Clinical trial results:
A Randomized, Double-blind, Placebo- and Active-controlled, Multicenter, Phase 3 Study to Assess the Efficacy and Safety of Filgotinib Administered for 52 weeks in Combination with Methotrexate to Subjects with Moderately to Severely Active Rheumatoid Arthritis Who Have an Inadequate Response to Methotrexate

Summary

EudraCT number	2016-000568-41
Trial protocol	SK GB BE HU CZ DE ES BG PL NL IT
Global end of trial date	20 June 2019

Results information

Result version number	v2 (current)
This version publication date	04 June 2021
First version publication date	05 July 2020
Version creation reason	• New data added to full data set Added additional secondary endpoints.

Trial information

Trial identification

Sponsor protocol code	GS-US-417-0301

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02889796
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Gilead Sciences
Sponsor organisation address	333 Lakeside Drive, Foster City, CA, United States, 94404
Public contact	Gilead Clinical Study Information Center, Gilead Sciences, GileadClinicalTrials@gilead.com
Scientific contact	Gilead Clinical Study Information Center, Gilead Sciences, GileadClinicalTrials@gilead.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	20 June 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 July 2018
Global end of trial reached?	Yes
Global end of trial date	20 June 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to evaluate the effects of filgotinib versus placebo for the treatment of signs and symptoms of rheumatoid arthritis (RA) as measured by the percentage of participants achieving an American College of Rheumatology 20% improvement response (ACR20) at Week 12.

Protection of trial subjects:

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

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

Background therapy:

Methotrexate (MTX) was used across all the arms as background therapy.

Evidence for comparator: -

Actual start date of recruitment	30 August 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	Slovakia: 8
Country: Number of subjects enrolled	South Africa: 34
Country: Number of subjects enrolled	Spain: 30
Country: Number of subjects enrolled	Taiwan: 44
Country: Number of subjects enrolled	Thailand: 23
Country: Number of subjects enrolled	Ukraine: 235
Country: Number of subjects enrolled	United Kingdom: 14
Country: Number of subjects enrolled	United States: 200
Country: Number of subjects enrolled	Argentina: 57
Country: Number of subjects enrolled	Australia: 1
Country: Number of subjects enrolled	Belgium: 10
Country: Number of subjects enrolled	Bulgaria: 34
Country: Number of subjects enrolled	Canada: 12

Country: Number of subjects enrolled	Czech Republic: 34
Country: Number of subjects enrolled	Germany: 20
Country: Number of subjects enrolled	Hong Kong: 7
Country: Number of subjects enrolled	Hungary: 47
Country: Number of subjects enrolled	India: 137
Country: Number of subjects enrolled	Ireland: 1
Country: Number of subjects enrolled	Israel: 11
Country: Number of subjects enrolled	Italy: 6
Country: Number of subjects enrolled	Japan: 147
Country: Number of subjects enrolled	Korea, Democratic People's Republic of: 33
Country: Number of subjects enrolled	Mexico: 125
Country: Number of subjects enrolled	Netherlands: 2
Country: Number of subjects enrolled	New Zealand: 18
Country: Number of subjects enrolled	Poland: 299
Country: Number of subjects enrolled	Romania: 31
Country: Number of subjects enrolled	Russian Federation: 118
Country: Number of subjects enrolled	Serbia: 21
Worldwide total number of subjects	1759
EEA total number of subjects	536

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)	1425
From 65 to 84 years	333
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled at study sites in Asia, South Africa, Australia, Europe, North America, South America and New Zealand. The first participant was screened on 30 August 2016. The last study visit occurred on 20 June 2019.

Pre-assignment

Screening details:

2582 participants were screened. Completed in the 'Placebo never received Filgotinib' arm included participants who completed 24 weeks of placebo treatment and were not rerandomized to Filgotinib 200 mg or 100 mg groups.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Filgotinib 200 mg

Arm description:

Participants were administered a filgotinib 200 mg tablet orally, once daily + placebo to match [PTM] filgotinib 100 mg tablet orally, once daily + PTM adalimumab 40 mg subcutaneous (SC) injection, once every 2 weeks in addition to a weekly stable dose of MTX, orally for median exposure of 52.1 weeks.

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

Dosage and administration details:

200 mg administered once daily

Investigational medicinal product name	PTM Filgotinib 100 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

PTM filgotinib 100 mg administered once daily

Investigational medicinal product name	PTM Adalimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

PTM adalimumab 40 mg administered once every 2 weeks

Arm title	Filgotinib 100 mg

Arm description:

Participants were administered a filgotinib 100 mg tablet orally, once daily + PTM filgotinib 200 mg tablet orally, once daily + PTM adalimumab 40 mg SC injection, once every 2 weeks in addition to a

weekly stable dose of MTX, orally for median exposure of 52.1 weeks.

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

Dosage and administration details:

100 mg administered once daily

Investigational medicinal product name	PTM Filgotinib 200 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

PTM filgotinib 200 mg administered once daily

Investigational medicinal product name	PTM Adalimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

PTM adalimumab 40 mg administered once every 2 weeks

Arm title	Adalimumab

Arm description:

Participants were administered PTM filgotinib 200 mg tablet orally, once daily + PTM filgotinib 100 mg tablet orally, once daily + adalimumab 40 mg SC injection, once every 2 weeks in addition to a weekly stable dose of MTX, orally for median exposure of 52.1 weeks.

Arm type	Active comparator
Investigational medicinal product name	PTM Filgotinib 200 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

PTM filgotinib 200 mg administered once daily

Investigational medicinal product name	PTM Filgotinib 100 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

PTM filgotinib 100 mg administered once daily

Investigational medicinal product name	Adalimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

40 mg administered once every 2 weeks

Arm title	Placebo to Filgotinib 200 mg

Arm description:

Participants in the placebo arm were administered a PTM filgotinib 200 mg tablet orally, once daily+ a PTM filgotinib 100 mg tablet orally, once daily + PTM adalimumab 40 mg SC injection, once every 2 weeks in addition to a weekly stable dose of MTX, orally for median exposure of 24 weeks. Then the participants in the placebo arm were rerandomized to filgotinib 200 mg and were administered a filgotinib 200 mg tablet orally, once daily + PTM filgotinib 100 mg tablet orally, once daily + PTM adalimumab 40 mg SC injection, once every 2 weeks in addition to a weekly stable dose of MTX, orally for median exposure of 28.1 weeks.

Arm type	Experimental
Investigational medicinal product name	PTM Filgotinib 200 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

PTM filgotinib 200 mg administered once daily

Investigational medicinal product name	PTM Filgotinib 100 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

PTM filgotinib 100 mg administered once daily

Investigational medicinal product name	PTM Adalimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

PTM adalimumab 40 mg administered once every 2 weeks

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

Dosage and administration details:

200 mg administered once daily

Arm title	Placebo to Filgotinib 100 mg

Arm description:

Participants in the placebo arm were administered a PTM filgotinib 200 mg tablet orally, once daily+ a PTM filgotinib 100 mg tablet orally, once daily + PTM adalimumab 40 mg SC injection, once every 2 weeks in addition to a weekly stable dose of MTX, orally for median exposure of 24 weeks. Then the participants in the placebo arm were rerandomized to filgotinib 100 mg and were administered a filgotinib 100 mg tablet orally, once daily + PTM filgotinib 200 mg tablet orally, once daily + PTM adalimumab 40 mg SC injection, once every 2 weeks in addition to a weekly stable dose of MTX, orally for median exposure of 28.1 weeks.

Arm type	Experimental
Investigational medicinal product name	PTM Filgotinib 200 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

PTM filgotinib 200 mg administered once daily

Investigational medicinal product name	PTM Filgotinib 100 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

PTM filgotinib 100 mg administered once daily

Investigational medicinal product name	PTM Adalimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

PTM adalimumab 40 mg administered once every 2 weeks

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

Dosage and administration details:

100 mg administered once daily

Arm title	Placebo never received Filgotinib

Arm description:

Participants in the placebo arm were administered a PTM filgotinib 200 mg tablet orally, once daily+ a PTM filgotinib 100 mg tablet orally, once daily + PTM adalimumab 40 mg SC injection, once every 2 weeks in addition to a weekly stable dose of MTX, orally for median exposure of 24 weeks.

Arm type	Placebo
Investigational medicinal product name	PTM Filgotinib 200 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

PTM filgotinib 200 mg administered once daily

Investigational medicinal product name	PTM Filgotinib 100 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

PTM filgotinib 100 mg administered once daily

Investigational medicinal product name	PTM Adalimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

PTM adalimumab 40 mg administered once every 2 weeks

Number of subjects in period 1[1]	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab
Started	475	480	325
Completed	424	422	281
Not completed	51	58	44
Protocol violation	-	1	3
Death	1	1	-
Pregnancy	-	1	1
Adverse event	17	8	8
Non-compliance with study drug	-	2	-
Investigator`s discretion	10	9	10
Withdrew consent	18	29	20
Lost to follow-up	5	7	2

Number of subjects in period 1[1]	Placebo to Filgotinib 200 mg	Placebo to Filgotinib 100 mg	Placebo never received Filgotinib
Started	190	191	94
Completed	181	185	24
Not completed	9	6	70
Protocol violation	-	-	4
Death	1	-	1
Pregnancy	-	-	-
Adverse event	4	1	7
Non-compliance with study drug	-	1	2
Investigator`s discretion	3	-	15
Withdrew consent	1	2	35
Lost to follow-up	-	2	6

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Four participants who were randomized but did not receive the study drug are not included in analysis.

Baseline characteristics

Reporting groups

Reporting group title	Overall Study

Reporting group description: -

Reporting group values	Overall Study	Total	
Number of subjects	1755	1755	
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	53.0		
standard deviation	± 12.7	-	
Gender categorical Units: Subjects			
Female	1435	1435	
Male	320	320	
Race			
For participants in Not Permitted category: local regulators did not allow collection of race information.			
Units: Subjects			
American Indian or Alaska Native	103	103	
Asian: Japanese	147	147	
Asian: Chinese/Taiwanese/Hong Kong Chinese	51	51	
Asian: Korean	34	34	
Asian: Other	179	179	
Black or African American	35	35	
Native Hawaiian or Pacific Islander	3	3	
White	1184	1184	
Other	17	17	
Not Permitted	2	2	
Ethnicity			
For participants in Not Permitted category: local regulators did not allow collection of ethnicity information.			
Units: Subjects			
Hispanic or Latino	262	262	
Not Hispanic or Latino	1471	1471	
Not Permitted	22	22	

Subject analysis sets

Subject analysis set title	Filgotinib 200 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants were administered a filgotinib 200 mg tablet orally, once daily + a placebo to match (PTM) filgotinib 100 mg tablet orally, once daily + PTM adalimumab 40 mg subcutaneous (SC) injection, once every 2 weeks in addition to a weekly stable dose of methotrexate (MTX), orally for median exposure of 52.1 weeks.

Subject analysis set title	Filgotinib 100 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants were administered a filgotinib 100 mg tablet orally, once daily + a PTM filgotinib 200 mg tablet orally, once daily + PTM adalimumab 40 mg SC injection, once every 2 weeks in addition to a weekly stable dose of MTX, orally for median exposure of 52.1 weeks.

Subject analysis set title	Adalimumab
Subject analysis set type	Full analysis

Subject analysis set description:

Participants were administered a PTM filgotinib 200 mg tablet orally, once daily + a PTM filgotinib 100 mg tablet orally, once daily + adalimumab 40 mg SC injection, once every 2 weeks in addition to a weekly stable dose of MTX, orally for median exposure of 52.1 weeks.

Subject analysis set title	Placebo
Subject analysis set type	Full analysis

Subject analysis set description:

The Placebo arm included all participants who received placebo in the study. Participants were administered a PTM filgotinib 200 mg tablet orally, once daily+ a PTM filgotinib 100 mg tablet orally, once daily + PTM adalimumab 40 mg SC injection, once every 2 weeks in addition to a weekly stable dose of MTX, orally for median exposure of 24 weeks. Participants could be rerandomized to filgotinib 200 mg or 100 mg groups.

Reporting group values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab
Number of subjects	475	480	325
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	52.0	53.0	53.0
standard deviation	± 12.8	± 12.6	± 12.9
Gender categorical Units: Subjects			
Female	379	399	266
Male	96	81	59
Race			
For participants in Not Permitted category: local regulators did not allow collection of race information.			
Units: Subjects			
American Indian or Alaska Native	27	27	20
Asian: Japanese	40	41	28
Asian: Chinese/Taiwanese/Hong Kong Chinese	13	12	8
Asian: Korean	13	10	4
Asian: Other	56	52	25
Black or African American	6	7	10
Native Hawaiian or Pacific Islander	1	0	0
White	312	324	229
Other	7	6	1
Not Permitted	0	1	0
Ethnicity			
For participants in Not Permitted category: local regulators did not allow collection of ethnicity information.			
Units: Subjects			
Hispanic or Latino	67	71	54
Not Hispanic or Latino	404	399	268

Not Permitted	4	10	3

Reporting group values	Placebo		
Number of subjects	475		
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	53.0		
standard deviation	± 12.8		
Gender categorical Units: Subjects			
Female	391		
Male	84		
Race			
For participants in Not Permitted category: local regulators did not allow collection of race information.			
Units: Subjects			
American Indian or Alaska Native	29		
Asian: Japanese	38		
Asian: Chinese/Taiwanese/Hong Kong Chinese	18		
Asian: Korean	7		
Asian: Other	46		
Black or African American	12		
Native Hawaiian or Pacific Islander	2		
White	319		
Other	3		
Not Permitted	1		
Ethnicity			
For participants in Not Permitted category: local regulators did not allow collection of ethnicity information.			
Units: Subjects			
Hispanic or Latino	70		
Not Hispanic or Latino	400		
Not Permitted	5		

End points reporting groups

Reporting group title	Filgotinib 200 mg
Reporting group description:	
Participants were administered a filgotinib 200 mg tablet orally, once daily + placebo to match [PTM] filgotinib 100 mg tablet orally, once daily + PTM adalimumab 40 mg subcutaneous (SC) injection, once every 2 weeks in addition to a weekly stable dose of MTX, orally for median exposure of 52.1 weeks.	
Reporting group title	Filgotinib 100 mg
Reporting group description:	
Participants were administered a filgotinib 100 mg tablet orally, once daily + PTM filgotinib 200 mg tablet orally, once daily + PTM adalimumab 40 mg SC injection, once every 2 weeks in addition to a weekly stable dose of MTX, orally for median exposure of 52.1 weeks.	
Reporting group title	Adalimumab
Reporting group description:	
Participants were administered PTM filgotinib 200 mg tablet orally, once daily + PTM filgotinib 100 mg tablet orally, once daily + adalimumab 40 mg SC injection, once every 2 weeks in addition to a weekly stable dose of MTX, orally for median exposure of 52.1 weeks.	
Reporting group title	Placebo to Filgotinib 200 mg
Reporting group description:	
Participants in the placebo arm were administered a PTM filgotinib 200 mg tablet orally, once daily+ a PTM filgotinib 100 mg tablet orally, once daily + PTM adalimumab 40 mg SC injection, once every 2 weeks in addition to a weekly stable dose of MTX, orally for median exposure of 24 weeks. Then the participants in the placebo arm were rerandomized to filgotinib 200 mg and were administered a filgotinib 200 mg tablet orally, once daily + PTM filgotinib 100 mg tablet orally, once daily + PTM adalimumab 40 mg SC injection, once every 2 weeks in addition to a weekly stable dose of MTX, orally for median exposure of 28.1 weeks.	
Reporting group title	Placebo to Filgotinib 100 mg
Reporting group description:	
Participants in the placebo arm were administered a PTM filgotinib 200 mg tablet orally, once daily+ a PTM filgotinib 100 mg tablet orally, once daily + PTM adalimumab 40 mg SC injection, once every 2 weeks in addition to a weekly stable dose of MTX, orally for median exposure of 24 weeks. Then the participants in the placebo arm were rerandomized to filgotinib 100 mg and were administered a filgotinib 100 mg tablet orally, once daily + PTM filgotinib 200 mg tablet orally, once daily + PTM adalimumab 40 mg SC injection, once every 2 weeks in addition to a weekly stable dose of MTX, orally for median exposure of 28.1 weeks.	
Reporting group title	Placebo never received Filgotinib
Reporting group description:	
Participants in the placebo arm were administered a PTM filgotinib 200 mg tablet orally, once daily+ a PTM filgotinib 100 mg tablet orally, once daily + PTM adalimumab 40 mg SC injection, once every 2 weeks in addition to a weekly stable dose of MTX, orally for median exposure of 24 weeks.	
Subject analysis set title	Filgotinib 200 mg
Subject analysis set type	Full analysis
Subject analysis set description:	
Participants were administered a filgotinib 200 mg tablet orally, once daily + a placebo to match (PTM) filgotinib 100 mg tablet orally, once daily + PTM adalimumab 40 mg subcutaneous (SC) injection, once every 2 weeks in addition to a weekly stable dose of methotrexate (MTX), orally for median exposure of 52.1 weeks.	
Subject analysis set title	Filgotinib 100 mg
Subject analysis set type	Full analysis
Subject analysis set description:	
Participants were administered a filgotinib 100 mg tablet orally, once daily + a PTM filgotinib 200 mg tablet orally, once daily + PTM adalimumab 40 mg SC injection, once every 2 weeks in addition to a weekly stable dose of MTX, orally for median exposure of 52.1 weeks.	
Subject analysis set title	Adalimumab
Subject analysis set type	Full analysis
Subject analysis set description:	
Participants were administered a PTM filgotinib 200 mg tablet orally, once daily + a PTM filgotinib 100	

mg tablet orally, once daily + adalimumab 40 mg SC injection, once every 2 weeks in addition to a weekly stable dose of MTX, orally for median exposure of 52.1 weeks.

