total subjects affected by serious adverse events			
subjects affected / exposed	16 / 245 (6.53%)	15 / 237 (6.33%)	18 / 222 (8.11%)
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)			
Metastases to lung			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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 / 237 (0.00%)	0 / 222 (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
Thrombophlebitis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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			
Asthenia			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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 / 237 (0.00%)	0 / 222 (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
Systemic inflammatory response syndrome			

subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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 respiratory failure			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Asthma			
subjects affected / exposed	0 / 245 (0.00%)	1 / 237 (0.42%)	0 / 222 (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
Dyspnoea			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Epistaxis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			

subjects affected / exposed	0 / 245 (0.00%)	1 / 237 (0.42%)	0 / 222 (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
Investigations			
Influenza A virus test positive			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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			
Hip fracture			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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 / 237 (0.00%)	0 / 222 (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
Post procedural haemorrhage			
subjects affected / exposed	0 / 245 (0.00%)	1 / 237 (0.42%)	0 / 222 (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
Procedural intestinal perforation			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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			
Atrioventricular block			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Autoimmune myocarditis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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

Palpitations			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Ventricular tachycardia			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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			
Cauda equina syndrome			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Intensive care unit acquired weakness			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Paraesthesia			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Sciatica			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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 / 237 (0.42%)	0 / 222 (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
Anaemia of chronic disease			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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 loss anaemia			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Lymphopenia			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Myelosuppression			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	1 / 222 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	1 / 222 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Central serous chorioretinopathy			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Corneal scar			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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			
Abdominal pain			

subjects affected / exposed	1 / 245 (0.41%)	1 / 237 (0.42%)	0 / 222 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fistula			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Crohn's disease			
subjects affected / exposed	9 / 245 (3.67%)	7 / 237 (2.95%)	7 / 222 (3.15%)
occurrences causally related to treatment / all	1 / 9	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 245 (0.00%)	1 / 237 (0.42%)	0 / 222 (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 fistula			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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 wall thickening			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Ileal perforation			
subjects affected / exposed	1 / 245 (0.41%)	0 / 237 (0.00%)	0 / 222 (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
Haematochezia			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Inguinal hernia			

subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Intestinal fistula			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Intestinal obstruction			
subjects affected / exposed	2 / 245 (0.82%)	0 / 237 (0.00%)	0 / 222 (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
Intestinal perforation			
subjects affected / exposed	1 / 245 (0.41%)	0 / 237 (0.00%)	0 / 222 (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
Intra-abdominal fluid collection			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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 stenosis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	1 / 222 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	2 / 245 (0.82%)	0 / 237 (0.00%)	1 / 222 (0.45%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Megacolon			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Lower gastrointestinal haemorrhage			

subjects affected / exposed	1 / 245 (0.41%)	0 / 237 (0.00%)	0 / 222 (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
Nausea			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Obstructive pancreatitis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	1 / 222 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal ulcer haemorrhage			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Small intestinal obstruction			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	1 / 222 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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	1 / 245 (0.41%)	0 / 237 (0.00%)	0 / 222 (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
Hepatobiliary disorders			
Cholecystitis			

subjects affected / exposed	0 / 245 (0.00%)	1 / 237 (0.42%)	0 / 222 (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
Cholelithiasis			
subjects affected / exposed	0 / 245 (0.00%)	2 / 237 (0.84%)	0 / 222 (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
Drug-induced liver injury			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	1 / 222 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Calculus urinary			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	1 / 222 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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 / 237 (0.00%)	1 / 222 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal infarct			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 245 (0.00%)	1 / 237 (0.42%)	0 / 222 (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
Primary adrenal insufficiency			

subjects affected / exposed	0 / 245 (0.00%)	1 / 237 (0.42%)	0 / 222 (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
Musculoskeletal and connective tissue disorders			
Arthritis enteropathic			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Peripheral spondyloarthritis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Intervertebral disc degeneration			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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			
Abdominal abscess			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	1 / 222 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess intestinal			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Appendicitis perforated			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	1 / 222 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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

Bacteraemia			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	1 / 222 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bartholinitis			
subjects affected / exposed	1 / 245 (0.41%)	0 / 237 (0.00%)	0 / 222 (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
COVID-19			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	2 / 222 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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 colitis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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 / 237 (0.00%)	0 / 222 (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
Colonic abscess			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Escherichia bacteraemia			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	1 / 222 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epstein-Barr virus infection			

subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Herpes zoster			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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%)	0 / 237 (0.00%)	0 / 222 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine infection			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	1 / 222 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral candidiasis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	1 / 222 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral herpes			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	1 / 222 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Pelvic abscess			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Peritoneal abscess			

subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Peritonsillar abscess			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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	1 / 245 (0.41%)	0 / 237 (0.00%)	0 / 222 (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
Pyelonephritis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	1 / 222 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	1 / 222 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic candida			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Urinary tract infection			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (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
Hypokalaemia			
subjects affected / exposed	0 / 245 (0.00%)	1 / 237 (0.42%)	1 / 222 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Filgotinib 100 mg to Filgotinib 100 mg (Maintenance Study)	Filgotinib 100 mg to Placebo (Maintenance Study)	Filgotinib 200 mg to Filgotinib 200 mg (Maintenance Study)
Total subjects affected by serious adverse events			
subjects affected / exposed	14 / 104 (13.46%)	3 / 55 (5.45%)	13 / 118 (11.02%)
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)			
Metastases to lung			
subjects affected / exposed	1 / 104 (0.96%)	0 / 55 (0.00%)	0 / 118 (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 / 104 (0.00%)	0 / 55 (0.00%)	1 / 118 (0.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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			
Asthenia			

subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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 / 104 (0.00%)	0 / 55 (0.00%)	1 / 118 (0.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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 respiratory failure			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Asthma			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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 / 104 (0.00%)	0 / 55 (0.00%)	1 / 118 (0.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	1 / 118 (0.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 104 (0.96%)	0 / 55 (0.00%)	0 / 118 (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
Investigations			
Influenza A virus test positive			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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			
Hip fracture			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Post procedural haemorrhage			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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			
Atrioventricular block			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Autoimmune myocarditis			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Palpitations			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Ventricular tachycardia			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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			
Cauda equina syndrome			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Intensive care unit acquired weakness			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Paraesthesia			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	1 / 118 (0.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 104 (0.00%)	1 / 55 (1.82%)	0 / 118 (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

Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 104 (0.96%)	0 / 55 (0.00%)	0 / 118 (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
Anaemia of chronic disease			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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 loss anaemia			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Lymphopenia			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Myelosuppression			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Eye disorders			
Central serous chorioretinopathy			

subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Corneal scar			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	1 / 118 (0.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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 fistula			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	1 / 118 (0.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	7 / 104 (6.73%)	1 / 55 (1.82%)	3 / 118 (2.54%)
occurrences causally related to treatment / all	0 / 7	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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 fistula			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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 wall thickening			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Ileal perforation			

subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Haematochezia			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Inguinal hernia			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	1 / 118 (0.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal fistula			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Intestinal obstruction			
subjects affected / exposed	1 / 104 (0.96%)	0 / 55 (0.00%)	0 / 118 (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
Intestinal perforation			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Intra-abdominal fluid collection			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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 stenosis			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			

subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	1 / 118 (0.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Megacolon			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Obstructive pancreatitis			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal ulcer haemorrhage			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Small intestinal obstruction			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Subileus			

subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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			
Cholecystitis			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Drug-induced liver injury			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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			
Calculus urinary			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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	1 / 104 (0.96%)	0 / 55 (0.00%)	0 / 118 (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 infarct			

subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Primary adrenal insufficiency			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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			
Arthritis enteropathic			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Peripheral spondyloarthritis			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Intervertebral disc degeneration			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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			
Abdominal abscess			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Abscess intestinal			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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

Appendicitis perforated			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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 / 104 (0.00%)	0 / 55 (0.00%)	2 / 118 (1.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Bartholinitis			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
COVID-19			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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	1 / 104 (0.96%)	0 / 55 (0.00%)	0 / 118 (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
Clostridium difficile colitis			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Colonic abscess			

subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Escherichia bacteraemia			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Epstein-Barr virus infection			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Herpes zoster			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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	1 / 104 (0.96%)	0 / 55 (0.00%)	0 / 118 (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 intestine infection			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Oral candidiasis			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Oral herpes			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Pelvic abscess			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Peritoneal abscess			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Peritonsillar abscess			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	1 / 118 (0.85%)
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 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Pyelonephritis			
subjects affected / exposed	0 / 104 (0.00%)	1 / 55 (1.82%)	0 / 118 (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
Sepsis			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Systemic candida			

subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Urinary tract infection			
subjects affected / exposed	1 / 104 (0.96%)	0 / 55 (0.00%)	0 / 118 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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
Hypokalaemia			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (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	Filgotinib 200 mg to Placebo (Maintenance Study)	Placebo to Placebo (Maintenance Study)	Cohort B: Filgotinib 200 mg (Induction Study)
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 56 (8.93%)	14 / 145 (9.66%)	19 / 202 (9.41%)
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)			
Metastases to lung			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Thrombophlebitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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			
Asthenia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	1 / 202 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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 respiratory failure			

subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Asthma			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Epistaxis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	1 / 202 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Influenza A virus test positive			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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			
Hip fracture			
subjects affected / exposed	0 / 56 (0.00%)	1 / 145 (0.69%)	0 / 202 (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 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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

Post procedural haemorrhage			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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			
Atrioventricular block			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Autoimmune myocarditis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Palpitations			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Ventricular tachycardia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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			
Cauda equina syndrome			
subjects affected / exposed	0 / 56 (0.00%)	1 / 145 (0.69%)	0 / 202 (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
Intensive care unit acquired weakness			
subjects affected / exposed	0 / 56 (0.00%)	1 / 145 (0.69%)	0 / 202 (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

Paraesthesia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Sciatica			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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 / 56 (0.00%)	1 / 145 (0.69%)	0 / 202 (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
Anaemia of chronic disease			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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 loss anaemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Lymphopenia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	1 / 202 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelosuppression			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Ear and labyrinth disorders			

Vertigo positional			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Eye disorders			
Central serous chorioretinopathy			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Corneal scar			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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			
Abdominal pain			
subjects affected / exposed	1 / 56 (1.79%)	1 / 145 (0.69%)	1 / 202 (0.50%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fistula			
subjects affected / exposed	0 / 56 (0.00%)	1 / 145 (0.69%)	0 / 202 (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
Crohn's disease			
subjects affected / exposed	2 / 56 (3.57%)	4 / 145 (2.76%)	9 / 202 (4.46%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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 fistula			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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 wall thickening			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Ileal perforation			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Haematochezia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Inguinal hernia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Intestinal fistula			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Intestinal obstruction			
subjects affected / exposed	1 / 56 (1.79%)	0 / 145 (0.00%)	0 / 202 (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
Intestinal perforation			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	1 / 202 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-abdominal fluid collection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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 stenosis			

subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Megacolon			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Obstructive pancreatitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal ulcer haemorrhage			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Small intestinal obstruction			

subjects affected / exposed	0 / 56 (0.00%)	2 / 145 (1.38%)	1 / 202 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	1 / 56 (1.79%)	0 / 145 (0.00%)	0 / 202 (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
Vomiting			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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			
Cholecystitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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 / 56 (0.00%)	0 / 145 (0.00%)	1 / 202 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-induced liver injury			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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			
Calculus urinary			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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 / 56 (0.00%)	0 / 145 (0.00%)	1 / 202 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			

subjects affected / exposed	0 / 56 (0.00%)	1 / 145 (0.69%)	0 / 202 (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
Renal infarct			
subjects affected / exposed	0 / 56 (0.00%)	1 / 145 (0.69%)	0 / 202 (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
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Primary adrenal insufficiency			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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			
Arthritis enteropathic			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Peripheral spondyloarthritis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Intervertebral disc degeneration			
subjects affected / exposed	0 / 56 (0.00%)	1 / 145 (0.69%)	0 / 202 (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			
Abdominal abscess			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	1 / 202 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Abscess intestinal			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	1 / 202 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis perforated			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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 / 56 (0.00%)	1 / 145 (0.69%)	0 / 202 (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
Bacteraemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Bartholinitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
COVID-19			
subjects affected / exposed	0 / 56 (0.00%)	1 / 145 (0.69%)	0 / 202 (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
Cellulitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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 colitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Colonic abscess			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Escherichia bacteraemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Epstein-Barr virus infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	1 / 202 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Oral candidiasis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Oral herpes			

subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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 / 56 (0.00%)	1 / 145 (0.69%)	0 / 202 (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
Pelvic abscess			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Peritoneal abscess			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	1 / 202 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonsillar abscess			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	1 / 202 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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 / 56 (0.00%)	1 / 145 (0.69%)	0 / 202 (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
Pyelonephritis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Systemic candida			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Urinary tract infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (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
Hypokalaemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	1 / 202 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort B: Filgotinib 100 mg (Induction Study)	Cohort B: Placebo (Induction Study)	
Total subjects affected by serious adverse events			
subjects affected / exposed	36 / 228 (15.79%)	26 / 229 (11.35%)	
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)			
Metastases to lung			

subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (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 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic inflammatory response syndrome			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (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			
Acute respiratory distress syndrome			

subjects affected / exposed	0 / 228 (0.00%)	1 / 229 (0.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory failure			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (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 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epistaxis			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Influenza A virus test positive			
subjects affected / exposed	0 / 228 (0.00%)	1 / 229 (0.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Hip fracture			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (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 / 228 (0.44%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haemorrhage			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural intestinal perforation			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Atrioventricular block			
subjects affected / exposed	0 / 228 (0.00%)	1 / 229 (0.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune myocarditis			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Palpitations			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cauda equina syndrome			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Intensive care unit acquired weakness			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraesthesia			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (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	1 / 228 (0.44%)	1 / 229 (0.44%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia of chronic disease			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood loss anaemia			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency anaemia			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphopenia			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Myelosuppression			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Central serous chorioretinopathy			
subjects affected / exposed	0 / 228 (0.00%)	1 / 229 (0.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Corneal scar			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 228 (0.00%)	1 / 229 (0.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal fistula			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Crohn's disease			
subjects affected / exposed	10 / 228 (4.39%)	10 / 229 (4.37%)	
occurrences causally related to treatment / all	1 / 10	2 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			

subjects affected / exposed	0 / 228 (0.00%)	1 / 229 (0.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal fistula			
subjects affected / exposed	0 / 228 (0.00%)	1 / 229 (0.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal wall thickening			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileal perforation			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematochezia			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal fistula			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	1 / 228 (0.44%)	1 / 229 (0.44%)	
occurrences causally related to treatment / all	0 / 1	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal perforation			

subjects affected / exposed	0 / 228 (0.00%)	1 / 229 (0.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intra-abdominal fluid collection			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal stenosis			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine perforation			
subjects affected / exposed	0 / 228 (0.00%)	1 / 229 (0.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Megacolon			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (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	1 / 228 (0.44%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive pancreatitis			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal haemorrhage			

subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal ulcer haemorrhage			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subileus			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug-induced liver injury			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (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			

Calculus urinary			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (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 / 228 (0.00%)	0 / 229 (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	1 / 228 (0.44%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal infarct			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Primary adrenal insufficiency			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (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			
Arthritis enteropathic			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral spondyloarthritis			
subjects affected / exposed	0 / 228 (0.00%)	1 / 229 (0.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Intervertebral disc degeneration			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (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			
Abdominal abscess			
subjects affected / exposed	0 / 228 (0.00%)	1 / 229 (0.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess intestinal			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis perforated			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal abscess			
subjects affected / exposed	3 / 228 (1.32%)	1 / 229 (0.44%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteraemia			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bartholinitis			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			

subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile colitis			
subjects affected / exposed	0 / 228 (0.00%)	1 / 229 (0.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colonic abscess			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia bacteraemia			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epstein-Barr virus infection			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster			
subjects affected / exposed	0 / 228 (0.00%)	1 / 229 (0.44%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	1 / 228 (0.44%)	1 / 229 (0.44%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine infection			

subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral candidiasis			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral herpes			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (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 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic abscess			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritoneal abscess			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonsillar abscess			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (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	1 / 228 (0.44%)	1 / 229 (0.44%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (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 / 228 (0.00%)	1 / 229 (0.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic candida			
subjects affected / exposed	0 / 228 (0.00%)	1 / 229 (0.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus inadequate control			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (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: 2 %

Non-serious adverse events	Cohort A: Filgotinib 100 mg (Induction Study)	Cohort A: Placebo (Induction Study)	Cohort A: Filgotinib 200 mg (Induction Study)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	90 / 245 (36.73%)	90 / 237 (37.97%)	87 / 222 (39.19%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Seborrhoeic keratosis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	3 / 245 (1.22%)	5 / 237 (2.11%)	2 / 222 (0.90%)
occurrences (all)	3	5	2
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 245 (0.82%)	2 / 237 (0.84%)	3 / 222 (1.35%)
occurrences (all)	2	2	3
Fatigue			
subjects affected / exposed	5 / 245 (2.04%)	4 / 237 (1.69%)	7 / 222 (3.15%)
occurrences (all)	5	4	7
Pyrexia			
subjects affected / exposed	10 / 245 (4.08%)	6 / 237 (2.53%)	10 / 222 (4.50%)
occurrences (all)	10	7	11
Oedema peripheral			
subjects affected / exposed	1 / 245 (0.41%)	1 / 237 (0.42%)	2 / 222 (0.90%)
occurrences (all)	1	1	2
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	5 / 245 (2.04%)	4 / 237 (1.69%)	4 / 222 (1.80%)
occurrences (all)	5	4	4
Cough			
subjects affected / exposed	0 / 245 (0.00%)	1 / 237 (0.42%)	3 / 222 (1.35%)
occurrences (all)	0	1	3
Psychiatric disorders			

Insomnia			
subjects affected / exposed	2 / 245 (0.82%)	0 / 237 (0.00%)	3 / 222 (1.35%)
occurrences (all)	2	0	3
Investigations			
Weight decreased			
subjects affected / exposed	3 / 245 (1.22%)	0 / 237 (0.00%)	1 / 222 (0.45%)
occurrences (all)	3	0	1
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	0 / 222 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	4 / 245 (1.63%)	4 / 237 (1.69%)	5 / 222 (2.25%)
occurrences (all)	4	4	7
Headache			
subjects affected / exposed	16 / 245 (6.53%)	12 / 237 (5.06%)	13 / 222 (5.86%)
occurrences (all)	17	12	14
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	8 / 245 (3.27%)	7 / 237 (2.95%)	3 / 222 (1.35%)
occurrences (all)	8	7	3
Lymphopenia			
subjects affected / exposed	2 / 245 (0.82%)	4 / 237 (1.69%)	2 / 222 (0.90%)
occurrences (all)	2	5	2
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 245 (0.00%)	3 / 237 (1.27%)	3 / 222 (1.35%)
occurrences (all)	0	3	3
Abdominal pain			
subjects affected / exposed	6 / 245 (2.45%)	8 / 237 (3.38%)	16 / 222 (7.21%)
occurrences (all)	6	8	16
Abdominal pain upper			
subjects affected / exposed	2 / 245 (0.82%)	2 / 237 (0.84%)	5 / 222 (2.25%)
occurrences (all)	2	2	5
Aphthous ulcer			

subjects affected / exposed	2 / 245 (0.82%)	3 / 237 (1.27%)	2 / 222 (0.90%)
occurrences (all)	2	3	2
Crohn's disease			
subjects affected / exposed	15 / 245 (6.12%)	16 / 237 (6.75%)	5 / 222 (2.25%)
occurrences (all)	15	16	5
Diarrhoea			
subjects affected / exposed	2 / 245 (0.82%)	2 / 237 (0.84%)	4 / 222 (1.80%)
occurrences (all)	2	2	4
Dyspepsia			
subjects affected / exposed	2 / 245 (0.82%)	1 / 237 (0.42%)	0 / 222 (0.00%)
occurrences (all)	2	1	0
Flatulence			
subjects affected / exposed	4 / 245 (1.63%)	2 / 237 (0.84%)	3 / 222 (1.35%)
occurrences (all)	4	2	3
Gastroesophageal reflux disease			
subjects affected / exposed	1 / 245 (0.41%)	0 / 237 (0.00%)	2 / 222 (0.90%)
occurrences (all)	1	0	2
Nausea			
subjects affected / exposed	10 / 245 (4.08%)	11 / 237 (4.64%)	11 / 222 (4.95%)
occurrences (all)	10	11	11
Vomiting			
subjects affected / exposed	7 / 245 (2.86%)	7 / 237 (2.95%)	2 / 222 (0.90%)
occurrences (all)	7	8	2
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	2 / 245 (0.82%)	2 / 237 (0.84%)	5 / 222 (2.25%)
occurrences (all)	2	2	5
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	2 / 245 (0.82%)	0 / 237 (0.00%)	1 / 222 (0.45%)
occurrences (all)	2	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	11 / 245 (4.49%)	6 / 237 (2.53%)	5 / 222 (2.25%)
occurrences (all)	12	7	6
Back pain			

subjects affected / exposed	7 / 245 (2.86%)	2 / 237 (0.84%)	0 / 222 (0.00%)
occurrences (all)	7	2	0
Muscle spasms			
subjects affected / exposed	1 / 245 (0.41%)	2 / 237 (0.84%)	0 / 222 (0.00%)
occurrences (all)	1	2	0
Pain in extremity			
subjects affected / exposed	0 / 245 (0.00%)	2 / 237 (0.84%)	0 / 222 (0.00%)
occurrences (all)	0	2	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 245 (0.00%)	0 / 237 (0.00%)	1 / 222 (0.45%)
occurrences (all)	0	0	2
Gastroenteritis			
subjects affected / exposed	2 / 245 (0.82%)	4 / 237 (1.69%)	3 / 222 (1.35%)
occurrences (all)	2	4	3
COVID-19			
subjects affected / exposed	0 / 245 (0.00%)	2 / 237 (0.84%)	3 / 222 (1.35%)
occurrences (all)	0	2	3
Nasopharyngitis			
subjects affected / exposed	6 / 245 (2.45%)	8 / 237 (3.38%)	7 / 222 (3.15%)
occurrences (all)	6	9	8
Influenza			
subjects affected / exposed	1 / 245 (0.41%)	0 / 237 (0.00%)	2 / 222 (0.90%)
occurrences (all)	1	0	2
Sinusitis			
subjects affected / exposed	2 / 245 (0.82%)	2 / 237 (0.84%)	0 / 222 (0.00%)
occurrences (all)	2	2	0
Tooth abscess			
subjects affected / exposed	0 / 245 (0.00%)	1 / 237 (0.42%)	0 / 222 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection			
subjects affected / exposed	5 / 245 (2.04%)	1 / 237 (0.42%)	3 / 222 (1.35%)
occurrences (all)	5	1	3
Upper respiratory tract infection			
subjects affected / exposed	1 / 245 (0.41%)	5 / 237 (2.11%)	4 / 222 (1.80%)
occurrences (all)	1	5	4

Metabolism and nutrition disorders			
Hypophosphataemia			
subjects affected / exposed	1 / 245 (0.41%)	2 / 237 (0.84%)	3 / 222 (1.35%)
occurrences (all)	1	2	4

Non-serious adverse events	Filgotinib 100 mg to Filgotinib 100 mg (Maintenance Study)	Filgotinib 100 mg to Placebo (Maintenance Study)	Filgotinib 200 mg to Filgotinib 200 mg (Maintenance Study)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	59 / 104 (56.73%)	25 / 55 (45.45%)	59 / 118 (50.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Seborrhoeic keratosis			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	3 / 104 (2.88%)	0 / 55 (0.00%)	0 / 118 (0.00%)
occurrences (all)	3	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 104 (1.92%)	1 / 55 (1.82%)	2 / 118 (1.69%)
occurrences (all)	2	1	2
Fatigue			
subjects affected / exposed	2 / 104 (1.92%)	0 / 55 (0.00%)	2 / 118 (1.69%)
occurrences (all)	2	0	2
Pyrexia			
subjects affected / exposed	3 / 104 (2.88%)	2 / 55 (3.64%)	6 / 118 (5.08%)
occurrences (all)	4	2	6
Oedema peripheral			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	2 / 118 (1.69%)
occurrences (all)	0	0	2
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	2 / 104 (1.92%)	0 / 55 (0.00%)	1 / 118 (0.85%)
occurrences (all)	2	0	1
Cough			
subjects affected / exposed	5 / 104 (4.81%)	2 / 55 (3.64%)	2 / 118 (1.69%)
occurrences (all)	5	2	2