Subject analysis set title	Placebo
Subject analysis set type	Full analysis

Subject analysis set description:

The Placebo arm included all participants who received placebo in the study. Participants were administered a PTM filgotinib 200 mg tablet orally, once daily+ a PTM filgotinib 100 mg tablet orally, once daily + PTM adalimumab 40 mg SC injection, once every 2 weeks in addition to a weekly stable dose of MTX, orally for median exposure of 24 weeks. Participants could be rerandomized to filgotinib 200 mg or 100 mg groups.

Primary: Percentage of Participants who Achieved an American College of Rheumatology (ACR) 20% Improvement (ACR20) Response at Week 12

End point title	Percentage of Participants who Achieved an American College of Rheumatology (ACR) 20% Improvement (ACR20) Response at Week 12

End point description:

ACR20 response is achieved when the participant has: ≥20% improvement (reduction) from baseline in tender joint count based on 68 joints (TJC68), swollen joint count based on 66 joints (SJC66) and in at least 3 of the following 5 items: physician's global assessment of disease activity (PGA), subject's global assessment of disease activity (SGA) using visual analog scale (VAS) on a scale of 0 (no disease activity) to 100 (maximum disease activity),participant`s pain assessment using VAS on a scale of 0 (no pain) to 100 (unbearable pain),health assessment questionnaire disability index (HAQ-DI) score contains 20 questions,8 components: dressing/grooming, arising, eating, walking, hygiene, reach, grip and activities scored on a scale of 0 (without difficulty) to 3 (unable to do);high-sensitivity C-reactive protein (hsCRP). Full Analysis Set included participants who were randomized and received at least 1 dose of study drug. Participants with missing outcomes were set as non-responders.

End point type	Primary

End point timeframe:

Week 12

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: percentage of participants				
number (confidence interval 95%)	76.6 (72.7 to 80.5)	69.8 (65.6 to 74.0)	70.5 (65.3 to 75.6)	49.9 (45.3 to 54.5)

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo
Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [1]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	26.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	20.6
upper limit	32.8

Notes:

[1] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 100 mg vs Placebo
Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [2]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	19.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.6
upper limit	26.2

Notes:

[2] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Secondary: Percentage of Participants who Achieved Disease Activity Score for 28 Joint Count Using C-Reactive Protein [DAS28 (CRP)] ≤ 3.2 at Week 12

End point title	Percentage of Participants who Achieved Disease Activity Score for 28 Joint Count Using C-Reactive Protein [DAS28 (CRP)] ≤ 3.2 at Week 12

End point description:

The DAS28 score is a measure of the participant's disease activity calculated using the tender joint counts (28 joints), swollen joint counts (28 joints), Patient's Global Assessment of Disease Activity (visual analog scale: 0 = no disease activity to 100 = maximum disease activity), and hsCRP for a total possible score of 1 to 9.4. Higher values indicate higher disease activity. Participants in the Full Analysis Set were analyzed. Participants with missing outcomes were set as non-responders.

End point type	Secondary

End point timeframe:

Week 12

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: percentage of participants				
number (confidence interval 95%)	49.7 (45.1 to 54.3)	38.8 (34.3 to 43.2)	43.4 (37.8 to 48.9)	23.4 (19.5 to 27.3)

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo
Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [3]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	26.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	20.2
upper limit	32.4

Notes:

[3] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 100 mg vs Placebo
Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [4]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	15.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.4
upper limit	21.4

Notes:

[4] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 200 mg vs Adalimumab
Comparison groups	Filgotinib 200 mg v Adalimumab

Number of subjects included in analysis	800
Analysis specification	Pre-specified
Analysis type	non-inferiority[5]
P-value	< 0.001 [6]
Method	Method proposed by [Liu 2014]

Notes:

[5] - For non-inferiority test, the approach proposed by Liu 2014 was used to demonstrate that each filgotinib dose preserves more than 50% of the effect of adalimumab on the response rate of DAS28 (CRP) ≤ 3.2 using NRI.

[6] - P-value of non-inferiority test was calculated from approach proposed by [Liu 2014].

Statistical analysis title	Filgotinib 100 mg vs Adalimumab
Comparison groups	Filgotinib 100 mg v Adalimumab
Number of subjects included in analysis	805
Analysis specification	Pre-specified
Analysis type	non-inferiority[7]
P-value	= 0.054 [8]
Method	Method proposed by [Liu 2014]

Notes:

[7] - For non-inferiority test, the approach proposed by Liu 2014 was used to demonstrate that each filgotinib dose preserves more than 50% of the effect of adalimumab on the response rate of DAS28 (CRP) ≤ 3.2 using NRI.

[8] - P-value of non-inferiority test was calculated from approach proposed by [Liu 2014].

Statistical analysis title	Filgotinib 200 mg vs Adalimumab
Comparison groups	Filgotinib 200 mg v Adalimumab
Number of subjects included in analysis	800
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.069 [9]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	6.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	13.6

Notes:

[9] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 100 mg vs Adalimumab
Comparison groups	Filgotinib 100 mg v Adalimumab
Number of subjects included in analysis	805
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.18 [10]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	-4.6

Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.8
upper limit	2.6

Notes:

[10] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Secondary: Change from Baseline in the Health Assessment Questionnaire-Disability Index (HAQ-DI) Score at Week 12

End point title	Change from Baseline in the Health Assessment Questionnaire-Disability Index (HAQ-DI) Score at Week 12

End point description:

The HAQ-DI score is defined as the average of the scores of eight functional categories (dressing and grooming, arising, eating, walking, hygiene, reach, grip, and other activities), usually completed by the participant. Responses in each functional category are collected as 0 (without any difficulty) to 3 (unable to do a task in that area), with or without aids or devices. The eight category scores are averaged into an overall HAQ-DI score on a scale from 0 (no disability) to 3 (completely disabled). When 6 or more categories are non-missing, total possible score is 3. If more than 2 categories are missing, the HAQ-DI score is set to missing. Negative change from baseline indicates improvement (less disability). Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Week 12

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	1.59 (± 0.611)	1.55 (± 0.625)	1.59 (± 0.600)	1.63 (± 0.613)
Change at Week 12 (n=457, 459, 311, 435)	-0.69 (± 0.613)	-0.56 (± 0.564)	-0.61 (± 0.560)	-0.42 (± 0.544)

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo
Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority[11]
P-value	< 0.001 [12]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.29

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.36
upper limit	-0.22
Variability estimate	Standard error of the mean
Dispersion value	0.034

Notes:

[11] - Least squares (LS)-Mean, 95% CI, and P-value were provided from mixed effects model for repeated measure (MMRM). Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.
[12] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo
Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority[13]
P-value	< 0.001 [14]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.24
upper limit	-0.1
Variability estimate	Standard error of the mean
Dispersion value	0.034

Notes:

[13] - LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.
[14] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Secondary: Percentage of Participants who Achieved DAS28 (CRP) < 2.6 at Week 24

End point title	Percentage of Participants who Achieved DAS28 (CRP) < 2.6 at Week 24

End point description:

The DAS28 score is a measure of the participant’s disease activity calculated using the tender joint counts (28 joints), swollen joint counts (28 joints), Patient’s Global Assessment of Disease Activity (visual analog scale: 0 = no disease activity to 100 = maximum disease activity), and hsCRP for a total possible score of 1 to 9.4. Higher values indicate higher disease activity. Participants in the Full Analysis Set were analyzed. Participants with missing outcomes were set as non-responders.

End point type	Secondary

End point timeframe:

Week 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: percentage of participants				
number (confidence interval 95%)	48.4 (43.8 to 53.0)	35.2 (30.8 to 39.6)	35.7 (30.3 to 41.1)	16.2 (12.8 to 19.6)

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo
Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [15]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	32.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	26.4
upper limit	38

Notes:

[15] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 100 mg vs Placebo
Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [16]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	19
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.4
upper limit	24.6

Notes:

[16] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Secondary: Change from Baseline in Modified Total Sharp Score (mTSS) at Week 24

End point title	Change from Baseline in Modified Total Sharp Score (mTSS) at Week 24

End point description:

Participant`s radiographs of bilateral hands, wrists and feet are taken and evaluated through central

review using the mTSS method. The mTSS (range [0-448]) is defined as the erosion score (range [0-280]) plus the joint space narrowing (JSN) score (range [0-168]). An erosion score of 0 to 5 is given to each joint in the hands and wrists, and a score of 0 to 10 is given to each joint in the feet where 0 indicates no erosion while 5 or 10 indicates extensive loss of bone (maximum erosion). JSN is scored from 0 to 4, with 0 indicating normal or no narrowing and 4 indicating complete loss of joint space. The maximal TSS is 448. Negative change in value indicates improvement (less erosion of bone, normal joint spaces). Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Week 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	467	471	319	466
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	32.47 (± 47.939)	36.70 (± 53.065)	34.82 (± 55.013)	31.60 (± 53.217)
Change at Week 24 (n=405, 404, 271, 351)	0.13 (± 0.937)	0.17 (± 0.905)	0.16 (± 0.948)	0.37 (± 1.417)

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo
Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	933
Analysis specification	Pre-specified
Analysis type	superiority[17]
P-value	< 0.001 [18]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.43
upper limit	-0.12
Variability estimate	Standard error of the mean
Dispersion value	0.078

Notes:

[17] - LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

[18] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo
Comparison groups	Filgotinib 100 mg v Placebo

Number of subjects included in analysis	937
Analysis specification	Pre-specified
Analysis type	superiority[19]
P-value	= 0.001 [20]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.4
upper limit	-0.1
Variability estimate	Standard error of the mean
Dispersion value	0.078

Notes:

[19] - LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

[20] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Secondary: Percentage of Participants who Achieved ACR 50% Improvement (ACR50) at Weeks 2, 4, 12, and 24

End point title	Percentage of Participants who Achieved ACR 50% Improvement (ACR50) at Weeks 2, 4, 12, and 24

End point description:

ACR50 response is achieved when the participant has: ≥50% improvement (reduction) from baseline in TJC68, SJC66 and in at least 3 of the following 5 items: PGA and SGA assessed using VAS on a scale of 0-100 [0 and 100 indicating no disease activity and maximum disease activity]; subject`s pain assessment using VAS on a scale of 0-100 [0 and 100 indicating no pain and unbearable pain]; HAQ-DI score contains 20 questions, 8 components: dressing/grooming, arising, eating, walking, hygiene, reach, grip and activities and scored on a scale of 0 (without difficulty) to 3 (unable to do); hsCRP. Participants with missing outcomes were set as non-responders. Participants in the Full Analysis Set were analyzed.

End point type	Secondary

End point timeframe:

Weeks 2, 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: percentage of participants				
number (confidence interval 95%)				
Week 2	9.1 (6.4 to 11.7)	5.8 (3.6 to 8.0)	6.8 (3.9 to 9.7)	1.1 (0.0 to 2.1)
Week 4	22.3 (18.5 to 26.2)	12.9 (9.8 to 16.0)	17.2 (13.0 to 21.5)	5.9 (3.7 to 8.1)
Week 12	47.2 (42.6 to 51.8)	36.5 (32.0 to 40.9)	35.1 (29.7 to 40.4)	19.8 (16.1 to 23.5)
Week 24	57.9 (53.3 to 62.4)	52.7 (48.1 to 57.3)	52.3 (46.7 to 57.9)	33.3 (28.9 to 37.6)

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo
Statistical analysis description:	
Week 2	
Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [21]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	8
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.1
upper limit	10.9

Notes:

[21] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 100 mg vs Placebo
Statistical analysis description:	
Week 2	
Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [22]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	4.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.3
upper limit	7.3

Notes:

[22] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 200 mg vs Placebo
Statistical analysis description:	
Week 4	
Comparison groups	Filgotinib 200 mg v Placebo

Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [23]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	16.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.9
upper limit	20.9

Notes:

[23] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 4

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [24]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	7
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.1
upper limit	10.9

Notes:

[24] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 12

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [25]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	27.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	21.4
upper limit	33.3

Notes:

[25] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 100 mg vs Placebo
Statistical analysis description:	
Week 12	
Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [26]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	16.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	10.9
upper limit	22.5

Notes:

[26] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 200 mg vs Placebo
Statistical analysis description:	
Week 24	
Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [27]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	24.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	18.3
upper limit	31

Notes:

[27] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 100 mg vs Placebo
Statistical analysis description:	
Week 24	
Comparison groups	Filgotinib 100 mg v Placebo

Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [28]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	19.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.1
upper limit	25.8

Notes:

[28] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Secondary: Percentage of Participants Who Achieved ACR50 at Weeks 36 and 52

End point title	Percentage of Participants Who Achieved ACR50 at Weeks 36 and 52[29]

End point description:

ACR50 response is achieved when the participant has: ≥50% improvement (reduction) from baseline in TJC68, SJC66 and in at least 3 of the following 5 items: PGA and SGA assessed using VAS on a scale of 0-100 [0 and 100 indicating no disease activity and maximum disease activity]; subject`s pain assessment using VAS on a scale of 0-100 [0 and 100 indicating no pain and unbearable pain]; HAQ-DI score contains 20 questions, 8 components: dressing/grooming, arising, eating, walking, hygiene, reach, grip and activities and scored on a scale of 0 (without difficulty) to 3 (unable to do); hsCRP. Participants with missing outcomes were set as non-responders. Participants in the Full Analysis Set were analyzed.

End point type	Secondary

End point timeframe:

Weeks 36 and 52

Notes:

[29] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	475	480	325	190
Units: percentage of participants				
number (confidence interval 95%)				
Week 36	63.2 (58.7 to 67.6)	57.7 (53.2 to 62.2)	57.5 (52.0 to 63.1)	67.9 (61.0 to 74.8)
Week 52	64.2 (59.8 to 68.6)	60.6 (56.2 to 65.1)	62.2 (56.7 to 67.6)	68.4 (61.5 to 75.3)

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	191			
Units: percentage of participants				

number (confidence interval 95%)				
Week 36	63.4 (56.3 to 70.4)			
Week 52	66.0 (59.0 to 72.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved ACR 70% Improvement (ACR70) at Weeks 2, 4, 12, and 24

End point title	Percentage of Participants Who Achieved ACR 70% Improvement (ACR70) at Weeks 2, 4, 12, and 24

End point description:

ACR70 response is achieved when the participant has: ≥70% improvement (reduction) from baseline in TJC68, SJC66 and in at least 3 of the following 5 items: PGA and SGA assessed using VAS on a scale of 0-100 [0 and 100 indicating no disease activity and maximum disease activity]; subject`s pain assessment using VAS on a scale of 0-100 [0 and 100 indicating no pain and unbearable pain]; HAQ-DI score contains 20 questions, 8 components: dressing/grooming, arising, eating, walking, hygiene, reach, grip and activities and scored on a scale of 0 (without difficulty) to 3 (unable to do); hsCRP. Participants with missing outcomes were set as non-responders. Participants in the Full Analysis Set were analyzed.

End point type	Secondary

End point timeframe:

Weeks 2, 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: percentage of participants				
number (confidence interval 95%)				
Week 2	2.7 (1.2 to 4.3)	1.3 (0.2 to 2.3)	0.9 (0.0 to 2.1)	0.4 (0.0 to 1.1)
Week 4	9.1 (6.4 to 11.7)	3.3 (1.6 to 5.0)	3.7 (1.5 to 5.9)	1.5 (0.3 to 2.7)
Week 12	26.1 (22.1 to 30.2)	18.5 (15.0 to 22.1)	14.2 (10.2 to 18.1)	6.7 (4.4 to 9.1)
Week 24	36.2 (31.8 to 40.6)	29.6 (25.4 to 33.8)	29.5 (24.4 to 34.7)	14.9 (11.6 to 18.3)

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 2

Comparison groups	Filgotinib 200 mg v Placebo

Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.008 [30]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	2.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	4.1

Notes:

[30] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 2

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.18 [31]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.5
upper limit	2.2

Notes:

[31] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 4

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [32]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	7.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.6
upper limit	10.6

Notes:

[32] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 100 mg vs Placebo
Statistical analysis description:	
Week 4	
Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.067 [33]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	1.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3
upper limit	4

Notes:

[33] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 200 mg vs Placebo
Statistical analysis description:	
Week 12	
Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [34]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	19.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	14.6
upper limit	24.1

Notes:

[34] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 100 mg vs Placebo
Statistical analysis description:	
Week 12	
Comparison groups	Filgotinib 100 mg v Placebo

Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [35]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	11.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.5
upper limit	16.2

Notes:

[35] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 24

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [36]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	21.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	15.7
upper limit	26.9

Notes:

[36] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 24

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [37]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	14.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.2
upper limit	20

Notes:

[37] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Secondary: Percentage of Participants Who Achieved ACR70 at Weeks 36 and 52

End point title	Percentage of Participants Who Achieved ACR70 at Weeks 36 and 52[38]

End point description:

ACR70 response is achieved when the participant has: ≥70% improvement (reduction) from baseline in TJC68, SJC66 and in at least 3 of the following 5 items: PGA and SGA assessed using VAS on a scale of 0-100 [0 and 100 indicating no disease activity and maximum disease activity]; subject`s pain assessment using VAS on a scale of 0-100 [0 and 100 indicating no pain and unbearable pain]; HAQ-DI score contains 20 questions, 8 components: dressing/grooming, arising, eating, walking, hygiene, reach, grip and activities and scored on a scale of 0 (without difficulty) to 3 (unable to do); hsCRP. Participants with missing outcomes were set as non-responders. Participants in the Full Analysis Set were analyzed.

End point type	Secondary

End point timeframe:

Weeks 36 and 52

Notes:

[38] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	475	480	325	190
Units: percentage of participants				
number (confidence interval 95%)				
Week 36	40.2 (35.7 to 44.7)	35.4 (31.0 to 39.8)	32.9 (27.7 to 38.2)	44.7 (37.4 to 52.1)
Week 52	44.4 (39.8 to 49.0)	39.0 (34.5 to 43.4)	41.2 (35.7 to 46.7)	48.4 (41.1 to 55.8)

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	191			
Units: percentage of participants				
number (confidence interval 95%)				
Week 36	34.6 (27.5 to 41.6)			
Week 52	37.7 (30.6 to 44.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved ACR20 Response at Weeks 2, 4, and 24

End point title	Percentage of Participants Who Achieved ACR20 Response at Weeks 2, 4, and 24

End point description:

ACR20 response is achieved when the participant has: ≥20% improvement (reduction) from baseline in TJC68, SJC66 and in at least 3 of the following 5 items: PGA and SGA assessed using VAS on a scale of 0-100 [0 and 100 indicating no disease activity and maximum disease activity]; subject`s pain assessment using VAS on a scale of 0-100 [0 and 100 indicating no pain and unbearable pain]; HAQ-DI score contains 20 questions, 8 components: dressing/grooming, arising, eating, walking, hygiene, reach, grip and activities and scored on a scale of 0 (without difficulty) to 3 (unable to do); hsCRP. Participants with missing outcomes were set as non-responders. Participants in the Full Analysis Set were analyzed.

End point type	Secondary

End point timeframe:

Weeks 2, 4, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: percentage of participants				
number (confidence interval 95%)				
Week 2	37.3 (32.8 to 41.7)	27.5 (23.4 to 31.6)	33.5 (28.3 to 38.8)	14.9 (11.6 to 18.3)
Week 4	51.6 (47.0 to 56.2)	45.6 (41.1 to 50.2)	47.1 (41.5 to 52.7)	31.8 (27.5 to 36.1)
Week 24	78.1 (74.3 to 81.9)	77.7 (73.9 to 81.5)	74.5 (69.6 to 79.4)	59.2 (54.6 to 63.7)

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 2

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [39]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	22.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	16.7
upper limit	27.9

Notes:

[39] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 100 mg vs Placebo
Statistical analysis description:	
Week 2	
Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [40]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	12.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.2
upper limit	17.9

Notes:

[40] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 200 mg vs Placebo
Statistical analysis description:	
Week 4	
Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [41]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	19.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.4
upper limit	26.1

Notes:

[41] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 100 mg vs Placebo
Statistical analysis description:	
Week 4	
Comparison groups	Filgotinib 100 mg v Placebo

Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [42]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	13.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.5
upper limit	20.2

Notes:

[42] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 24

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [43]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	18.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	13
upper limit	24.9

Notes:

[43] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 24

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [44]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	18.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.6
upper limit	24.5

Notes:

[44] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Secondary: Percentage of Participants Who Achieved ACR20 Response at Weeks 36 and 52

End point title	Percentage of Participants Who Achieved ACR20 Response at Weeks 36 and 52[45]

End point description:

ACR20 response is achieved when the participant has: ≥20% improvement (reduction) from baseline in TJC68, SJC66 and in at least 3 of the following 5 items: PGA and SGA assessed using VAS on a scale of 0-100 [0 and 100 indicating no disease activity and maximum disease activity]; subject`s pain assessment using VAS on a scale of 0-100 [0 and 100 indicating no pain and unbearable pain]; HAQ-DI score contains 20 questions, 8 components: dressing/grooming, arising, eating, walking, hygiene, reach, grip and activities and scored on a scale of 0 (without difficulty) to 3 (unable to do); hsCRP. Participants with missing outcomes were set as non-responders. Participants in the Full Analysis Set were analyzed.

End point type	Secondary

End point timeframe:

Weeks 36 and 52

Notes:

[45] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	475	480	325	190
Units: percentage of participants				
number (confidence interval 95%)				
Week 36	82.9 (79.5 to 86.4)	79.2 (75.4 to 82.9)	76.3 (71.5 to 81.1)	90.5 (86.1 to 95.0)
Week 52	82.9 (79.5 to 86.4)	79.6 (75.9 to 83.3)	77.8 (73.2 to 82.5)	86.3 (81.2 to 91.5)

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	191			
Units: percentage of participants				
number (confidence interval 95%)				
Week 36	86.9 (81.9 to 92.0)			
Week 52	85.9 (80.7 to 91.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Individual ACR Component: HAQ-DI at Weeks 2, 4, and 24

End point title	Change From Baseline in Individual ACR Component: HAQ-DI at Weeks 2, 4, and 24

End point description:

The HAQ-DI score is defined as the average of the scores of eight functional categories (dressing and grooming, arising, eating, walking, hygiene, reach, grip, and other activities), usually completed by the participant. Responses in each functional category are collected as 0 (without any difficulty) to 3 (unable to do a task in that area), with or without aids or devices. The eight category scores are averaged into an overall HAQ-DI score on a scale from 0 (no disability) to 3 (completely disabled). A negative change from baseline indicates improvement. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 2, 4, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	1.59 (± 0.611)	1.55 (± 0.625)	1.59 (± 0.600)	1.63 (± 0.613)
Change from Baseline at Week 2 (N=463,474,317,466)	-0.30 (± 0.443)	-0.22 (± 0.406)	-0.29 (± 0.440)	-0.15 (± 0.357)
Change from Baseline at Week 4 (N=469,471,320,461)	-0.43 (± 0.493)	-0.33 (± 0.454)	-0.40 (± 0.460)	-0.26 (± 0.431)
Change from Baseline at Week 24(N=418,423,283,376)	-0.82 (± 0.632)	-0.75 (± 0.597)	-0.78 (± 0.632)	-0.62 (± 0.598)

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 2; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [46]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.22
upper limit	-0.12

Variability estimate	Standard error of the mean
Dispersion value	0.025

Notes:

[46] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 2; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [47]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.14
upper limit	-0.04
Variability estimate	Standard error of the mean
Dispersion value	0.025

Notes:

[47] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 4; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [48]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.24
upper limit	-0.13
Variability estimate	Standard error of the mean
Dispersion value	0.028

Notes:

[48] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 4; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [49]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.15
upper limit	-0.04
Variability estimate	Standard error of the mean
Dispersion value	0.028

Notes:

[49] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 24; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [50]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.34
upper limit	-0.19
Variability estimate	Standard error of the mean
Dispersion value	0.037

Notes:

[50] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 24; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo

Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [51]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.26
upper limit	-0.11
Variability estimate	Standard error of the mean
Dispersion value	0.037

Notes:

[51] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Secondary: Change From Baseline in Individual ACR Component: HAQ-DI at Weeks 36 and 52

End point title	Change From Baseline in Individual ACR Component: HAQ-DI at Weeks 36 and 52[52]

End point description:

The HAQ-DI score is defined as the average of the scores of eight functional categories (dressing and grooming, arising, eating, walking, hygiene, reach, grip, and other activities), usually completed by the participant. Responses in each functional category are collected as 0 (without any difficulty) to 3 (unable to do a task in that area), with or without aids or devices. The eight category scores are averaged into an overall HAQ-DI score on a scale from 0 (no disability) to 3 (completely disabled). A negative change from baseline indicates improvement. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 36 and 52

Notes:

[52] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	475	480	325	190
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	1.59 (± 0.611)	1.55 (± 0.625)	1.59 (± 0.600)	1.68 (± 0.578)
Change from BL at Week 36 (N=412,417,275,180,188)	-0.88 (± 0.633)	-0.80 (± 0.611)	-0.81 (± 0.634)	-0.96 (± 0.637)
Change from BL at Week 52 (N=400,398,265,173,177)	-0.93 (± 0.649)	-0.85 (± 0.621)	-0.85 (± 0.647)	-0.99 (± 0.644)

End point values	Placebo to Filgotinib 100			

	mg			
Subject group type	Reporting group			
Number of subjects analysed	191			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	1.58 (± 0.603)			
Change from BL at Week 36 (N=412,417,275,180,188)	-0.69 (± 0.610)			
Change from BL at Week 52 (N=400,398,265,173,177)	-0.73 (± 0.650)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Individual ACR Component: Tender Joint Count Based on 68 Joints (TJC68) at Weeks 2, 4, 12, and 24

End point title	Change From Baseline in Individual ACR Component: Tender Joint Count Based on 68 Joints (TJC68) at Weeks 2, 4, 12, and 24

End point description:

TJC was examined on 68 joints of the fingers, elbows, hips, knees, ankles, and toes distal for pain in response to pressure or passive motion at the study time points. Joint pain was scored as 0 = Absent; 1 = Present for each joint. The overall Tender Joint Count ranged from 0 to 68. A negative change from baseline indicates improvement. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 2, 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: tender joint count				
arithmetic mean (standard deviation)				
Baseline (BL)	25 (± 13.5)	25 (± 13.4)	24 (± 13.2)	24 (± 13.5)
Change from BL at Week 2 (N=464,473,317,464)	-8 (± 10.1)	-7 (± 9.3)	-7 (± 8.8)	-5 (± 9.0)
Change from BL at Week 4 (N=469,471,320,461)	-11 (± 11.1)	-10 (± 10.3)	-9 (± 9.2)	-8 (± 10.5)
Change from BL at Week 12 (N=458,458,311,435)	-17 (± 11.1)	-15 (± 10.7)	-15 (± 9.9)	-13 (± 11.6)
Change from BL at Week 24 (N=418,423,283,375)	-20 (± 12.1)	-19 (± 10.9)	-18 (± 11.1)	-17 (± 11.7)

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 2; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [53]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4
upper limit	-2
Variability estimate	Standard error of the mean
Dispersion value	0.6

Notes:

[53] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 2; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.01 [54]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3
upper limit	0
Variability estimate	Standard error of the mean
Dispersion value	0.6

Notes:

[54] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 4; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo

Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [55]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5
upper limit	-2
Variability estimate	Standard error of the mean
Dispersion value	0.6

Notes:

[55] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 4; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [56]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4
upper limit	-1
Variability estimate	Standard error of the mean
Dispersion value	0.6

Notes:

[56] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 12; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo

Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [57]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5
upper limit	-2
Variability estimate	Standard error of the mean
Dispersion value	0.6

Notes:

[57] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 12; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [58]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4
upper limit	-1
Variability estimate	Standard error of the mean
Dispersion value	0.6

Notes:

[58] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 24; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo

Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [59]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4
upper limit	-2
Variability estimate	Standard error of the mean
Dispersion value	0.5

Notes:

[59] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 24; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [60]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3
upper limit	-1
Variability estimate	Standard error of the mean
Dispersion value	0.5

Notes:

[60] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Secondary: Change From Baseline in Individual ACR Component: TJC68 at Weeks 36 and 52

End point title	Change From Baseline in Individual ACR Component: TJC68 at Weeks 36 and 52[61]

End point description:

TJC was examined on 68 joints of the fingers, elbows, hips, knees, ankles, and toes distal for pain in response to pressure or passive motion at the study time points. Joint pain was scored as 0 = Absent; 1 = Present for each joint. The overall Tender Joint Count ranged from 0 to 68. A negative change from baseline indicates improvement. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 36 and 52

Notes:

[61] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	475	480	325	190
Units: tender joint count				
arithmetic mean (standard deviation)				
Baseline (BL)	25 (± 13.5)	25 (± 13.4)	24 (± 13.2)	25 (± 12.8)
Change from BL at Week 36 (N=411,417,275,178,188)	-21 (± 11.9)	-20 (± 11.2)	-19 (± 11.0)	-21 (± 11.4)
Change from BL at Week 52 (N=400,397,265,173,177)	-21 (± 12.2)	-21 (± 11.4)	-20 (± 11.4)	-21 (± 11.9)

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	191			
Units: tender joint count				
arithmetic mean (standard deviation)				
Baseline (BL)	24 (± 12.9)			
Change from BL at Week 36 (N=411,417,275,178,188)	-19 (± 11.5)			
Change from BL at Week 52 (N=400,397,265,173,177)	-20 (± 11.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Individual ACR Component: Swollen Joint Count Based on 66 Joints (SJC66) at Weeks 2, 4, 12, and 24

End point title	Change From Baseline in Individual ACR Component: Swollen Joint Count Based on 66 Joints (SJC66) at Weeks 2, 4, 12, and 24

End point description:

The total SJC66 was based on 66 joints (same 68 joints counted in TJC68 minus hips). It was derived as the sum of all "1s" (presence of a joint swelling was scored as "1" and the absence of swelling was scored as "0," provided the joint was not replaced or could not be assessed due to other reasons) thus collected with no penalty considered for the joints not assessed or those which had been replaced. The range for SJC66 is 0 to 66. A negative change from baseline indicates improvement. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 2, 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: swollen joint count				
arithmetic mean (standard deviation)				
Baseline (BL)	15 (± 8.5)	15 (± 8.5)	16 (± 8.4)	16 (± 8.5)
Change from BL at Week 2 (N=464,473,317,464)	-6 (± 6.7)	-5 (± 6.8)	-6 (± 5.8)	-5 (± 6.9)
Change from BL at Week 4 (N=469,471,320,461)	-8 (± 7.1)	-8 (± 7.8)	-7 (± 6.6)	-6 (± 7.8)
Change from BL at Week 12 (N=458,458,311,435)	-11 (± 7.5)	-11 (± 8.1)	-11 (± 7.1)	-10 (± 8.4)
Change from BL at Week 24 (N=418,423,283,375)	-13 (± 7.8)	-13 (± 7.4)	-13 (± 6.9)	-12 (± 7.7)

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 2; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002 [62]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2
upper limit	0
Variability estimate	Standard error of the mean
Dispersion value	0.4

Notes:

[62] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 2; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo

Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.047 [63]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2
upper limit	0
Variability estimate	Standard error of the mean
Dispersion value	0.4

Notes:

[63] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 4; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [64]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3
upper limit	-1
Variability estimate	Standard error of the mean
Dispersion value	0.4

Notes:

[64] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 4; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo

Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [65]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3
upper limit	-1
Variability estimate	Standard error of the mean
Dispersion value	0.4

Notes:

[65] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 12; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [66]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3
upper limit	-1
Variability estimate	Standard error of the mean
Dispersion value	0.4

Notes:

[66] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 12; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo

Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [67]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2
upper limit	-1
Variability estimate	Standard error of the mean
Dispersion value	0.4

Notes:

[67] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 24; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [68]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3
upper limit	-1
Variability estimate	Standard error of the mean
Dispersion value	0.3

Notes:

[68] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 24; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo

Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [69]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2
upper limit	-1
Variability estimate	Standard error of the mean
Dispersion value	0.3

Notes:

[69] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Secondary: Change From Baseline in Individual ACR Component: SJC66 at Weeks 36 and 52

End point title	Change From Baseline in Individual ACR Component: SJC66 at Weeks 36 and 52[70]

End point description:

The total SJC66 was based on 66 joints. It was derived as the sum of all "1s" (presence of a joint swelling was scored as "1" and the absence of swelling was scored as "0," provided the joint was not replaced or could not be assessed due to other reasons) thus collected with no penalty considered for the joints not assessed or those which had been replaced. The range for SJC66 is 0 to 66. A negative change from baseline indicates improvement. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 36 and 52

Notes:

[70] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	475	480	325	190
Units: swollen joint count				
arithmetic mean (standard deviation)				
Baseline (BL)	15 (± 8.5)	15 (± 8.5)	16 (± 8.4)	16 (± 8.2)
Change from BL at Week 36 (N=411,417,275,178,188)	-14 (± 7.8)	-13 (± 7.6)	-14 (± 7.1)	-14 (± 7.3)
Change from BL at Week 52 (N=400,397,265,173,177)	-14 (± 8.1)	-13 (± 7.6)	-14 (± 7.5)	-14 (± 7.8)

End point values	Placebo to Filgotinib 100 mg			

Subject group type	Reporting group			
Number of subjects analysed	191			
Units: swollen joint count				
arithmetic mean (standard deviation)				
Baseline (BL)	15 (± 7.9)			
Change from BL at Week 36 (N=411,417,275,178,188)	-13 (± 7.2)			
Change from BL at Week 52 (N=400,397,265,173,177)	-13 (± 7.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Individual ACR Component: Subject's Global Assessment of Disease Activity (SGA) at Weeks 2, 4, 12, and 24

End point title	Change From Baseline in Individual ACR Component: Subject's Global Assessment of Disease Activity (SGA) at Weeks 2, 4, 12, and 24

End point description:

SGA was assessed by the participant using a VAS on a scale of 0 (no disease activity) to 100 (maximum disease activity). A negative change from baseline indicates improvement. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 2, 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	67 (± 19.2)	65 (± 19.7)	67 (± 19.1)	68 (± 18.7)
Change from BL at Week 2 (N=464,474,318,466)	-16 (± 20.1)	-11 (± 18.4)	-13 (± 18.1)	-8 (± 17.2)
Change from BL at Week 4 (N=469,472,319,461)	-22 (± 21.5)	-16 (± 20.8)	-19 (± 20.8)	-13 (± 20.2)
Change from BL at Week 12 (N=457,458,311,435)	-33 (± 24.8)	-28 (± 24.7)	-28 (± 23.2)	-21 (± 24.8)
Change from BL at Week 24 (N=418,423,283,376)	-39 (± 25.8)	-36 (± 24.9)	-36 (± 24.9)	-31 (± 26.9)

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 2; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not

imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [71]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11
upper limit	-7
Variability estimate	Standard error of the mean
Dispersion value	1.1

Notes:

[71] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 2; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [72]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7
upper limit	-2
Variability estimate	Standard error of the mean
Dispersion value	1.1

Notes:

[72] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 4; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo

Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [73]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12
upper limit	-7
Variability estimate	Standard error of the mean
Dispersion value	1.3

Notes:

[73] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 4; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [74]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7
upper limit	-2
Variability estimate	Standard error of the mean
Dispersion value	1.3

Notes:

[74] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 12; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo

Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [75]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16
upper limit	-10
Variability estimate	Standard error of the mean
Dispersion value	1.5

Notes:

[75] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 12; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [76]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-10
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12
upper limit	-7
Variability estimate	Standard error of the mean
Dispersion value	1.5

Notes:

[76] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 24; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo

Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [77]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14
upper limit	-7
Variability estimate	Standard error of the mean
Dispersion value	1.6

Notes:

[77] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 24; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [78]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11
upper limit	-5
Variability estimate	Standard error of the mean
Dispersion value	1.6

Notes:

[78] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Secondary: Change From Baseline in Individual ACR Component: SGA at Weeks 36 and 52

End point title	Change From Baseline in Individual ACR Component: SGA at Weeks 36 and 52[79]

End point description:

SGA was assessed by the participant using a VAS on a scale of 0 (no disease activity) to 100 (maximum disease activity). A negative change from baseline indicates improvement. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 36 and 52

Notes:

[79] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	475	480	325	190
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	67 (± 19.2)	65 (± 19.7)	67 (± 19.1)	70 (± 17.8)
Change from BL at Week 36 (N=412,417,274,180,188)	-42 (± 24.2)	-39 (± 25.3)	-39 (± 25.2)	-45 (± 24.7)
Change from BL at Week 52 (N=400,398,265,173,177)	-44 (± 24.4)	-41 (± 25.4)	-42 (± 25.7)	-45 (± 27.6)

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	191			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	66 (± 18.7)			
Change from BL at Week 36 (N=412,417,274,180,188)	-38 (± 25.5)			
Change from BL at Week 52 (N=400,398,265,173,177)	-41 (± 25.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Individual ACR Component: Physician’s Global Assessment of Disease Activity (PGA) at Weeks 2, 4, 12, and 24

End point title	Change From Baseline in Individual ACR Component: Physician’s Global Assessment of Disease Activity (PGA) at Weeks 2, 4, 12, and 24

End point description:

PGA was assessed by the physician using a VAS on a scale of 0 (no disease activity) to 100 (maximum disease activity). A negative change from baseline indicates improvement. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 2, 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	66 (± 16.0)	65 (± 16.5)	67 (± 15.5)	66 (± 16.2)
Change from BL at Week 2 (N=463,469,315,463)	-20 (± 19.3)	-18 (± 18.5)	-19 (± 17.9)	-13 (± 17.8)
Change from BL at Week 4 (N=468,466,318,457)	-28 (± 21.2)	-26 (± 19.7)	-26 (± 19.6)	-20 (± 19.6)
Change from BL at Week 12 (N=457,450,308,433)	-41 (± 20.2)	-39 (± 20.3)	-39 (± 20.4)	-34 (± 22.4)
Change from BL at Week 24 (N=413,419,283,373)	-48 (± 19.2)	-46 (± 19.6)	-47 (± 19.4)	-42 (± 20.4)

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 2; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [80]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10
upper limit	-6
Variability estimate	Standard error of the mean
Dispersion value	1.1

Notes:

[80] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 2; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo

Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [81]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8
upper limit	-4
Variability estimate	Standard error of the mean
Dispersion value	1.1

Notes:

[81] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 4; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [82]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11
upper limit	-6
Variability estimate	Standard error of the mean
Dispersion value	1.2

Notes:

[82] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 4; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo

Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [83]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9
upper limit	-5
Variability estimate	Standard error of the mean
Dispersion value	1.2

Notes:

[83] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 12; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [84]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10
upper limit	-6
Variability estimate	Standard error of the mean
Dispersion value	1.2

Notes:

[84] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 12; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo

Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [85]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10
upper limit	-5
Variability estimate	Standard error of the mean
Dispersion value	1.2

Notes:

[85] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 24; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [86]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11
upper limit	-6
Variability estimate	Standard error of the mean
Dispersion value	1.1

Notes:

[86] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 24; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo

Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [87]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10
upper limit	-5
Variability estimate	Standard error of the mean
Dispersion value	1.1

Notes:

[87] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Secondary: Change From Baseline in Individual ACR Component: PGA at Weeks 36 and 52

End point title	Change From Baseline in Individual ACR Component: PGA at Weeks 36 and 52[88]

End point description:

PGA was assessed by the physician using a VAS on a scale of 0 (no disease activity) to 100 (maximum disease activity). A negative change from baseline indicates improvement. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 36 and 52

Notes:

[88] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	475	480	325	190
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	66 (± 16.0)	65 (± 16.5)	67 (± 15.5)	68 (± 15.6)
Change from BL at Week 36 (N=409,416,273,176,187)	-51 (± 19.0)	-49 (± 19.8)	-50 (± 18.6)	-53 (± 19.5)
Change from BL at Week 52 (N=400,398,265,173,177)	-53 (± 18.2)	-50 (± 19.2)	-52 (± 18.9)	-54 (± 19.7)

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	191			

Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	64 (± 16.3)			
Change from BL at Week 36 (N=409,416,273,176,187)	-47 (± 20.0)			
Change from BL at Week 52 (N=400,398,265,173,177)	-50 (± 19.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Individual ACR Component: Subject`s Pain Assessment at Weeks 2, 4, 12, and 24

End point title	Change From Baseline in Individual ACR Component: Subject`s Pain Assessment at Weeks 2, 4, 12, and 24

End point description:

The participant assessed their pain severity using a VAS on a scale of 0 (no pain) to 100 (severe pain). A negative change from baseline indicates improvement. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 2, 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	65 (± 20.4)	64 (± 20.1)	64 (± 19.5)	66 (± 19.0)
Change from BL at Week 2 (N=463,474,317,466)	-16 (± 21.0)	-12 (± 18.7)	-13 (± 20.4)	-7 (± 18.2)
Change from BL at Week 4 (N=469,471,319,461)	-21 (± 23.7)	-18 (± 20.9)	-18 (± 21.9)	-12 (± 20.8)
Change from BL at Week 12 (N=457,458,311,435)	-31 (± 26.9)	-29 (± 25.3)	-27 (± 23.6)	-21 (± 26.0)
Change from BL at Week 24 (N=418,423,283,376)	-38 (± 27.0)	-37 (± 25.6)	-35 (± 24.2)	-30 (± 27.0)

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 2; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo

Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [89]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12
upper limit	-7
Variability estimate	Standard error of the mean
Dispersion value	1.2

Notes:

[89] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 2; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [90]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8
upper limit	-3
Variability estimate	Standard error of the mean
Dispersion value	1.2

Notes:

[90] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 4; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo

Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [91]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12
upper limit	-7
Variability estimate	Standard error of the mean
Dispersion value	1.3

Notes:

[91] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 4; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [92]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9
upper limit	-4
Variability estimate	Standard error of the mean
Dispersion value	1.3

Notes:

[92] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 12; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo

Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [93]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15
upper limit	-9
Variability estimate	Standard error of the mean
Dispersion value	1.5

Notes:

[93] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 12; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [94]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-10
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13
upper limit	-7
Variability estimate	Standard error of the mean
Dispersion value	1.5

Notes:

[94] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 24; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo

Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [95]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14
upper limit	-7
Variability estimate	Standard error of the mean
Dispersion value	1.6

Notes:

[95] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 24; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [96]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12
upper limit	-6
Variability estimate	Standard error of the mean
Dispersion value	1.6

Notes:

[96] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Secondary: Change From Baseline in Individual ACR Component: Subject`s Pain Assessment at Weeks 36 and 52

End point title	Change From Baseline in Individual ACR Component: Subject`s Pain Assessment at Weeks 36 and 52[97]

End point description:

The participant assessed their pain severity using a VAS on a scale of 0 (no pain) to 100 (severe pain). A negative change from baseline indicates improvement. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 36 and 52

Notes:

[97] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	475	480	325	190
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	65 (± 20.4)	64 (± 20.1)	64 (± 19.5)	68 (± 18.0)
Change from BL at Week 36 (N=412,417,274,180,188)	-40 (± 26.3)	-38 (± 26.2)	-37 (± 25.5)	-44 (± 24.9)
Change from BL at Week 52 (N=400,398,265,173,177)	-43 (± 26.2)	-41 (± 25.9)	-41 (± 25.6)	-45 (± 26.6)

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	191			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	65 (± 19.2)			
Change from BL at Week 36 (N=412,417,274,180,188)	-39 (± 25.9)			
Change from BL at Week 52 (N=400,398,265,173,177)	-41 (± 25.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Individual ACR Component: High-Sensitivity C-Reactive Protein (hsCRP) at Weeks 2, 4, 12, and 24

End point title	Change From Baseline in Individual ACR Component: High-Sensitivity C-Reactive Protein (hsCRP) at Weeks 2, 4, 12, and 24

End point description:

Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 2, 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: mg/L				
arithmetic mean (standard deviation)				
Baseline (BL)	16.13 (± 21.005)	16.74 (± 22.982)	14.56 (± 18.003)	16.25 (± 24.051)
Change from BL at Week 2 (N=455,467,315,463)	-10.85 (± 20.154)	-7.67 (± 17.888)	-8.03 (± 15.594)	-0.07 (± 17.244)
Change from BL at Week 4 (N=465,468,319,456)	-9.99 (± 21.146)	-8.44 (± 20.201)	-7.17 (± 16.896)	-1.12 (± 19.940)
Change from BL at Week 12 (N=456,454,308,431)	-11.00 (± 18.659)	-9.55 (± 21.330)	-7.85 (± 20.632)	-3.26 (± 22.711)
Change from BL at Week 24 (N=416,419,281,370)	-11.84 (± 20.693)	-10.54 (± 22.215)	-6.17 (± 24.224)	-4.00 (± 19.614)

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 2; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [98]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-10.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.7
upper limit	-8.96
Variability estimate	Standard error of the mean
Dispersion value	0.952

Notes:

[98] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 2; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo

Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [99]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-7.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.58
upper limit	-5.87
Variability estimate	Standard error of the mean
Dispersion value	0.947

Notes:

[99] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 4; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [100]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-9.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.33
upper limit	-7.45
Variability estimate	Standard error of the mean
Dispersion value	0.989

Notes:

[100] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 4; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo

Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [101]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-7.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.29
upper limit	-5.42
Variability estimate	Standard error of the mean
Dispersion value	0.987

Notes:

[101] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 12; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [102]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-8.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.9
upper limit	-6.13
Variability estimate	Standard error of the mean
Dispersion value	0.961

Notes:

[102] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 12; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo

Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [103]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-6.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.35
upper limit	-4.58
Variability estimate	Standard error of the mean
Dispersion value	0.96

Notes:

[103] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 24; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [104]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-7.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.88
upper limit	-5.93
Variability estimate	Standard error of the mean
Dispersion value	1.007

Notes:

[104] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 24; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo

Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [105]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-6.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.56
upper limit	-4.62
Variability estimate	Standard error of the mean
Dispersion value	1.005

Notes:

[105] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Secondary: Change From Baseline in Individual ACR Component: hsCRP at Weeks 36 and 52

End point title	Change From Baseline in Individual ACR Component: hsCRP at Weeks 36 and 52[106]

End point description:

Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 36 and 52

Notes:

[106] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	475	480	325	190
Units: mg/L				
arithmetic mean (standard deviation)				
Baseline (BL)	16.13 (± 21.005)	16.74 (± 22.982)	14.56 (± 18.003)	16.54 (± 24.782)
Change from BL at Week 36 (N=408,413,273,179,184)	-11.51 (± 21.990)	-10.72 (± 22.569)	-8.73 (± 18.214)	-12.12 (± 23.151)
Change from BL at Week 52 (N=396,386,259,169,171)	-12.19 (± 20.773)	-11.27 (± 23.129)	-9.60 (± 16.511)	-11.43 (± 20.873)

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	191			
Units: mg/L				

arithmetic mean (standard deviation)				
Baseline (BL)	15.76 (± 21.871)			
Change from BL at Week 36 (N=408,413,273,179,184)	-8.50 (± 19.749)			
Change from BL at Week 52 (N=396,386,259,169,171)	-8.74 (± 19.921)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved an Improvement (Decrease) in the HAQ-DI Score ≥ 0.22 at Weeks 2, 4, 12, and 24

End point title	Percentage of Participants Who Achieved an Improvement (Decrease) in the HAQ-DI Score ≥ 0.22 at Weeks 2, 4, 12, and 24

End point description:

The HAQ-DI score is defined as the average of the scores of eight functional categories (dressing and grooming, arising, eating, walking, hygiene, reach, grip, and other activities), usually completed by the participant. Responses in each functional category are collected as 0 (without any difficulty) to 3 (unable to do a task in that area), with or without aids or devices. The eight category scores are averaged into an overall HAQ-DI score on a scale from 0-3 [0 (no disability) to 3 (completely disabled) when 6 or more categories are non-missing, so total possible score is 3. Improvement is defined as reduction in HAQ-DI, (baseline value - postbaseline value) ≥ 0.22. If more than 2 categories are missing, the HAQ-DI score is set to missing. Participants with missing outcomes were set as non-responders. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 2, 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: percentage of participants				
number (confidence interval 95%)				
Week 2 (N=459,467,316,463)	52.5 (47.8 to 57.2)	46.7 (42.0 to 51.3)	51.9 (46.2 to 57.6)	40.2 (35.6 to 44.7)
Week 4 (N=459,467,316,463)	66.2 (61.8 to 70.7)	58.0 (53.4 to 62.6)	63.9 (58.5 to 69.4)	49.9 (45.2 to 54.6)
Week 12 (N=459,467,316,463)	78.9 (75.0 to 82.7)	71.5 (67.3 to 75.7)	72.8 (67.6 to 77.9)	57.9 (53.3 to 62.5)
Week 24 (N=459,467,316,463)	76.0 (72.0 to 80.0)	73.4 (69.3 to 77.6)	71.2 (66.1 to 76.4)	59.4 (54.8 to 64.0)

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo
Statistical analysis description:	
Week 2	
Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [107]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	12.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.7
upper limit	18.9

Notes:

[107] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 100 mg vs Placebo
Statistical analysis description:	
Week 2	
Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.043 [108]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	6.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	13.1

Notes:

[108] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 200 mg vs Placebo
Statistical analysis description:	
Week 4	
Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [109]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	16.3

Confidence interval	
level	95 %
sides	2-sided
lower limit	9.8
upper limit	22.8

Notes:

[109] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 4

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.011 [110]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.5
upper limit	14.7

Notes:

[110] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 12

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [111]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	21
Confidence interval	
level	95 %
sides	2-sided
lower limit	14.9
upper limit	27

Notes:

[111] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 12

Comparison groups	Filgotinib 100 mg v Placebo

Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [112]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	13.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.3
upper limit	19.9

Notes:

[112] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 24

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [113]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	16.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	10.5
upper limit	22.8

Notes:

[113] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 24

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [114]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	14.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.8
upper limit	20.3

Notes:

[114] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Secondary: Percentage of Participants Who Achieved an Improvement (Decrease) in the HAQ-DI Score ≥ 0.22 at Weeks 36 and 52

End point title	Percentage of Participants Who Achieved an Improvement (Decrease) in the HAQ-DI Score ≥ 0.22 at Weeks 36 and 52[115]

End point description:

The HAQ-DI score is defined as the average of the scores of eight functional categories (dressing and grooming, arising, eating, walking, hygiene, reach, grip, and other activities), usually completed by the participant. Responses in each functional category are collected as 0 (without any difficulty) to 3 (unable to do a task in that area), with or without aids or devices. The eight category scores are averaged into an overall HAQ-DI score on a scale from 0-3 [0 (no disability) to 3 (completely disabled) when 6 or more categories are non-missing, so total possible score is 3. Improvement is defined as reduction in HAQ-DI, (baseline value - postbaseline value) ≥ 0.22. If more than 2 categories are missing, the HAQ-DI score is set to missing. Participants with missing outcomes were set as non-responders. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 36 and 52

Notes:

[115] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	475	480	325	190
Units: percentage of participants				
number (confidence interval 95%)				
Week 36 (N=459,467,316,185,188)	77.1 (73.2 to 81.1)	74.9 (70.9 to 79.0)	71.5 (66.4 to 76.7)	83.2 (77.6 to 88.9)
Week 52 (N=459,467,316,185,188)	75.8 (71.8 to 79.8)	73.0 (68.9 to 77.2)	70.3 (65.1 to 75.5)	81.6 (75.8 to 87.5)

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	191			
Units: percentage of participants				
number (confidence interval 95%)				
Week 36 (N=459,467,316,185,188)	77.7 (71.4 to 83.9)			
Week 52 (N=459,467,316,185,188)	71.8 (65.1 to 78.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in DAS28 (CRP) at Weeks 2, 4, 12, and 24

End point title	Change From Baseline in DAS28 (CRP) at Weeks 2, 4, 12, and 24

End point description:

The DAS28 score is a measure of the participant's disease activity calculated using the tender joint counts (28 joints), swollen joint counts (28 joints), SGA (VAS: 0 = no disease activity to 100 = maximum disease activity), and hsCRP for a total possible score of 1 to 9.4. Higher values indicate higher disease activity. A negative change from baseline indicates improvement. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 2, 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	5.8 (± 0.88)	5.7 (± 0.95)	5.7 (± 0.88)	5.7 (± 0.91)
Change from Baseline at Week 2 (N=452,464,314,461)	-1.3 (± 1.05)	-1.0 (± 0.90)	-1.1 (± 0.90)	-0.6 (± 0.79)
Change from Baseline at Week 4 (N=463,467,318,454)	-1.7 (± 1.19)	-1.4 (± 1.07)	-1.4 (± 1.04)	-0.9 (± 0.98)
Change from Baseline at Week 12(N=455,452,308,431)	-2.5 (± 1.24)	-2.2 (± 1.17)	-2.2 (± 1.12)	-1.6 (± 1.19)
Change from Baseline at Week 24(N=415,419,281,368)	-3.1 (± 1.17)	-2.8 (± 1.08)	-2.7 (± 1.20)	-2.2 (± 1.20)

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 2; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [116]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.9
upper limit	-0.6
Variability estimate	Standard error of the mean
Dispersion value	0.06

Notes:

[116] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 2; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [117]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.5
upper limit	-0.3
Variability estimate	Standard error of the mean
Dispersion value	0.06

Notes:

[117] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 4; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [118]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.9
upper limit	-0.7

Variability estimate	Standard error of the mean
Dispersion value	0.07

Notes:

[118] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 4; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [119]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	-0.4
Variability estimate	Standard error of the mean
Dispersion value	0.07

Notes:

[119] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 12; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [120]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	-0.8
Variability estimate	Standard error of the mean
Dispersion value	0.07

Notes:

[120] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 12; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [121]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.8
upper limit	-0.5
Variability estimate	Standard error of the mean
Dispersion value	0.07

Notes:

[121] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 24; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [122]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	-0.8
Variability estimate	Standard error of the mean
Dispersion value	0.08

Notes:

[122] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 24; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo

Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [123]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.8
upper limit	-0.5
Variability estimate	Standard error of the mean
Dispersion value	0.08

Notes:

[123] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Secondary: Change From Baseline in DAS28 (CRP) at Weeks 36 and 52

End point title	Change From Baseline in DAS28 (CRP) at Weeks 36 and 52[124]

End point description:

The DAS28 score is a measure of the participant's disease activity calculated using the tender joint counts (28 joints), swollen joint counts (28 joints), SGA (VAS: 0 = no disease activity to 100 = maximum disease activity), and hsCRP for a total possible score of 1 to 9.4. Higher values indicate higher disease activity. A negative change from baseline indicates improvement. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 36 and 52

Notes:

[124] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	475	480	325	190
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	5.8 (± 0.88)	5.7 (± 0.95)	5.7 (± 0.88)	5.9 (± 0.89)
Change from BL at Week 36 (N=407,413,272,177,184)	-3.2 (± 1.09)	-2.9 (± 1.17)	-2.9 (± 1.16)	-3.3 (± 1.10)
Change from BL at Week 52 (N=393,385,259,169,171)	-3.4 (± 1.11)	-3.1 (± 1.09)	-3.1 (± 1.13)	-3.3 (± 1.16)

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	191			

Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	5.6 (± 0.89)			
Change from BL at Week 36 (N=407,413,272,177,184)	-2.8 (± 1.08)			
Change from BL at Week 52 (N=393,385,259,169,171)	-3.0 (± 1.04)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved DAS28 (CRP) ≤ 3.2 at Weeks 2, 4, and 24

End point title	Percentage of Participants Who Achieved DAS28 (CRP) ≤ 3.2 at Weeks 2, 4, and 24

End point description:

The DAS28 score is a measure of the participant's disease activity calculated using the tender joint counts (28 joints), swollen joint counts (28 joints), SGA (VAS: 0 = no disease activity to 100 = maximum disease activity), and hsCRP for a total possible score of 1 to 9.4. Higher values indicate higher disease activity. Participants with missing outcomes were set as non-responders. Participants in the Full Analysis Set were analyzed.

End point type	Secondary

End point timeframe:

Weeks 2, 4, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: percentage of participants				
number (confidence interval 95%)				
Week 2	13.1 (9.9 to 16.2)	8.1 (5.6 to 10.7)	9.8 (6.5 to 13.2)	3.6 (1.8 to 5.4)
Week 4	25.5 (21.5 to 29.5)	20.4 (16.7 to 24.1)	20.9 (16.3 to 25.5)	9.3 (6.6 to 12.0)
Week 24	60.6 (56.1 to 65.1)	53.1 (48.6 to 57.7)	50.5 (44.9 to 56.1)	33.7 (29.3 to 38.0)

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 2

Comparison groups	Filgotinib 200 mg v Placebo

Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [125]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	9.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.8
upper limit	13.1

Notes:

[125] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 2

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004 [126]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	4.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.4
upper limit	7.7

Notes:

[126] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 4

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [127]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.3
upper limit	21.1

Notes:

[127] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 100 mg vs Placebo
Statistical analysis description:	
Week 4	
Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [128]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	11.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.5
upper limit	15.8

Notes:

[128] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 200 mg vs Placebo
Statistical analysis description:	
Week 24	
Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [129]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	26.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	20.6
upper limit	33.3

Notes:

[129] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 100 mg vs Placebo
Statistical analysis description:	
Week 24	
Comparison groups	Filgotinib 100 mg v Placebo

Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [130]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	19.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.1
upper limit	25.8

Notes:

[130] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Secondary: Percentage of Participants Who Achieved DAS28 (CRP) ≤ 3.2 at Weeks 36 and 52

End point title	Percentage of Participants Who Achieved DAS28 (CRP) ≤ 3.2 at Weeks 36 and 52[131]

End point description:

The DAS28 score is a measure of the participant's disease activity calculated using the tender joint counts (28 joints), swollen joint counts (28 joints), SGA (VAS: 0 = no disease activity to 100 = maximum disease activity), and hsCRP for a total possible score of 1 to 9.4. Higher values indicate higher disease activity. Participants with missing outcomes were set as non-responders. Participants in the Full Analysis Set were analyzed.

End point type	Secondary

End point timeframe:

Weeks 36 and 52

Notes:

[131] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	475	480	325	190
Units: percentage of participants				
number (confidence interval 95%)				
Week 36	67.4 (63.0 to 71.7)	60.2 (55.7 to 64.7)	58.2 (52.6 to 63.7)	74.7 (68.3 to 81.2)
Week 52	68.2 (63.9 to 72.5)	62.1 (57.6 to 66.5)	61.8 (56.4 to 67.3)	69.5 (62.7 to 76.3)

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	191			
Units: percentage of participants				
number (confidence interval 95%)				

Week 36	66.5 (59.5 to 73.4)			
Week 52	67.5 (60.6 to 74.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved DAS28 (CRP) < 2.6 at Weeks 2, 4, and 12

End point title	Percentage of Participants Who Achieved DAS28 (CRP) < 2.6 at Weeks 2, 4, and 12

End point description:

The DAS28 score is a measure of the participant's disease activity calculated using the tender joint counts (28 joints), swollen joint counts (28 joints), SGA (VAS: 0 = no disease activity to 100 = maximum disease activity), and hsCRP for a total possible score of 1 to 9.4. Higher values indicate higher disease activity. Participants with missing outcomes were set as non-responders. Participants in the Full Analysis Set were analyzed.

End point type	Secondary

End point timeframe:

Weeks 2, 4, and 12

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: percentage of participants				
number (confidence interval 95%)				
Week 2	5.1 (3.0 to 7.1)	1.7 (0.4 to 2.9)	3.4 (1.3 to 5.5)	0.6 (0.0 to 1.4)
Week 4	13.7 (10.5 to 16.9)	8.8 (6.1 to 11.4)	8.0 (4.9 to 11.1)	2.9 (1.3 to 4.6)
Week 12	34.1 (29.7 to 38.5)	23.8 (19.8 to 27.7)	23.7 (18.9 to 28.5)	9.3 (6.6 to 12.0)

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 2

Comparison groups	Filgotinib 200 mg v Placebo

Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [132]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	4.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.1
upper limit	6.7

Notes:

[132] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 2

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.17 [133]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.5
upper limit	2.6

Notes:

[133] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 4

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [134]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	10.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.1
upper limit	14.4

Notes:

[134] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 100 mg vs Placebo
Statistical analysis description:	
Week 4	
Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [135]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	5.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	9

Notes:

[135] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 200 mg vs Placebo
Statistical analysis description:	
Week 12	
Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [136]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	24.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	19.6
upper limit	30

Notes:

[136] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 100 mg vs Placebo
Statistical analysis description:	
Week 12	
Comparison groups	Filgotinib 100 mg v Placebo

Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [137]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	14.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.7
upper limit	19.3

Notes:

[137] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Secondary: Percentage of Participants Who Achieved DAS28 (CRP) < 2.6 at Weeks 36 and 52

End point title	Percentage of Participants Who Achieved DAS28 (CRP) < 2.6 at Weeks 36 and 52[138]

End point description:

The DAS28 score is a measure of the participant's disease activity calculated using the tender joint counts (28 joints), swollen joint counts (28 joints), SGA (VAS: 0 = no disease activity to 100 = maximum disease activity), and hsCRP for a total possible score of 1 to 9.4. Higher values indicate higher disease activity. Participants with missing outcomes were set as non-responders. Participants in the Full Analysis Set were analyzed.

End point type	Secondary

End point timeframe:

Weeks 36 and 52

Notes:

[138] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	475	480	325	190
Units: percentage of participants				
number (confidence interval 95%)				
Week 36	50.3 (45.7 to 54.9)	42.9 (38.4 to 47.4)	42.5 (36.9 to 48.0)	52.1 (44.7 to 59.5)
Week 52	54.5 (49.9 to 59.1)	44.8 (40.2 to 49.3)	48.6 (43.0 to 54.2)	50.5 (43.2 to 57.9)

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	191			
Units: percentage of participants				
number (confidence interval 95%)				

Week 36	46.1 (38.7 to 53.4)			
Week 52	50.8 (43.4 to 58.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology N Percent Improvement (ACR-N) at Weeks 2, 4, 12, and 24

End point title	American College of Rheumatology N Percent Improvement (ACR-N) at Weeks 2, 4, 12, and 24

End point description:

ACR-N is defined as the smallest percentage improvement from baseline in swollen joints, tender joints and the median of the following 5 items (PGA, SGA, subject`s pain assessment, HAQ-DI and hsCRP). It has a range between 0 and 100%. PGA and SGA assessed using VAS on a scale of 0-100 [0 and 100 indicating no disease activity and maximum disease activity]; subject`s pain assessment using VAS on a scale of 0-100 [0 and 100 indicating no pain and unbearable pain]; HAQ-DI score contains 20 questions,8 components: dressing/grooming, arising, eating, walking, hygiene, reach, grip and activities and scored on a scale of 0 (without difficulty) to 3 (unable to do). If this calculation results in a negative value, then the ACR-N is set to 0. The ACR-N value indicates an improvement of N%, with higher numbers indicating greater improvement. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 2, 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: percent improvement				
arithmetic mean (standard deviation)				
Week 2 (N=441,451,306,450)	18.3 (± 19.98)	14.0 (± 17.14)	16.3 (± 18.41)	8.0 (± 12.82)
Week 4 (N=453,453,311,443)	27.4 (± 25.24)	23.0 (± 22.26)	23.8 (± 22.94)	15.1 (± 18.92)
Week 12 (N=445,436,300,422)	46.8 (± 28.46)	40.6 (± 27.32)	40.4 (± 26.18)	28.1 (± 25.22)
Week 24 (N=402,408,276,360)	58.8 (± 27.76)	55.4 (± 26.47)	54.3 (± 28.13)	42.6 (± 27.73)

Statistical analyses

No statistical analyses for this end point

Secondary: ACR N Percent Improvement (ACR-N) at Weeks 36 and 52

End point title	ACR N Percent Improvement (ACR-N) at Weeks 36 and 52[139]

End point description:

ACR-N is defined as the smallest percentage improvement from baseline in swollen joints, tender joints and the median of the following 5 items (PGA, SGA, subject`s pain assessment, HAQ-DI and hsCRP). It

has a range between 0 and 100%. PGA and SGA assessed using VAS on a scale of 0-100 [0 and 100 indicating no disease activity and maximum disease activity]; subject`s pain assessment using VAS on a scale of 0-100 [0 and 100 indicating no pain and unbearable pain]; HAQ-DI score contains 20 questions,8 components: dressing/grooming, arising, eating, walking, hygiene, reach, grip and activities and scored on a scale of 0 (without difficulty) to 3 (unable to do). If this calculation results in a negative value, then the ACR-N is set to 0. The ACR-N value indicates an improvement of N%, with higher numbers indicating greater improvement. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 36 and 52

Notes:

[139] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	475	480	325	190
Units: percent improvement				
arithmetic mean (standard deviation)				
Week 36 (N=397,406,267,171,181)	62.5 (± 26.01)	59.1 (± 27.47)	58.6 (± 27.17)	63.2 (± 24.59)
Week 52 (N=385,379,255,165,170)	66.0 (± 25.89)	63.1 (± 26.34)	63.5 (± 27.03)	63.8 (± 28.00)

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	191			
Units: percent improvement				
arithmetic mean (standard deviation)				
Week 36 (N=397,406,267,171,181)	56.1 (± 27.30)			
Week 52 (N=385,379,255,165,170)	59.7 (± 26.81)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With European League Against Rheumatism (EULAR) Response at Weeks 2, 4, 12, and 24

End point title	Number of Participants With European League Against Rheumatism (EULAR) Response at Weeks 2, 4, 12, and 24

End point description:

Good Response: DAS28(CRP) at visit ≤3.2 and improvement from baseline >1.2.
Moderate Response: DAS28(CRP) at visit ≤3.2 and improvement from baseline >0.6 and ≤1.2; DAS28(CRP) at visit >3.2 and ≤5.1 and improvement from baseline >0.6; DAS 28(CRP) at visit >5.1 and improvement from baseline >1.2.
No Response: DAS28(CRP) at visit ≤5.1 and improvement from baseline ≤0.6; DAS 28(CRP) >5.1 at visit and improvement from baseline ≤1.2.

Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 2, 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: participants				
Week 2: Good Response (N=452,464,314,461)	58	32	27	15
Week 2: Moderate Response (N=452,464,314,461)	237	213	158	133
Week 2: No Response (N=452,464,314,461)	157	219	129	313
Week 4: Good Response (N=463,467,318,454)	117	86	61	37
Week 4: Moderate Response (N=463,467,318,454)	231	242	156	189
Week 4: No Response (N=463,467,318,454)	115	139	101	228
Week 12: Good Response (N=455,452,308,431)	234	177	138	106
Week 12: Moderate Response (N=455,452,308,431)	188	225	138	224
Week 12: No Response (N=455,452,308,431)	33	50	32	101
Week 24: Good Response (N=415,419,281,368)	284	250	163	154
Week 24: Moderate Response (N=415,419,281,368)	124	156	97	170
Week 24: No Response (N=415,419,281,368)	7	13	21	44

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With EULAR Response at Weeks 36 and 52

End point title	Number of Participants With EULAR Response at Weeks 36 and 52[140]

End point description:

Good Response: DAS28(CRP) at visit ≤3.2 and improvement from baseline >1.2.
Moderate Response: DAS28(CRP) at visit ≤3.2 and improvement from baseline >0.6 and ≤1.2; DAS28(CRP) at visit >3.2 and ≤5.1 and improvement from baseline >0.6; DAS 28(CRP) at visit >5.1 and improvement from baseline >1.2.
No Response: DAS28(CRP) at visit ≤5.1 and improvement from baseline ≤0.6; DAS 28(CRP) >5.1 at visit and improvement from baseline ≤1.2.
Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 36 and 52

Notes:

[140] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	475	480	325	190
Units: participants				
Week 36: Good Response (N=407,413,272,177,184)	306	276	180	139
Week 36: Moderate Response (N=407,413,272,177,184)	99	126	84	38
Week 36: No Response (N=407,413,272,177,184)	2	11	8	0
Week 52: Good Response (N=393,385,259,169,171)	308	282	189	129
Week 52: Moderate Response (N=393,385,259,169,171)	82	98	66	38
Week 52: No Response (N=393,385,259,169,171)	3	5	4	2

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	191			
Units: participants				
Week 36: Good Response (N=407,413,272,177,184)	124			
Week 36: Moderate Response (N=407,413,272,177,184)	54			
Week 36: No Response (N=407,413,272,177,184)	6			
Week 52: Good Response (N=393,385,259,169,171)	126			
Week 52: Moderate Response (N=393,385,259,169,171)	42			
Week 52: No Response (N=393,385,259,169,171)	3			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Clinical Disease Activity Index (CDAI) at Weeks 2, 4, 12, and 24

End point title	Change From Baseline in Clinical Disease Activity Index (CDAI) at Weeks 2, 4, 12, and 24

End point description:

CDAI is calculated using formula: CDAI = TJC based on 28 joints (TJC28) + SJC based on 28 joints (SJC28) + SGA + PGA. PGA and SGA are assessed using a VAS on a scale of 0-10 [0 and 10 indicating no disease activity and maximum disease activity]. CDAI can range from 0 to 76, with higher score indicating more severe disease activity status. A negative change from baseline indicates improvement. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 2, 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	39.5 (± 11.85)	38.6 (± 12.23)	39.2 (± 11.51)	39.6 (± 11.66)
Change from BL at Week 2 (N=463,469,315,461)	-12.7 (± 11.86)	-10.7 (± 11.17)	-11.7 (± 10.06)	-8.2 (± 10.10)
Change from BL at Week 4 (N=468,466,317,457)	-17.6 (± 12.66)	-15.6 (± 12.07)	-15.4 (± 11.13)	-12.4 (± 11.79)
Change from BL at Week 12 (N=456,449,308,433)	-26.0 (± 12.41)	-23.3 (± 12.32)	-23.5 (± 11.43)	-20.3 (± 13.30)
Change from BL at Week 24 (N=413,419,283,373)	-30.6 (± 11.88)	-28.6 (± 11.57)	-28.4 (± 11.45)	-26.3 (± 12.38)

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 2; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [141]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-4.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.9
upper limit	-3.2
Variability estimate	Standard error of the mean
Dispersion value	0.68

Notes:

[141] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 2; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [142]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.3
upper limit	-1.6
Variability estimate	Standard error of the mean
Dispersion value	0.68

Notes:

[142] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 4; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [143]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-5.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.6
upper limit	-3.8
Variability estimate	Standard error of the mean
Dispersion value	0.73

Notes:

[143] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 4; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [144]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-3.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.3
upper limit	-2.4
Variability estimate	Standard error of the mean
Dispersion value	0.73

Notes:

[144] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 12; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [145]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-5.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.3
upper limit	-4.6
Variability estimate	Standard error of the mean
Dispersion value	0.69

Notes:

[145] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 12; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo

Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [146]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-4.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.8
upper limit	-3.1
Variability estimate	Standard error of the mean
Dispersion value	0.69

Notes:

[146] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 24; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [147]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-5.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.9
upper limit	-4.5
Variability estimate	Standard error of the mean
Dispersion value	0.62

Notes:

[147] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 24; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo

Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [148]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-4.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.3
upper limit	-2.9
Variability estimate	Standard error of the mean
Dispersion value	0.62

Notes:

[148] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Secondary: Change From Baseline in CDAI at Weeks 36 and 52

End point title	Change From Baseline in CDAI at Weeks 36 and 52[149]

End point description:

CDAI is calculated using formula: CDAI = TJC28 + SJC28 + SGA + PGA. PGA and SGA are assessed using a VAS on a scale of 0-10 [0 and 10 indicating no disease activity and maximum disease activity]. CDAI can range from 0 to 76, with higher score indicating more severe disease activity status. A negative change from baseline indicates improvement. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 36 and 52

Notes:

[149] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	475	480	325	190
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	39.5 (± 11.85)	38.6 (± 12.23)	39.2 (± 11.51)	41.4 (± 11.03)
Change from BL at Week 36 (N=409,416,273,176,187)	-32.1 (± 11.60)	-29.9 (± 12.18)	-30.4 (± 11.21)	-33.8 (± 11.15)
Change from BL at Week 52 (N=399,397,265,173,177)	-32.9 (± 11.69)	-30.9 (± 11.70)	-31.6 (± 11.44)	-34.0 (± 11.20)

End point values	Placebo to Filgotinib 100 mg			

Subject group type	Reporting group			
Number of subjects analysed	191			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	37.8 (± 11.23)			
Change from BL at Week 36 (N=409,416,273,176,187)	-29.0 (± 11.02)			
Change from BL at Week 52 (N=399,397,265,173,177)	-30.7 (± 10.80)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Simplified Disease Activity Index (SDAI) at Weeks 2, 4, 12, and 24

End point title	Change From Baseline in Simplified Disease Activity Index (SDAI) at Weeks 2, 4, 12, and 24

End point description:

SDAI is a composite measure that sums the TJC28, SJC28, SGA, PGA, and the hsCRP (in mg/dL). PGA and SGA assessed using VAS on a scale of 0-10 [0 and 10 indicating no disease activity and maximum disease activity]. Higher score indicates more severe disease activity status and total possible score is 0 to 86. A negative change from baseline indicates improvement. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 2, 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	41.2 (± 12.26)	40.2 (± 12.79)	40.6 (± 11.88)	41.2 (± 12.37)
Change from BL at Week 2 (N=451,460,312,458)	-14.0 (± 12.19)	-11.4 (± 11.41)	-12.5 (± 10.52)	-8.2 (± 10.38)
Change from BL at Week 4 (N=462,462,316,450)	-18.6 (± 13.08)	-16.4 (± 12.31)	-16.1 (± 11.47)	-12.5 (± 12.18)
Change from BL at Week 12 (N=454,444,305,429)	-27.1 (± 12.69)	-24.1 (± 12.54)	-24.3 (± 12.03)	-20.6 (± 13.85)
Change from BL at Week 24 (N=410,415,281,366)	-31.8 (± 12.18)	-29.7 (± 12.01)	-29.0 (± 12.19)	-26.6 (± 12.91)

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 2; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [150]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-5.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.1
upper limit	-4.4
Variability estimate	Standard error of the mean
Dispersion value	0.7

Notes:

[150] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 2; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [151]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-3.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5
upper limit	-2.2
Variability estimate	Standard error of the mean
Dispersion value	0.7

Notes:

[151] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 4; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo

Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [152]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-6.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.6
upper limit	-4.6
Variability estimate	Standard error of the mean
Dispersion value	0.75

Notes:

[152] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 4; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [153]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-4.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6
upper limit	-3.1
Variability estimate	Standard error of the mean
Dispersion value	0.75

Notes:

[153] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 12; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo

Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [154]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-6.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.2
upper limit	-5.4
Variability estimate	Standard error of the mean
Dispersion value	0.71

Notes:

[154] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 12; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [155]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-5.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.5
upper limit	-3.7
Variability estimate	Standard error of the mean
Dispersion value	0.71

Notes:

[155] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 24; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo

Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [156]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-6.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.8
upper limit	-5.3
Variability estimate	Standard error of the mean
Dispersion value	0.65

Notes:

[156] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 24; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [157]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-4.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.1
upper limit	-3.5
Variability estimate	Standard error of the mean
Dispersion value	0.65

Notes:

[157] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Secondary: Change From Baseline in SDAI at Weeks 36 and 52

End point title	Change From Baseline in SDAI at Weeks 36 and 52[158]

End point description:

SDAI is a composite measure that sums the TJC28, SJC28, SGA, PGA, and the hsCRP (in mg/dL). PGA and SGA assessed using VAS on a scale of 0-10 [0 and 10 indicating no disease activity and maximum disease activity]. Higher score indicates more severe disease activity status and total possible score is 0 to 86. A negative change from baseline indicates improvement. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 36 and 52

Notes:

[158] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	475	480	325	190
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	41.2 (± 12.26)	40.2 (± 12.79)	40.6 (± 11.88)	43.0 (± 11.81)
Change from BL at Week 36 (N=405,412,271,175,183)	-33.3 (± 11.92)	-31.0 (± 12.69)	-31.2 (± 11.73)	-35.1 (± 11.83)
Change from BL at Week 52 (N=393,385,259,169,171)	-34.1 (± 12.15)	-32.0 (± 12.25)	-32.6 (± 11.99)	-34.9 (± 11.83)

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	191			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	39.4 (± 11.81)			
Change from BL at Week 36 (N=405,412,271,175,183)	-29.9 (± 11.40)			
Change from BL at Week 52 (N=393,385,259,169,171)	-31.6 (± 11.11)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in mTSS at Week 52

End point title	Change From Baseline in mTSS at Week 52[159]

End point description:

Participant`s radiographs of bilateral hands, wrists and feet are taken and evaluated through central review using the mTSS method. The mTSS (range [0-448]) is defined as the erosion score (range [0-280]) plus the joint space narrowing (JSN) score (range [0-168]). An erosion score of 0 to 5 is given to each joint in the hands and wrists, and a score of 0 to 10 is given to each joint in the feet where 0 indicates no erosion while 5 or 10 indicates extensive loss of bone (maximum erosion). JSN is scored from 0 to 4, with 0 indicating normal or no narrowing and 4 indicating complete loss of joint space. The maximal TSS is 448. Negative change in value indicates improvement (less erosion of bone, normal joint spaces). Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Week 52

Notes:

[159] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	468	472	319	187
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	32.62 (± 48.306)	36.24 (± 52.956)	33.94 (± 53.803)	26.68 (± 45.870)
Change from BL at Week 52 (N=417,411,273,180,178)	0.21 (± 1.434)	0.50 (± 2.098)	0.58 (± 3.621)	0.63 (± 2.782)

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	188			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	32.38 (± 55.012)			
Change from BL at Week 52 (N=417,411,273,180,178)	0.90 (± 3.152)			

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo to Filgotinib 200 mg

Statistical analysis description:

LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Placebo to Filgotinib 200 mg v Filgotinib 200 mg
Number of subjects included in analysis	655
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.042 [160]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.77
upper limit	-0.01

Notes:

[160] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo to Filgotinib 100 mg

Statistical analysis description:

LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo to Filgotinib 100 mg
Number of subjects included in analysis	660
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.039 [161]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.77
upper limit	-0.02

Notes:

[161] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Secondary: Percentage of Participants With no Radiographic Progression From Baseline at Week 24

End point title	Percentage of Participants With no Radiographic Progression From Baseline at Week 24

End point description:

Participant`s radiographs of bilateral hands, wrists and feet are taken and evaluated through central review using the mTSS method. No radiographic progression is defined by the change from baseline in mTSS and is reported for the following categories: Change in mTSS ≤ 0.5, Change in mTSS ≤ 0 and Change in mTSS ≤ smallest detectable change (SDC). Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: percentage of participants				
number (confidence interval 95%)				
Change in mTSS ≤ 0.5 (N=405,404,271,351)	93.8 (91.4 to 96.3)	91.1 (88.2 to 94.0)	91.9 (88.4 to 95.3)	87.2 (83.5 to 90.8)
Change in mTSS ≤ 0 (N=405,404,271,351)	87.9 (84.6 to 91.2)	85.9 (82.4 to 89.4)	86.3 (82.1 to 90.6)	80.9 (76.7 to 85.2)
Change in mTSS ≤ SDC (1.36) (N=405,404,271,351)	95.8 (93.7 to 97.9)	95.0 (92.8 to 97.3)	94.5 (91.6 to 97.4)	90.3 (87.1 to 93.6)

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo
Statistical analysis description:	
Change in mTSS ≤ 0.5.	
Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002 [162]
Method	Regression, Logistic
Parameter estimate	Difference in non-progression rate
Point estimate	6.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.2
upper limit	11.1

Notes:

[162] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 100 mg vs Placebo
Statistical analysis description:	
Change in mTSS ≤ 0.5.	
Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.073 [163]
Method	Regression, Logistic
Parameter estimate	Difference in non-progression rate
Point estimate	3.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.8
upper limit	8.6

Notes:

[163] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 200 mg vs Placebo
Statistical analysis description:	
Change in mTSS ≤ 0.	
Comparison groups	Filgotinib 200 mg v Placebo

Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.009 [164]
Method	Regression, Logistic
Parameter estimate	Difference in non-progression rate
Point estimate	7
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.5
upper limit	12.5

Notes:

[164] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Change in mTSS ≤ 0.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.061 [165]
Method	Regression, Logistic
Parameter estimate	Difference in non-progression rate
Point estimate	5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.6
upper limit	10.6

Notes:

[165] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Change in mTSS ≤ SDC (1.36).

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	950
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004 [166]
Method	Regression, Logistic
Parameter estimate	Difference in non-progression rate
Point estimate	5.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.6
upper limit	9.4

Notes:

[166] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 100 mg vs Placebo
Statistical analysis description:	
Change in mTSS ≤ SDC (1.36).	
Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	955
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.012 [167]
Method	Regression, Logistic
Parameter estimate	Difference in non-progression rate
Point estimate	4.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	8.8

Notes:

[167] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Secondary: Percentage of Participants With no Radiographic Progression From Baseline at Week 52

End point title	Percentage of Participants With no Radiographic Progression From Baseline at Week 52[168]

End point description:

Participant`s radiographs of bilateral hands, wrists and feet are taken and evaluated through central review using the mTSS method. No radiographic progression is defined by the change from baseline in mTSS and is reported for the following categories: Change in mTSS ≤ 0.5, Change in mTSS ≤ 0 and Change in mTSS ≤ smallest detectable change (SDC). Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Week 52

Notes:

[168] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	475	480	325	190
Units: percentage of participants				
number (confidence interval 95%)				
Change in mTSS ≤ 0.5 (N=417,411,273,180,178)	92.1 (89.4 to 94.8)	87.1 (83.7 to 90.5)	88.6 (84.7 to 92.6)	83.9 (78.2 to 89.5)
Change in mTSS ≤ 0 (N=417,411,273,180,178)	87.5 (84.2 to 90.8)	81.3 (77.4 to 85.2)	82.4 (77.7 to 87.1)	73.3 (66.6 to 80.1)
Change in mTSS ≤ SDC(1.83) (N=417,411,273,180,178)	95.0 (92.7 to 97.2)	91.5 (88.7 to 94.3)	94.1 (91.2 to 97.1)	90.0 (85.3 to 94.7)

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	191			
Units: percentage of participants				
number (confidence interval 95%)				
Change in mTSS ≤ 0.5 (N=417,411,273,180,178) Change in mTSS ≤ 0 (N=417,411,273,180,178) Change in mTSS ≤ SDC(1.83) (N=417,411,273,180,178)	83.7 (78.0 to 89.4) 77.0 (70.5 to 83.4) 87.6 (82.5 to 92.8)			

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo to Filgotinib 200 mg
Statistical analysis description: Change in mTSS ≤ 0.5	
Comparison groups	Filgotinib 200 mg v Placebo to Filgotinib 200 mg
Number of subjects included in analysis	665
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003 [169]
Method	Regression, Logistic
Parameter estimate	Difference in non-progression rate
Point estimate	8.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.8
upper limit	14.6

Notes:

[169] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 100 mg vs Placebo to Filgotinib 100 mg
Statistical analysis description: Change in mTSS ≤ 0.5	
Comparison groups	Filgotinib 100 mg v Placebo to Filgotinib 100 mg
Number of subjects included in analysis	671
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.26 [170]
Method	Regression, Logistic
Parameter estimate	Difference in non-progression rate
Point estimate	3.4

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.3
upper limit	10.1

Notes:

[170] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 200 mg vs Placebo to Filgotinib 200 mg
Statistical analysis description:	
Change in mTSS ≤ 0	
Comparison groups	Filgotinib 200 mg v Placebo to Filgotinib 200 mg
Number of subjects included in analysis	665
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [171]
Method	Regression, Logistic
Parameter estimate	Difference in non-progression rate
Point estimate	14.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.6
upper limit	21.8

Notes:

[171] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 100 mg vs Placebo to Filgotinib 100 mg
Statistical analysis description:	
Change in mTSS ≤ 0	
Comparison groups	Filgotinib 100 mg v Placebo to Filgotinib 100 mg
Number of subjects included in analysis	671
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.22 [172]
Method	Regression, Logistic
Parameter estimate	Difference in non-progression rate
Point estimate	4.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.3
upper limit	11.9

Notes:

[172] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 200 mg vs Placebo to Filgotinib 200 mg
Statistical analysis description:	
Change in mTSS ≤ SDC (1.36)	
Comparison groups	Filgotinib 200 mg v Placebo to Filgotinib 200 mg

Number of subjects included in analysis	665
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.027 [173]
Method	Regression, Logistic
Parameter estimate	Difference in non-progression rate
Point estimate	5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3
upper limit	10.2

Notes:

[173] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Statistical analysis title	Filgotinib 100 mg vs Placebo to Filgotinib 100 mg

Statistical analysis description:

Change in mTSS ≤ SDC (1.36)

Comparison groups	Filgotinib 100 mg v Placebo to Filgotinib 100 mg
Number of subjects included in analysis	671
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.12 [174]
Method	Regression, Logistic
Parameter estimate	Difference in non-progression rate
Point estimate	3.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.1
upper limit	9.8

Notes:

[174] - P-value was calculated from the logistic regression with treatment groups and stratification factors in the model.

Secondary: 36-Item Short Form Survey (SF-36) Physical Component Summary (PCS) Score at Weeks 4, 12, and 24

End point title	36-Item Short Form Survey (SF-36) Physical Component Summary (PCS) Score at Weeks 4, 12, and 24

End point description:

The SF-36 is a 36-item, self-reported, generic, comprehensive, and health-related quality of life questionnaire based on 8 health domains in 2 components: physical well-being (physical functioning, role-physical, bodily pain, general health perceptions), mental well-being (vitality, social functioning, role-emotional, and mental health). Each domain is scored by summing the individual items and transforming the scores into a 0 to 100 scale with highest possible score of 100. Higher scores indicate better health status or functioning. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 4 (N=471,475,321,465)	39.0 (± 8.22)	38.2 (± 8.35)	37.7 (± 8.07)	36.1 (± 7.40)
Week 12 (N=461,464,312,441)	42.7 (± 8.30)	42.1 (± 8.69)	41.3 (± 8.57)	38.8 (± 7.83)
Week 24 (N=426,427,285,376)	43.9 (± 8.49)	43.7 (± 8.64)	43.2 (± 8.95)	40.7 (± 8.10)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 PCS Score at Weeks 36 and 52

End point title	SF-36 PCS Score at Weeks 36 and 52[175]

End point description:

The SF-36 is a 36-item, self-reported, generic, comprehensive, and health-related quality of life questionnaire based on 8 health domains in 2 components: physical well-being (physical functioning, role-physical, bodily pain, general health perceptions), mental well-being (vitality, social functioning, role-emotional, and mental health). Each domain is scored by summing the individual items and transforming the scores into a 0 to 100 scale with highest possible score of 100. Higher scores indicate better health status or functioning. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 36 and 52

Notes:

[175] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	475	480	325	190
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 36 (N=413,417,276,181,188)	45.2 (± 8.28)	44.4 (± 8.54)	43.8 (± 8.84)	45.2 (± 7.99)
Week 52 (N=400,399,267,174,180)	45.6 (± 8.35)	45.1 (± 8.57)	45.2 (± 8.55)	45.1 (± 8.26)

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	191			
Units: score on a scale				
arithmetic mean (standard deviation)				

Week 36 (N=413,417,276,181,188)	43.2 (± 8.82)			
Week 52 (N=400,399,267,174,180)	44.1 (± 8.88)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in SF-36 PCS Score at Weeks 4, 12, and 24

End point title	Change From Baseline in SF-36 PCS Score at Weeks 4, 12, and 24

End point description:

The SF-36 is a 36-item, self-reported, generic, comprehensive, and health-related quality of life questionnaire based on 8 health domains in 2 components: physical well-being (physical functioning, role-physical, bodily pain, general health perceptions), mental well-being (vitality, social functioning, role-emotional, and mental health). Each domain is scored by summing the individual items and transforming the scores into a 0 to 100 scale with highest possible score of 100. Higher scores indicate better health status or functioning. Positive change in value indicates improvement and better quality of life. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	473	479	323	474
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	33.4 (± 7.17)	33.6 (± 7.75)	32.8 (± 7.74)	32.9 (± 7.11)
Change from BL at Week 4 (N=469,474,319,464)	5.6 (± 6.57)	4.6 (± 6.50)	5.0 (± 6.65)	3.1 (± 6.32)
Change from BL at Week 12 (N=459,463,310,440)	9.2 (± 8.10)	8.5 (± 7.72)	8.4 (± 7.89)	5.8 (± 7.10)
Change from BL at Week 24 (N=424,426,283,376)	10.4 (± 8.49)	10.3 (± 8.64)	10.4 (± 8.47)	7.7 (± 7.97)

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 4; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo

Number of subjects included in analysis	947
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [176]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.9
upper limit	3.4
Variability estimate	Standard error of the mean
Dispersion value	0.4

Notes:

[176] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 4; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	953
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [177]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	1
upper limit	2.5
Variability estimate	Standard error of the mean
Dispersion value	0.4

Notes:

[177] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 12; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo

Number of subjects included in analysis	947
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [178]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	3.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.8
upper limit	4.6
Variability estimate	Standard error of the mean
Dispersion value	0.47

Notes:

[178] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 12; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	953
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [179]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	3.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.2
upper limit	4
Variability estimate	Standard error of the mean
Dispersion value	0.46

Notes:

[179] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 24; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo

Number of subjects included in analysis	947
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [180]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	3.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.1
upper limit	4.1
Variability estimate	Standard error of the mean
Dispersion value	0.52

Notes:

[180] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 24; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	953
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [181]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	3.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	2
upper limit	4.1
Variability estimate	Standard error of the mean
Dispersion value	0.52

Notes:

[181] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Secondary: Change From Baseline in SF-36 PCS Score at Weeks 36 and 52

End point title	Change From Baseline in SF-36 PCS Score at Weeks 36 and

End point description:

The SF-36 is a 36-item, self-reported, generic, comprehensive, and health-related quality of life questionnaire based on 8 health domains in 2 components: physical well-being (physical functioning, role-physical, bodily pain, general health perceptions), mental well-being (vitality, social functioning, role-emotional, and mental health). Each domain is scored by summing the individual items and transforming the scores into a 0 to 100 scale with highest possible score of 100. Higher scores indicate better health status or functioning. Positive change in value indicates improvement and better quality of life. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 36 and 52

Notes:

[182] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	473	479	323	190
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	33.4 (± 7.17)	33.6 (± 7.75)	32.8 (± 7.74)	32.2 (± 6.96)
Change from BL at Week 36 (N=412,416,274,181,188)	11.6 (± 8.28)	11.0 (± 8.53)	11.1 (± 9.07)	12.9 (± 8.92)
Change from BL at Week 52 (N=399,398,265,174,180)	12.0 (± 8.73)	11.5 (± 8.74)	12.4 (± 9.21)	13.0 (± 9.58)

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	191			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	33.7 (± 6.96)			
Change from BL at Week 36 (N=412,416,274,181,188)	9.5 (± 8.13)			
Change from BL at Week 52 (N=399,398,265,174,180)	10.4 (± 8.05)			

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Mental Component Summary (MCS) Score at Weeks 4, 12, and 24

End point title	SF-36 Mental Component Summary (MCS) Score at Weeks 4, 12, and 24

End point description:

The SF-36 is a 36-item, self-reported, generic, comprehensive, and health-related quality of life questionnaire based on 8 health domains in 2 components: physical well-being (physical functioning, role-physical, bodily pain, general health perceptions), mental well-being (vitality, social functioning, role-emotional, and mental health). Each domain is scored by summing the individual items and transforming the scores into a 0 to 100 scale with highest possible score of 100. Higher scores indicate better health status or functioning. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 4 (N=471,475,321,465)	47.8 (± 9.90)	47.9 (± 9.63)	47.9 (± 10.04)	45.8 (± 10.35)
Week 12 (N=460,464,312,441)	49.3 (± 9.14)	49.9 (± 8.90)	48.9 (± 10.28)	47.7 (± 10.16)
Week 24 (N=426,427,285,376)	50.0 (± 8.82)	50.2 (± 8.93)	49.3 (± 10.26)	49.2 (± 9.90)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 MCS Score at Weeks 36 and 52

End point title	SF-36 MCS Score at Weeks 36 and 52[183]

End point description:

The SF-36 is a 36-item, self-reported, generic, comprehensive, and health-related quality of life questionnaire based on 8 health domains in 2 components: physical well-being (physical functioning, role-physical, bodily pain, general health perceptions), mental well-being (vitality, social functioning, role-emotional, and mental health). Each domain is scored by summing the individual items and transforming the scores into a 0 to 100 scale with highest possible score of 100. Higher scores indicate better health status or functioning. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 36 and 52

Notes:

[183] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	475	480	325	190
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 36 (N=413,417,276,181,188)	50.1 (± 8.96)	51.3 (± 8.88)	50.7 (± 9.67)	50.7 (± 9.04)
Week 52 (N=400,399,267,174,180)	50.6 (± 9.30)	51.5 (± 8.99)	50.8 (± 9.51)	50.8 (± 8.55)

End point values	Placebo to Filgotinib 100 mg			

Subject group type	Reporting group			
Number of subjects analysed	191			
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 36 (N=413,417,276,181,188)	50.3 (± 9.47)			
Week 52 (N=400,399,267,174,180)	50.1 (± 9.21)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in SF-36 MCS Score at Weeks 4, 12, and 24

End point title	Change From Baseline in SF-36 MCS Score at Weeks 4, 12, and 24

End point description:

The SF-36 is a 36-item, self-reported, generic, comprehensive, and health-related quality of life questionnaire based on 8 health domains in 2 components: physical well-being (physical functioning, role-physical, bodily pain, general health perceptions), mental well-being (vitality, social functioning, role-emotional, and mental health). Each domain is scored by summing the individual items and transforming the scores into a 0 to 100 scale with highest possible score of 100. Higher scores indicate better health status or functioning. Positive change in value indicates improvement and better quality of life. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	473	479	323	474
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	43.9 (± 10.44)	44.6 (± 10.44)	44.1 (± 10.44)	43.4 (± 11.01)
Change from BL at Week 4 (N=469,474,319,464)	3.9 (± 7.96)	3.4 (± 8.35)	3.7 (± 7.66)	2.3 (± 8.72)
Change from BL at Week 12 (N=458,463,310,440)	5.4 (± 9.45)	5.4 (± 8.97)	4.9 (± 9.69)	4.1 (± 9.50)
Change from BL at Week 24 (N=424,426,283,376)	6.1 (± 9.23)	5.7 (± 9.57)	5.3 (± 9.25)	5.6 (± 10.28)

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 4; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo

Number of subjects included in analysis	947
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [184]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	1.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	2.8
Variability estimate	Standard error of the mean
Dispersion value	0.48

Notes:

[184] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 4; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	953
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002 [185]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	2.5
Variability estimate	Standard error of the mean
Dispersion value	0.48

Notes:

[185] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 12; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo

Number of subjects included in analysis	947
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.006 [186]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.4
upper limit	2.5
Variability estimate	Standard error of the mean
Dispersion value	0.52

Notes:

[186] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 12; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	953
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001 [187]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	2.7
Variability estimate	Standard error of the mean
Dispersion value	0.52

Notes:

[187] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 24; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo

Number of subjects included in analysis	947
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.086 [188]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	2
Variability estimate	Standard error of the mean
Dispersion value	0.55

Notes:

[188] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 24; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	953
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.12 [189]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	1.9
Variability estimate	Standard error of the mean
Dispersion value	0.55

Notes:

[189] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Secondary: Change From Baseline in SF-36 MCS Score at Weeks 36 and 52

End point title	Change From Baseline in SF-36 MCS Score at Weeks 36 and

End point description:

The SF-36 is a 36-item, self-reported, generic, comprehensive, and health-related quality of life questionnaire based on 8 health domains in 2 components: physical well-being (physical functioning, role-physical, bodily pain, general health perceptions), mental well-being (vitality, social functioning, role-emotional, and mental health). Each domain is scored by summing the individual items and transforming the scores into a 0 to 100 scale with highest possible score of 100. Higher scores indicate better health status or functioning. Positive change in value indicates improvement and better quality of life. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 36 and 52

Notes:

[190] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	473	479	323	190
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	43.9 (± 10.44)	44.6 (± 10.44)	44.1 (± 10.44)	43.9 (± 11.06)
Change from BL at Week 36 (N=412,416,274,181,188)	6.2 (± 10.03)	6.6 (± 10.46)	6.6 (± 9.40)	6.9 (± 12.05)
Change from BL at Week 52 (N=399,398,265,174,180)	6.7 (± 10.53)	6.9 (± 10.61)	6.7 (± 9.90)	7.2 (± 11.31)

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	191			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	43.4 (± 11.03)			
Change from BL at Week 36 (N=412,416,274,181,188)	6.8 (± 9.84)			
Change from BL at Week 52 (N=399,398,265,174,180)	6.5 (± 10.35)			

Statistical analyses

No statistical analyses for this end point

Secondary: Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue Score at Weeks 4, 12, and 24

End point title	Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue Score at Weeks 4, 12, and 24

End point description:

FACIT-Fatigue scale is a brief, 13-item, symptom-specific questionnaire that specifically assesses the self-reported severity of fatigue and its impact upon daily activities and functioning in the past 7 days. The FACIT-Fatigue uses 0 (not at all) to 4 (very much) numeric rating scales for a total possible score of 0 to 52. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 4 (N=468,471,319,457)	33.9 (± 10.32)	33.3 (± 9.76)	32.9 (± 10.11)	30.9 (± 10.43)
Week 12 (N=455,457,307,437)	36.8 (± 9.64)	36.7 (± 9.67)	36.1 (± 9.68)	33.9 (± 10.32)
Week 24 (N=416,419,277,372)	38.5 (± 9.17)	38.5 (± 8.74)	37.6 (± 9.82)	35.8 (± 9.94)

Statistical analyses

No statistical analyses for this end point

Secondary: FACIT-Fatigue Score at Weeks 36 and 52

End point title	FACIT-Fatigue Score at Weeks 36 and 52[191]

End point description:

FACIT-Fatigue scale is a brief, 13-item, symptom-specific questionnaire that specifically assesses the self-reported severity of fatigue and its impact upon daily activities and functioning in the past 7 days. The FACIT-Fatigue uses 0 (not at all) to 4 (very much) numeric rating scales for a total possible score of 0 to 52. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 36 and 52

Notes:

[191] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	475	480	325	190
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 36 (N=395,405,270,177,184)	38.9 (± 8.84)	39.5 (± 8.73)	38.6 (± 9.45)	39.6 (± 8.78)
Week 52 (N=386,379,257,167,174)	39.8 (± 8.64)	39.8 (± 8.54)	38.9 (± 9.87)	39.4 (± 8.78)

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	191			
Units: score on a scale				

arithmetic mean (standard deviation)				
Week 36 (N=395,405,270,177,184)	37.4 (± 9.88)			
Week 52 (N=386,379,257,167,174)	38.0 (± 9.77)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in FACIT-Fatigue Score at Weeks 4, 12, and 24

End point title	Change From Baseline in FACIT-Fatigue Score at Weeks 4, 12, and 24

End point description:

FACIT-Fatigue scale is a brief, 13-item, symptom-specific questionnaire that specifically assesses the self-reported severity of fatigue and its impact upon daily activities and functioning in the past 7 days. The FACIT-Fatigue uses 0 (not at all) to 4 (very much) numeric rating scales for a total possible score of 0 to 52. Positive change in value indicates improvement (no or less severity of fatigue). Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	472	477	319	469
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	27.6 (± 10.68)	27.8 (± 10.60)	27.2 (± 10.20)	26.9 (± 10.34)
Change from BL at Week 4 (N=465,470,316,455)	6.3 (± 8.59)	5.7 (± 8.77)	5.7 (± 8.47)	3.8 (± 8.76)
Change from BL at Week 12 (N=452,455,304,432)	9.2 (± 9.82)	9.1 (± 10.15)	8.8 (± 9.19)	6.8 (± 9.89)
Change from BL at Week 24 (N=413,417,273,369)	10.5 (± 10.63)	10.8 (± 10.77)	10.3 (± 9.67)	8.4 (± 10.48)

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 4; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo

Number of subjects included in analysis	941
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [192]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	2.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.8
upper limit	3.8
Variability estimate	Standard error of the mean
Dispersion value	0.51

Notes:

[192] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 4; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [193]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	2.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.2
upper limit	3.2
Variability estimate	Standard error of the mean
Dispersion value	0.51

Notes:

[193] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 12; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo

Number of subjects included in analysis	941
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [194]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	2.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.7
upper limit	3.9
Variability estimate	Standard error of the mean
Dispersion value	0.56

Notes:

[194] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 12; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [195]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	2.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.5
upper limit	3.7
Variability estimate	Standard error of the mean
Dispersion value	0.55

Notes:

[195] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 24; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo

Number of subjects included in analysis	941
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [196]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	2.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.5
upper limit	3.8
Variability estimate	Standard error of the mean
Dispersion value	0.59

Notes:

[196] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 24; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [197]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	2.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.6
upper limit	3.9
Variability estimate	Standard error of the mean
Dispersion value	0.59

Notes:

[197] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Secondary: Change From Baseline in FACIT-Fatigue Score at Weeks 36 and 52

End point title	Change From Baseline in FACIT-Fatigue Score at Weeks 36 and 52[198]

End point description:

FACIT-Fatigue scale is a brief, 13-item, symptom-specific questionnaire that specifically assesses the self-reported severity of fatigue and its impact upon daily activities and functioning in the past 7 days. The FACIT-Fatigue uses 0 (not at all) to 4 (very much) numeric rating scales for a total possible score of 0 to 52. Positive change in value indicates improvement (no or less severity of fatigue). Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 36 and 52

Notes:

[198] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	472	477	319	189
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	27.6 (± 10.68)	27.8 (± 10.60)	27.2 (± 10.20)	26.8 (± 10.13)
Change from BL at Week 36 (N=393,403,268,176,182)	11.0 (± 10.22)	11.7 (± 10.90)	11.3 (± 10.18)	12.8 (± 10.76)
Change from BL at Week 52 (N=384,376,254,166,172)	11.9 (± 10.21)	12.2 (± 10.88)	11.7 (± 10.79)	12.9 (± 11.55)

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	189			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	27.9 (± 10.56)			
Change from BL at Week 36 (N=393,403,268,176,182)	9.5 (± 10.25)			
Change from BL at Week 52 (N=384,376,254,166,172)	10.1 (± 10.06)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants by European Quality of Life 5 Dimensions (EQ-5D) Health Profile Categories at Weeks 4, 12, and 24

End point title	Number of Participants by European Quality of Life 5 Dimensions (EQ-5D) Health Profile Categories at Weeks 4, 12, and 24

End point description:

The EQ-5D-5 levels (EQ-5D-5L) is a standardized measure of health status of the participant at the visit (same day) that provides a simple, generic measure of health for clinical and economic appraisal. EQ-5D-5L consists of 2 components: a descriptive system of the participant`s health and a rating of his or her current health state on a 0-100 VAS. The descriptive system comprises the following 5 dimensions: mobility, self-care, usual activities (Usu Act), pain/discomfort (Pai/Disc), and anxiety/depression (Anx/Dep). Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems, and extreme problems. Rating gets recorded on a vertical VAS in which the endpoints are labelled best imaginable health state is 100 (on the top) and worst imaginable health state is 0 (on the bottom). Higher scores of EQ VAS indicate better health. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary
End point timeframe: Weeks (Wk) 4, 12, and 24	

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: participants				
Mobility: Wk4: No Problems (N=468,471,319,457)	130	129	84	100
Mobility: Wk4: Slight Problems (N=468,471,319,457)	176	173	107	149
Mobility:Wk4:Moderate Problems (N=468,471,319,457)	113	122	96	150
Mobility: Wk4: Severe Problems (N=468,471,319,457)	44	46	31	56
Mobility: Wk4:Extreme Problems (N=468,471,319,457)	5	1	1	2
Mobility: Wk12: No Problems (N=455,457,307,437)	178	177	116	132
Mobility: Wk12:Slight Problems (N=455,457,307,437)	153	151	103	154
Mobility:Wk12:Moderate Problems(N=455,457,307,437)	99	97	67	112
Mobility:Wk12:Severe Problems (N=455,457,307,437)	21	31	21	38
Mobility:Wk12:Extreme Problems (N=455,457,307,437)	4	1	0	1
Mobility: Wk24: No Problems (N=416,419,277,372)	182	189	117	131
Mobility: Wk24:Slight Problems (N=416,419,277,372)	142	136	90	126
Mobility:Wk24:Moderate Problems(N=416,419,277,372)	68	75	57	89
Mobility:Wk24:Severe Problems (N=416,419,277,372)	19	17	12	24
Mobility:Wk24:Extreme Problems (N=416,419,277,372)	5	2	1	2
Selfcare: Wk4: No Problems (N=468,471,319,457)	177	163	111	138
Selfcare: Wk4: Slight Problems (N=468,471,319,457)	180	183	120	164
Selfcare:Wk4:Moderate Problems (N=468,471,319,457)	86	103	74	124
Selfcare: Wk4: Severe Problems (N=468,471,319,457)	23	20	13	25
Selfcare: Wk4:Extreme Problems (N=468,471,319,457)	2	2	1	6
Selfcare: Wk12: No Problems (N=455,457,307,437)	243	222	147	165
Selfcare: Wk12:Slight Problems (N=455,457,307,437)	149	150	102	159
Selfcare:Wk12:Moderate Problems(N=455,457,307,437)	53	74	49	88
Selfcare: Wk12:Severe Problems (N=455,457,307,437)	8	9	9	21

Selfcare:Wk12:Extreme Problems (N=455,457,307,437)	2	2	0	4
Selfcare: Wk24: No Problems (N=416,419,277,372)	255	249	157	164
Selfcare: Wk24:Slight Problems (N=416,419,277,372)	109	121	75	140
Selfcare:Wk24:Moderate Problems(N=416,419,277,372)	45	39	36	54
Selfcare: Wk24:Severe Problems (N=416,419,277,372)	4	8	7	14
Selfcare:Wk24:Extreme Problems (N=416,419,277,372)	3	2	2	0
Usu Act: Wk4: No Problems (N=468,471,319,457)	110	102	69	65
Usu Act: Wk4: Slight Problems (N=468,471,319,457)	203	193	133	195
Usu Act: Wk4:Moderate Problems (N=468,471,319,457)	111	142	90	143
Usu Act: Wk4: Severe Problems (N=468,471,319,457)	38	33	25	52
Usu Act: Wk4: Extreme Problems (N=468,471,319,457)	6	1	2	2
Usu Act: Wk12: No Problems (N=455,457,307,437)	157	149	97	103
Usu Act: Wk12: Slight Problems (N=455,457,307,437)	200	191	130	184
Usu Act:Wk12:Moderate Problems (N=455,457,307,437)	80	90	67	116
Usu Act: Wk12: Severe Problems (N=455,457,307,437)	16	23	13	32
Usu Act: Wk12:Extreme Problems (N=455,457,307,437)	2	4	0	2
Usu Act: Wk24: No Problems (N=416,419,277,372)	184	175	109	107
Usu Act: Wk24: Slight Problems (N=416,419,277,372)	164	171	105	163
Usu Act:Wk24:Moderate Problems (N=416,419,277,372)	54	63	52	86
Usu Act: Wk24: Severe Problems (N=416,419,277,372)	13	9	9	15
Usu Act: Wk24:Extreme Problems (N=416,419,277,372)	1	1	2	1
Pain/Disc: Wk4: No Problems (N=468,471,319,457)	42	38	26	14
Pain/Disc: Wk4:Slight Problems (N=468,471,319,457)	215	185	118	157
Pain/Disc:Wk4:Moderate Problems(N=468,471,319,457)	154	204	127	198
Pain/Disc: Wk4:Severe Problems (N=468,471,319,457)	51	41	47	80
Pain/Disc:Wk4:Extreme Problems (N=468,471,319,457)	6	3	1	8
Pain/Disc: Wk12: No Problems (N=455,457,307,437)	58	71	34	29
Pain/Disc:Wk12:Slight Problems (N=455,457,307,437)	260	217	145	200
Pain/Disc:Wk12:Moderate Problem(N=455,457,307,437)	117	150	106	154
Pain/Disc:Wk12:Severe Problems (N=455,457,307,437)	20	17	22	51
Pain/Disc:Wk12:Extreme Problems(N=455,457,307,437)	0	2	0	3

Pain/Disc: Wk24: No Problems (N=416,419,277,372)	82	78	56	39
Pain/Disc:Wk24:Slight Problems (N=416,419,277,372)	226	224	127	196
Pain/Disc:Wk24:Moderate Problem(N=416,419,277,372)	86	103	82	110
Pain/Disc:Wk24:Severe Problems (N=416,419,277,372)	21	13	12	27
Pain/Disc:Wk24:Extreme Problems(N=416,419,277,372)	1	1	0	0
Anx/Dep: Wk4: No Problems (N=468,471,319,457)	211	224	151	196
Anx/Dep: Wk4: Slight Problems (N=468,471,319,457)	163	158	111	149
Anx/Dep: Wk4:Moderate Problems (N=468,471,319,457)	72	81	44	86
Anx/Dep: Wk4: Severe Problems (N=468,471,319,457)	21	8	13	25
Anx/Dep: Wk4: Extreme Problems (N=468,471,319,457)	1	0	0	1
Anx/Dep: Wk12: No Problems (N=455,457,307,437)	235	246	152	216
Anx/Dep: Wk12: Slight Problems (N=455,457,307,437)	154	143	106	137
Anx/Dep:Wk12:Moderate Problems (N=455,457,307,437)	54	63	44	62
Anx/Dep: Wk12: Severe Problems (N=455,457,307,437)	12	5	4	19
Anx/Dep: Wk12:Extreme Problems (N=455,457,307,437)	0	0	1	3
Anx/Dep: Wk24: No Problems (N=416,419,277,372)	230	256	160	204
Anx/Dep: Wk24: Slight Problems (N=416,419,277,372)	136	119	75	120
Anx/Dep:Wk24:Moderate Problems (N=416,419,277,372)	42	37	33	39
Anx/Dep: Wk24: Severe Problems (N=416,419,277,372)	8	5	6	8
Anx/Dep: Wk24:Extreme Problems (N=416,419,277,372)	0	2	3	1

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants by EQ-5D Health Profile Categories at Weeks 36 and 52

End point title	Number of Participants by EQ-5D Health Profile Categories at Weeks 36 and 52[199]

End point description:

The EQ-5D-5 levels (EQ-5D-5L) is a standardized measure of health status of the participant at the visit (same day) that provides a simple, generic measure of health for clinical and economic appraisal. EQ-5D-5L consists of 2 components: a descriptive system of the participant`s health and a rating of his or her current health state on a 0-100 VAS. The descriptive system comprises the following 5 dimensions: mobility, self-care, usual activities (Usu Act), pain/discomfort (Pai/Disc), and anxiety/depression (Anx/Dep). Each dimension has 5 levels: no problems, slight problems (Sli), moderate (Mod) problems, severe (Sev) problems, and extreme (Extre) problems. Rating gets recorded on a vertical VAS in which the endpoints are labelled best imaginable health state is 100 (on the top) and worst imaginable health

state is 0 (on the bottom). Higher scores of EQ VAS indicate better health. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks (Wk) 36 and 52

Notes:

[199] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	475	480	325	190
Units: participants				
Mobility:Wk36:No Problems(N=395,405,270,177,184)	202	189	122	86
Mobility:Wk36:Sli Problems(N=395,405,270,177,184)	121	136	82	58
Mobility:Wk36:Mod Problems(N=395,405,270,177,184)	58	64	48	26
Mobility:Wk36:Sev Problems(N=395,405,270,177,184)	13	15	16	7
Mobility:Wk36:Extre Problem(N=395,405,270,177,184)	1	1	2	0
Mobility:Wk52:No Problems(N=386,379,257,167,174)	197	187	130	82
Mobility:Wk52:Sli Problems(N=386,379,257,167,174)	117	115	79	47
Mobility:Wk52:Mod Problems(N=386,379,257,167,174)	57	58	38	34
Mobility:Wk52:Sev Problems(N=386,379,257,167,174)	11	19	10	3
Mobility:Wk52:Extre Problem(N=386,379,257,167,174)	4	0	0	1
Selfcare:Wk36:No Problems (N=395,405,270,177,184)	254	249	164	114
Selfcare:Wk36:Sli Problems (N=395,405,270,177,184)	104	113	67	45
Selfcare:Wk36:Mod Problems (N=395,405,270,177,184)	31	36	30	17
Selfcare:Wk36:Sev Problems (N=395,405,270,177,184)	5	5	6	1
Selfcare:Wk36:Extre Problem(N=395,405,270,177,184)	1	2	3	0
Selfcare:Wk52:No Problems (N=386,379,257,167,174)	251	245	159	105
Selfcare:Wk52:Sli Problems (N=386,379,257,167,174)	98	102	72	44
Selfcare:Wk52:Mod Problems (N=386,379,257,167,174)	30	25	24	16
Selfcare:Wk52:Sev Problems (N=386,379,257,167,174)	5	6	2	1
Selfcare:Wk52:Extre Problem(N=386,379,257,167,174)	2	1	0	1
Usu Act:Wk36:No Problems (N=395,405,270,177,184)	176	172	125	82

Usu Act:Wk36:Sli Problems (N=395,405,270,177,184)	160	171	90	71
Usu Act:Wk36:Mod Problems (N=395,405,270,177,184)	50	52	46	21
Usu Act:Wk36:Sev Problems (N=395,405,270,177,184)	7	9	7	3
Usu Act:Wk36:Extre Problems(N=395,405,270,177,184)	2	1	2	0
Usu Act:Wk52:No Problems (N=386,379,257,167,174)	183	177	121	75
Usu Act:Wk52:Sli Problems (N=386,379,257,167,174)	151	147	87	64
Usu Act:Wk52:Mod Problems (N=386,379,257,167,174)	40	41	42	22
Usu Act:Wk52:Sev Problems (N=386,379,257,167,174)	8	12	6	5
Usu Act:Wk52:Extre Problems(N=386,379,257,167,174)	4	2	1	1
Pain/Disc:Wk36:No Problems (N=395,405,270,177,184)	95	84	55	47
Pain/Disc:Wk36:Sli Problems(N=395,405,270,177,184)	206	220	127	94
Pain/Disc:Wk36:Mod Problems(N=395,405,270,177,184)	81	89	79	34
Pain/Disc:Wk36:Sev Problems(N=395,405,270,177,184)	13	11	8	2
Pain/Disc:Wk36:ExtreProblem(N=395,405,270,177,184)	0	1	1	0
Pain/Disc:Wk52:No Problems (N=386,379,257,167,174)	90	88	57	45
Pain/Disc:Wk52:Sli Problems(N=386,379,257,167,174)	209	210	130	80
Pain/Disc:Wk52:Mod Problems(N=386,379,257,167,174)	77	72	61	38
Pain/Disc:Wk52:Sev Problems(N=386,379,257,167,174)	10	9	9	3
Pain/Disc:Wk52:ExtreProblem(N=386,379,257,167,174)	0	0	0	1
Anx/Dep:Wk36:No Problems (N=395,405,270,177,184)	230	259	162	115
Anx/Dep:Wk36:Sli Problems (N=395,405,270,177,184)	123	113	79	44
Anx/Dep:Wk36:Mod Problems (N=395,405,270,177,184)	37	27	19	18
Anx/Dep:Wk36:Sev Problems (N=395,405,270,177,184)	4	5	7	0
Anx/Dep:Wk36:Extre Problems(N=395,405,270,177,184)	1	1	3	0
Anx/Dep:Wk52:No Problems (N=386,379,257,167,174)	227	254	169	111
Anx/Dep:Wk52:Sli Problems (N=386,379,257,167,174)	106	86	61	38
Anx/Dep:Wk52:Mod Problems (N=386,379,257,167,174)	48	34	23	17
Anx/Dep:Wk52:Sev Problems (N=386,379,257,167,174)	5	5	4	0
Anx/Dep:Wk52:Extre Problems(N=386,379,257,167,174)	0	0	0	1

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	191			
Units: participants				
Mobility:Wk36:No Problems(N=395,405,270,177,184)	78			
Mobility:Wk36:Sli Problems(N=395,405,270,177,184)	67			
Mobility:Wk36:Mod Problems(N=395,405,270,177,184)	28			
Mobility:Wk36:Sev Problems(N=395,405,270,177,184)	11			
Mobility:Wk36:Extre Problem(N=395,405,270,177,184)	0			
Mobility:Wk52:No Problems(N=386,379,257,167,174)	77			
Mobility:Wk52:Sli Problems(N=386,379,257,167,174)	61			
Mobility:Wk52:Mod Problems(N=386,379,257,167,174)	27			
Mobility:Wk52:Sev Problems(N=386,379,257,167,174)	8			
Mobility:Wk52:Extre Problem(N=386,379,257,167,174)	1			
Selfcare:Wk36:No Problems (N=395,405,270,177,184)	108			
Selfcare:Wk36:Sli Problems (N=395,405,270,177,184)	46			
Selfcare:Wk36:Mod Problems (N=395,405,270,177,184)	25			
Selfcare:Wk36:Sev Problems (N=395,405,270,177,184)	5			
Selfcare:Wk36:Extre Problem(N=395,405,270,177,184)	0			
Selfcare:Wk52:No Problems (N=386,379,257,167,174)	101			
Selfcare:Wk52:Sli Problems (N=386,379,257,167,174)	48			
Selfcare:Wk52:Mod Problems (N=386,379,257,167,174)	18			
Selfcare:Wk52:Sev Problems (N=386,379,257,167,174)	6			
Selfcare:Wk52:Extre Problem(N=386,379,257,167,174)	1			
Usu Act:Wk36:No Problems (N=395,405,270,177,184)	72			
Usu Act:Wk36:Sli Problems (N=395,405,270,177,184)	70			
Usu Act:Wk36:Mod Problems (N=395,405,270,177,184)	36			
Usu Act:Wk36:Sev Problems (N=395,405,270,177,184)	5			
Usu Act:Wk36:Extre Problems(N=395,405,270,177,184)	1			
Usu Act:Wk52:No Problems (N=386,379,257,167,174)	71			
Usu Act:Wk52:Sli Problems (N=386,379,257,167,174)	72			
Usu Act:Wk52:Mod Problems (N=386,379,257,167,174)	19			

Usu Act:Wk52:Sev Problems (N=386,379,257,167,174)	12			
Usu Act:Wk52:Extre Problems(N=386,379,257,167,174)	0			
Pain/Disc:Wk36:No Problems (N=395,405,270,177,184)	35			
Pain/Disc:Wk36:Sli Problems(N=395,405,270,177,184)	97			
Pain/Disc:Wk36:Mod Problems(N=395,405,270,177,184)	45			
Pain/Disc:Wk36:Sev Problems(N=395,405,270,177,184)	7			
Pain/Disc:Wk36:ExtreProblem(N=395,405,270,177,184)	0			
Pain/Disc:Wk52:No Problems (N=386,379,257,167,174)	44			
Pain/Disc:Wk52:Sli Problems(N=386,379,257,167,174)	93			
Pain/Disc:Wk52:Mod Problems(N=386,379,257,167,174)	31			
Pain/Disc:Wk52:Sev Problems(N=386,379,257,167,174)	6			
Pain/Disc:Wk52:ExtreProblem(N=386,379,257,167,174)	0			
Anx/Dep:Wk36:No Problems (N=395,405,270,177,184)	112			
Anx/Dep:Wk36:Sli Problems (N=395,405,270,177,184)	51			
Anx/Dep:Wk36:Mod Problems (N=395,405,270,177,184)	16			
Anx/Dep:Wk36:Sev Problems (N=395,405,270,177,184)	5			
Anx/Dep:Wk36:Extre Problems(N=395,405,270,177,184)	0			
Anx/Dep:Wk52:No Problems (N=386,379,257,167,174)	110			
Anx/Dep:Wk52:Sli Problems (N=386,379,257,167,174)	41			
Anx/Dep:Wk52:Mod Problems (N=386,379,257,167,174)	19			
Anx/Dep:Wk52:Sev Problems (N=386,379,257,167,174)	4			
Anx/Dep:Wk52:Extre Problems(N=386,379,257,167,174)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: EQ-5D Current Health VAS at Weeks 4, 12, and 24

End point title	EQ-5D Current Health VAS at Weeks 4, 12, and 24

End point description:

EQ-5D-5L is a standardized measure of health status of the participant at the visit (same day) that provides a simple, generic measure of health for clinical and economic appraisal. Participant rates their current health state on a 0-100 VAS. It gets recorded on a vertical VAS in which the endpoints are labeled best imaginable health state is 100 (on the top) and worst imaginable health state is 0 (on the bottom). Higher scores of EQ VAS indicate better health. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary
End point timeframe: Weeks 4, 12, and 24	

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 4 (N=468,471,319,457)	59 (± 20.5)	59 (± 19.9)	60 (± 20.4)	56 (± 19.5)
Week 12 (N=455,457,307,437)	66 (± 20.3)	66 (± 20.3)	65 (± 19.6)	59 (± 20.7)
Week 24 (N=416,419,277,372)	67 (± 23.1)	69 (± 21.6)	68 (± 22.2)	64 (± 21.4)

Statistical analyses

No statistical analyses for this end point

Secondary: EQ-5D Current Health VAS at Weeks 36 and 52

End point title	EQ-5D Current Health VAS at Weeks 36 and 52[200]

End point description:

EQ-5D-5L is a standardized measure of health status of the participant at the visit (same day) that provides a simple, generic measure of health for clinical and economic appraisal. Participant rates their current health state on a 0-100 VAS. It gets recorded on a vertical VAS in which the endpoints are labeled best imaginable health state is 100 (on the top) and worst imaginable health state is 0 (on the bottom). Higher scores of EQ VAS indicate better health. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary
End point timeframe: Weeks 36 and 52	

Notes:

[200] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	475	480	325	190
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 36 (N=395,405,270,177,184)	69 (± 22.7)	72 (± 21.2)	67 (± 24.3)	73 (± 19.9)
Week 52 (N=386,379,257,167,174)	72 (± 21.3)	73 (± 21.0)	71 (± 22.5)	73 (± 20.6)

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	191			
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 36 (N=395,405,270,177,184)	71 (± 21.1)			
Week 52 (N=386,379,257,167,174)	70 (± 22.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in EQ-5D Current Health VAS at Weeks 4, 12, and 24

End point title	Change From Baseline in EQ-5D Current Health VAS at Weeks 4, 12, and 24

End point description:

The EQ-5D-5L is a standardized measure of health status of the participant at the visit (same day) that provides a simple, generic measure of health for clinical and economic appraisal. Participant rates their current health state on a 0-100 VAS. It gets recorded on a vertical VAS in which the endpoints are labeled best imaginable health state is 100 (on the top) and worst imaginable health state is 0 (on the bottom). Higher scores of EQ VAS indicate better health. Positive change indicates improvement (better health). Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	472	477	319	469
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	48 (± 22.5)	49 (± 22.8)	47 (± 21.