Psychiatric disorders			
Insomnia			
subjects affected / exposed	3 / 104 (2.88%)	1 / 55 (1.82%)	1 / 118 (0.85%)
occurrences (all)	3	1	1
Investigations			
Weight decreased			
subjects affected / exposed	3 / 104 (2.88%)	0 / 55 (0.00%)	0 / 118 (0.00%)
occurrences (all)	3	0	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	4 / 104 (3.85%)	0 / 55 (0.00%)	0 / 118 (0.00%)
occurrences (all)	6	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 104 (0.96%)	1 / 55 (1.82%)	1 / 118 (0.85%)
occurrences (all)	1	1	1
Headache			
subjects affected / exposed	4 / 104 (3.85%)	2 / 55 (3.64%)	4 / 118 (3.39%)
occurrences (all)	4	2	4
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 104 (2.88%)	1 / 55 (1.82%)	3 / 118 (2.54%)
occurrences (all)	3	1	3
Lymphopenia			
subjects affected / exposed	1 / 104 (0.96%)	0 / 55 (0.00%)	1 / 118 (0.85%)
occurrences (all)	2	0	1
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 104 (0.96%)	0 / 55 (0.00%)	1 / 118 (0.85%)
occurrences (all)	1	0	1
Abdominal pain			
subjects affected / exposed	9 / 104 (8.65%)	3 / 55 (5.45%)	8 / 118 (6.78%)
occurrences (all)	9	3	8
Abdominal pain upper			
subjects affected / exposed	4 / 104 (3.85%)	0 / 55 (0.00%)	1 / 118 (0.85%)
occurrences (all)	4	0	1
Aphthous ulcer			

subjects affected / exposed	2 / 104 (1.92%)	2 / 55 (3.64%)	1 / 118 (0.85%)
occurrences (all)	2	2	3
Crohn's disease			
subjects affected / exposed	22 / 104 (21.15%)	15 / 55 (27.27%)	15 / 118 (12.71%)
occurrences (all)	24	15	16
Diarrhoea			
subjects affected / exposed	1 / 104 (0.96%)	1 / 55 (1.82%)	5 / 118 (4.24%)
occurrences (all)	1	1	6
Dyspepsia			
subjects affected / exposed	3 / 104 (2.88%)	2 / 55 (3.64%)	1 / 118 (0.85%)
occurrences (all)	3	2	1
Flatulence			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Gastroesophageal reflux disease			
subjects affected / exposed	1 / 104 (0.96%)	0 / 55 (0.00%)	1 / 118 (0.85%)
occurrences (all)	1	0	1
Nausea			
subjects affected / exposed	3 / 104 (2.88%)	2 / 55 (3.64%)	6 / 118 (5.08%)
occurrences (all)	3	3	6
Vomiting			
subjects affected / exposed	5 / 104 (4.81%)	1 / 55 (1.82%)	5 / 118 (4.24%)
occurrences (all)	5	1	5
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	1 / 118 (0.85%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	3 / 104 (2.88%)	0 / 55 (0.00%)	0 / 118 (0.00%)
occurrences (all)	3	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	10 / 104 (9.62%)	4 / 55 (7.27%)	3 / 118 (2.54%)
occurrences (all)	12	5	3
Back pain			

subjects affected / exposed	1 / 104 (0.96%)	2 / 55 (3.64%)	2 / 118 (1.69%)
occurrences (all)	1	2	2
Muscle spasms			
subjects affected / exposed	1 / 104 (0.96%)	0 / 55 (0.00%)	3 / 118 (2.54%)
occurrences (all)	1	0	3
Pain in extremity			
subjects affected / exposed	2 / 104 (1.92%)	0 / 55 (0.00%)	0 / 118 (0.00%)
occurrences (all)	3	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 104 (0.96%)	0 / 55 (0.00%)	4 / 118 (3.39%)
occurrences (all)	1	0	4
Gastroenteritis			
subjects affected / exposed	2 / 104 (1.92%)	2 / 55 (3.64%)	1 / 118 (0.85%)
occurrences (all)	2	3	1
COVID-19			
subjects affected / exposed	1 / 104 (0.96%)	0 / 55 (0.00%)	3 / 118 (2.54%)
occurrences (all)	1	0	3
Nasopharyngitis			
subjects affected / exposed	6 / 104 (5.77%)	2 / 55 (3.64%)	6 / 118 (5.08%)
occurrences (all)	6	2	11
Influenza			
subjects affected / exposed	2 / 104 (1.92%)	0 / 55 (0.00%)	0 / 118 (0.00%)
occurrences (all)	2	0	0
Sinusitis			
subjects affected / exposed	2 / 104 (1.92%)	1 / 55 (1.82%)	0 / 118 (0.00%)
occurrences (all)	2	1	0
Tooth abscess			
subjects affected / exposed	0 / 104 (0.00%)	0 / 55 (0.00%)	0 / 118 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	2 / 104 (1.92%)	0 / 55 (0.00%)	5 / 118 (4.24%)
occurrences (all)	2	0	5
Upper respiratory tract infection			
subjects affected / exposed	3 / 104 (2.88%)	1 / 55 (1.82%)	5 / 118 (4.24%)
occurrences (all)	3	1	6

Metabolism and nutrition disorders			
Hypophosphataemia			
subjects affected / exposed	1 / 104 (0.96%)	0 / 55 (0.00%)	4 / 118 (3.39%)
occurrences (all)	1	0	5

Non-serious adverse events	Filgotinib 200 mg to Placebo (Maintenance Study)	Placebo to Placebo (Maintenance Study)	Cohort B: Filgotinib 200 mg (Induction Study)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	28 / 56 (50.00%)	77 / 145 (53.10%)	106 / 202 (52.48%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Seborrhoeic keratosis			
subjects affected / exposed	0 / 56 (0.00%)	3 / 145 (2.07%)	0 / 202 (0.00%)
occurrences (all)	0	3	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 56 (0.00%)	4 / 145 (2.76%)	4 / 202 (1.98%)
occurrences (all)	0	4	4
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 56 (1.79%)	2 / 145 (1.38%)	2 / 202 (0.99%)
occurrences (all)	1	2	2
Fatigue			
subjects affected / exposed	0 / 56 (0.00%)	2 / 145 (1.38%)	3 / 202 (1.49%)
occurrences (all)	0	3	3
Pyrexia			
subjects affected / exposed	4 / 56 (7.14%)	2 / 145 (1.38%)	11 / 202 (5.45%)
occurrences (all)	4	2	17
Oedema peripheral			
subjects affected / exposed	0 / 56 (0.00%)	1 / 145 (0.69%)	1 / 202 (0.50%)
occurrences (all)	0	1	1
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	0 / 56 (0.00%)	2 / 145 (1.38%)	2 / 202 (0.99%)
occurrences (all)	0	2	2
Cough			
subjects affected / exposed	2 / 56 (3.57%)	2 / 145 (1.38%)	4 / 202 (1.98%)
occurrences (all)	2	2	4

Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 56 (0.00%)	2 / 145 (1.38%)	2 / 202 (0.99%)
occurrences (all)	0	2	2
Investigations			
Weight decreased			
subjects affected / exposed	2 / 56 (3.57%)	1 / 145 (0.69%)	4 / 202 (1.98%)
occurrences (all)	2	1	5
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 56 (0.00%)	1 / 145 (0.69%)	0 / 202 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 56 (1.79%)	0 / 145 (0.00%)	7 / 202 (3.47%)
occurrences (all)	1	0	7
Headache			
subjects affected / exposed	1 / 56 (1.79%)	10 / 145 (6.90%)	17 / 202 (8.42%)
occurrences (all)	1	13	19
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 56 (5.36%)	4 / 145 (2.76%)	6 / 202 (2.97%)
occurrences (all)	3	5	7
Lymphopenia			
subjects affected / exposed	1 / 56 (1.79%)	3 / 145 (2.07%)	5 / 202 (2.48%)
occurrences (all)	1	5	5
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	3 / 56 (5.36%)	1 / 145 (0.69%)	3 / 202 (1.49%)
occurrences (all)	3	1	4
Abdominal pain			
subjects affected / exposed	6 / 56 (10.71%)	9 / 145 (6.21%)	10 / 202 (4.95%)
occurrences (all)	9	11	14
Abdominal pain upper			
subjects affected / exposed	3 / 56 (5.36%)	4 / 145 (2.76%)	4 / 202 (1.98%)
occurrences (all)	3	4	4
Aphthous ulcer			

subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Crohn's disease			
subjects affected / exposed	10 / 56 (17.86%)	26 / 145 (17.93%)	8 / 202 (3.96%)
occurrences (all)	10	26	8
Diarrhoea			
subjects affected / exposed	1 / 56 (1.79%)	2 / 145 (1.38%)	3 / 202 (1.49%)
occurrences (all)	1	2	3
Dyspepsia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	4 / 202 (1.98%)
occurrences (all)	0	0	4
Flatulence			
subjects affected / exposed	3 / 56 (5.36%)	0 / 145 (0.00%)	7 / 202 (3.47%)
occurrences (all)	4	0	7
Gastroesophageal reflux disease			
subjects affected / exposed	0 / 56 (0.00%)	3 / 145 (2.07%)	4 / 202 (1.98%)
occurrences (all)	0	3	4
Nausea			
subjects affected / exposed	3 / 56 (5.36%)	4 / 145 (2.76%)	20 / 202 (9.90%)
occurrences (all)	4	4	21
Vomiting			
subjects affected / exposed	1 / 56 (1.79%)	3 / 145 (2.07%)	5 / 202 (2.48%)
occurrences (all)	1	3	11
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	2 / 56 (3.57%)	1 / 145 (0.69%)	4 / 202 (1.98%)
occurrences (all)	2	1	5
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 56 (0.00%)	1 / 145 (0.69%)	1 / 202 (0.50%)
occurrences (all)	0	1	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 56 (3.57%)	10 / 145 (6.90%)	7 / 202 (3.47%)
occurrences (all)	4	11	10
Back pain			

subjects affected / exposed	0 / 56 (0.00%)	3 / 145 (2.07%)	5 / 202 (2.48%)
occurrences (all)	0	3	5
Muscle spasms			
subjects affected / exposed	0 / 56 (0.00%)	0 / 145 (0.00%)	1 / 202 (0.50%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	0 / 56 (0.00%)	4 / 145 (2.76%)	1 / 202 (0.50%)
occurrences (all)	0	4	1
Infections and infestations			
Bronchitis			
subjects affected / exposed	2 / 56 (3.57%)	5 / 145 (3.45%)	2 / 202 (0.99%)
occurrences (all)	2	6	2
Gastroenteritis			
subjects affected / exposed	0 / 56 (0.00%)	4 / 145 (2.76%)	4 / 202 (1.98%)
occurrences (all)	0	4	4
COVID-19			
subjects affected / exposed	0 / 56 (0.00%)	3 / 145 (2.07%)	0 / 202 (0.00%)
occurrences (all)	0	4	0
Nasopharyngitis			
subjects affected / exposed	4 / 56 (7.14%)	9 / 145 (6.21%)	9 / 202 (4.46%)
occurrences (all)	4	9	9
Influenza			
subjects affected / exposed	2 / 56 (3.57%)	3 / 145 (2.07%)	2 / 202 (0.99%)
occurrences (all)	2	3	2
Sinusitis			
subjects affected / exposed	1 / 56 (1.79%)	3 / 145 (2.07%)	4 / 202 (1.98%)
occurrences (all)	1	3	4
Tooth abscess			
subjects affected / exposed	0 / 56 (0.00%)	3 / 145 (2.07%)	0 / 202 (0.00%)
occurrences (all)	0	3	0
Urinary tract infection			
subjects affected / exposed	1 / 56 (1.79%)	4 / 145 (2.76%)	5 / 202 (2.48%)
occurrences (all)	1	5	6
Upper respiratory tract infection			
subjects affected / exposed	0 / 56 (0.00%)	3 / 145 (2.07%)	4 / 202 (1.98%)
occurrences (all)	0	3	4

Metabolism and nutrition disorders Hypophosphataemia subjects affected / exposed occurrences (all)	 0 / 56 (0.00%) 0	 1 / 145 (0.69%) 2	 2 / 202 (0.99%) 2

Non-serious adverse events	Cohort B: Filgotinib 100 mg (Induction Study)	Cohort B: Placebo (Induction Study)	
Total subjects affected by non-serious adverse events subjects affected / exposed	 107 / 228 (46.93%)	 109 / 229 (47.60%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Seborrhoeic keratosis subjects affected / exposed occurrences (all)	 0 / 228 (0.00%) 0	 0 / 229 (0.00%) 0	
Vascular disorders Hypertension subjects affected / exposed occurrences (all)	 1 / 228 (0.44%) 1	 1 / 229 (0.44%) 2	
General disorders and administration site conditions Asthenia subjects affected / exposed occurrences (all) Fatigue subjects affected / exposed occurrences (all) Pyrexia subjects affected / exposed occurrences (all) Oedema peripheral subjects affected / exposed occurrences (all)	 3 / 228 (1.32%) 3 6 / 228 (2.63%) 6 8 / 228 (3.51%) 8 5 / 228 (2.19%) 5	 8 / 229 (3.49%) 9 5 / 229 (2.18%) 5 10 / 229 (4.37%) 12 0 / 229 (0.00%) 0	
Respiratory, thoracic and mediastinal disorders Oropharyngeal pain subjects affected / exposed occurrences (all) Cough subjects affected / exposed occurrences (all)	 4 / 228 (1.75%) 4 3 / 228 (1.32%) 3	 3 / 229 (1.31%) 3 3 / 229 (1.31%) 3	

Psychiatric disorders Insomnia subjects affected / exposed occurrences (all)	3 / 228 (1.32%) 3	5 / 229 (2.18%) 5	
Investigations Weight decreased subjects affected / exposed occurrences (all)	5 / 228 (2.19%) 6	4 / 229 (1.75%) 4	
Injury, poisoning and procedural complications Fall subjects affected / exposed occurrences (all)	1 / 228 (0.44%) 1	0 / 229 (0.00%) 0	
Nervous system disorders Dizziness subjects affected / exposed occurrences (all)	1 / 228 (0.44%) 2	3 / 229 (1.31%) 3	
Headache subjects affected / exposed occurrences (all)	14 / 228 (6.14%) 15	15 / 229 (6.55%) 18	
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	8 / 228 (3.51%) 8	2 / 229 (0.87%) 2	
Lymphopenia subjects affected / exposed occurrences (all)	0 / 228 (0.00%) 0	2 / 229 (0.87%) 2	
Gastrointestinal disorders Abdominal distension subjects affected / exposed occurrences (all)	3 / 228 (1.32%) 3	3 / 229 (1.31%) 3	
Abdominal pain subjects affected / exposed occurrences (all)	8 / 228 (3.51%) 12	15 / 229 (6.55%) 15	
Abdominal pain upper subjects affected / exposed occurrences (all)	7 / 228 (3.07%) 7	5 / 229 (2.18%) 5	
Aphthous ulcer			

subjects affected / exposed	2 / 228 (0.88%)	3 / 229 (1.31%)	
occurrences (all)	2	4	
Crohn's disease			
subjects affected / exposed	14 / 228 (6.14%)	18 / 229 (7.86%)	
occurrences (all)	16	18	
Diarrhoea			
subjects affected / exposed	6 / 228 (2.63%)	6 / 229 (2.62%)	
occurrences (all)	6	6	
Dyspepsia			
subjects affected / exposed	2 / 228 (0.88%)	3 / 229 (1.31%)	
occurrences (all)	2	3	
Flatulence			
subjects affected / exposed	1 / 228 (0.44%)	1 / 229 (0.44%)	
occurrences (all)	1	1	
Gastroesophageal reflux disease			
subjects affected / exposed	0 / 228 (0.00%)	4 / 229 (1.75%)	
occurrences (all)	0	4	
Nausea			
subjects affected / exposed	10 / 228 (4.39%)	18 / 229 (7.86%)	
occurrences (all)	12	19	
Vomiting			
subjects affected / exposed	6 / 228 (2.63%)	9 / 229 (3.93%)	
occurrences (all)	7	9	
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	1 / 228 (0.44%)	1 / 229 (0.44%)	
occurrences (all)	1	1	
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 228 (0.00%)	2 / 229 (0.87%)	
occurrences (all)	0	2	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	14 / 228 (6.14%)	9 / 229 (3.93%)	
occurrences (all)	14	15	
Back pain			

subjects affected / exposed	5 / 228 (2.19%)	2 / 229 (0.87%)	
occurrences (all)	5	2	
Muscle spasms			
subjects affected / exposed	3 / 228 (1.32%)	2 / 229 (0.87%)	
occurrences (all)	4	2	
Pain in extremity			
subjects affected / exposed	0 / 228 (0.00%)	2 / 229 (0.87%)	
occurrences (all)	0	2	
Infections and infestations			
Bronchitis			
subjects affected / exposed	3 / 228 (1.32%)	1 / 229 (0.44%)	
occurrences (all)	3	1	
Gastroenteritis			
subjects affected / exposed	5 / 228 (2.19%)	0 / 229 (0.00%)	
occurrences (all)	5	0	
COVID-19			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
subjects affected / exposed	9 / 228 (3.95%)	17 / 229 (7.42%)	
occurrences (all)	11	18	
Influenza			
subjects affected / exposed	2 / 228 (0.88%)	2 / 229 (0.87%)	
occurrences (all)	2	2	
Sinusitis			
subjects affected / exposed	0 / 228 (0.00%)	2 / 229 (0.87%)	
occurrences (all)	0	2	
Tooth abscess			
subjects affected / exposed	0 / 228 (0.00%)	1 / 229 (0.44%)	
occurrences (all)	0	1	
Urinary tract infection			
subjects affected / exposed	10 / 228 (4.39%)	3 / 229 (1.31%)	
occurrences (all)	11	3	
Upper respiratory tract infection			
subjects affected / exposed	10 / 228 (4.39%)	9 / 229 (3.93%)	
occurrences (all)	11	9	

Metabolism and nutrition disorders Hypophosphataemia subjects affected / exposed occurrences (all)	 2 / 228 (0.88%) 2	 5 / 229 (2.18%) 5	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 September 2016	– The number of possible sites had been updated based on results of recent feasibility analysis. – The text of the objectives was updated for further clarification and additional exploratory analyses were added. – Text was revised and added to reflect the new study design of the GS-US-419-3896 study and to ensure subjects who completed 58 weeks of therapy continued on their current dose in a blinded manner. – Criteria for discontinuation for febrile neutropenia, anemia, and international normalized ratio (INR) value when considering hepatic laboratory changes had been added at request of the Agency to ensure subject safety. Additional text surrounding departure from the study was added to clarify that pregnant subjects had to discontinue the study and that early termination (ET) and PTx visits were requested for subjects that withdrew. – Eligibility criteria: • Inclusion criteria: Duration of stable dosing had been updated at request of the Agency for 6-MP, MTX, and azathioprine. The same modification had been applied to 5-ASA for internal consistency. Clarity had been added to the stable dose duration to confirm that subjects had been prescribed stable doses as directed by their physicians. The duration of vaccine restriction had been lengthened at the request of the Agency. Minimum treatment requirement for newly diagnosed TB had been added at the request of the Agency. • An exclusion criterion of severe hepatic impairment defined by Child-Pugh Class C had been added at request of Agency.
11 November 2016	Upon Voluntary Harmonization Procedure request, additional Week 26 and Week 58 ECG procedures had been added to the protocol.
19 January 2017	- Upon FDA request, a VAS was replaced by an 11-point NRS to assess abdominal pain. - Eligibility criteria: • Text was added to clarify that known hypersensitivity to filgotinib metabolites or formulation excipients were exclusionary. Text was added to clarify that subjects with history of extensive colectomy were excluded, and only enteric pathogens detected in the stool sample were exclusionary. • Upon regulatory approval of ustekinumab, text was added in the eligibility criteria to exclude the entry of subjects who had been treated with ustekinumab.
15 June 2017	- The use of 200 mg in males in Korea was limited to subjects who had failed 2 classes of biologic therapies (any TNFα antagonist and vedolizumab), in response to the South Korean Ministry of Food and Drug Safety. - Consistency with the Investigator's Brochure (IB). - Eligibility criteria: • Inclusion criteria: To ensure subject safety and eligibility, the protocol now required that subjects be up to date on colorectal cancer screening and surveillance prior to entering the study. Quantiferon and reference laboratory text wording was revised and was administrative in nature. • Exclusion criteria: An administrative clarification made clear that any personal history of disseminated zoster (rather than any zoster) was exclusionary for the study.

05 March 2018	– Secondary endpoint: "At Week 58" text was added to the secondary endpoint considering PRO2 during the maintenance study to clarify the underlying intent of the endpoint; the corticosteroid free remission was analyzed only at the maintenance Week 58 timepoint, and the 6-month period was a lookback from the Week 58 timepoint rather than any 6-month period during maintenance – Additional clarity on eligibility criteria including those for hepatitis. – Additional flexibility for enhanced safety monitoring (with increased flexibility for DMC meeting scheduling and suggested infectious workups for disease worsening). – Exclusion criteria: • Text was updated to provide flexibility as there were multiple established therapeutic methods of cytapheresis (leukocytapheresis and granulocytapheresis) as treatment for CD and they had shown to be safe considering its mechanism of action. • Text was updated to enhance subject safety so that both the investigator and the sponsor determined the suitability of any chronic medical condition that was not specifically listed out but could impact efficacy and safety assessment in the study.
07 February 2019	- Due to the difficulty in recruiting subjects with moderately to severely active CD who had not been treated with a biologic agent, the protocol was amended to allow also biologic experienced subjects in Cohort A to facilitate enrolment completion in Cohort A. In recognition of the potential impact of exposure to a biologic agent on the efficacy results, an additional stratification factor accounting for prior exposure to a biologic agent (yes or no) was added for the Cohort A Induction Study, in addition to the existing stratification factors (concomitant use of oral, systemically absorbed corticosteroids, and concomitant use of immunomodulators). Several sections (design, eligibility criteria, stratification factors, …) were revised to allow for the inclusion of biologic-experienced subjects into Cohort A. - Inclusion criterion 5 was revised to reduce the minimum duration of disease from diagnosis from 6 months to 3 months to permit more recently diagnosed subjects to enroll. - The statistical analysis was updated to allow for sequential testing of co-primary endpoints and secondary endpoints.
22 August 2019	– Changed eligibility criteria to allow for the inclusion of subjects who had discontinued biological treatment for reasons other than inadequate response, loss of response, or intolerance into Cohort A, as well as the inclusion of subjects with active perianal fistulas into Cohorts A and B. – Additional applicable fistula assessment was added. – The exploratory objectives and endpoints were updated to include evaluation of the efficacy of filgotinib in establishing perianal fistula closure.

01 May 2020	- The co-primary endpoint had been revised from PRO2 to CDAI remission based on consultation with FDA. The rationale for the change in the clinical co-primary endpoint from PRO2 to CDAI is that the FDA informed Gilead, in 2019, that it had recently accepted proposals from other sponsors to define the co-primary endpoints in CD studies as clinical remission using a CDAI score of < 150 and endoscopic remission or response using the SESCD score. The rationale provided by the FDA for this recommendation was the paucity of available prospective data validating the best cut-offs for PRO-based scoring that define either eligibility or clinical remission. Secondary and exploratory endpoints were revised accordingly. As the endpoints were updated, several sections of the protocol were revised to reflect the changes to the endpoints. - The original Cohort A and Cohort B Induction Study and Maintenance Study objectives had been moved to be EU-specific objectives. - Sample size calculation was added for the non-EU co-primary endpoint clinical remission by CDAI, and sample size calculation was provided for EU-specific co-primary endpoint clinical remission by PRO2 as new text. - The following changes were also implemented at the request of FDA in response to safety information suggesting an increased risk of thromboembolism in patients treated with a JAK inhibitor: • Inclusion of discontinuation criteria for serious thromboembolic events. • Specification of follow-up testing/referral to a specialist for subjects who experienced a thromboembolic event, to evaluate for risk factors of thromboembolic events, and to document the result of that evaluation. • Inclusion of criteria to be met for the DMC to recommend study discontinuation and inclusion of a criterion to trigger an ad-hoc DMC meeting. • Description of a Cardiovascular Safety Endpoint Adjudication Committee(CVEAC) that Gilead was establishing. - A new section on blinding was added to clarify blinding procedur
02 December 2021	– Change of sponsorship from Gilead to Galapagos. – Information on filgotinib approval was added. – The Galapagos study number was added to ensure a link between Gilead and Galapagos study numbers for internal documentation purposes.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported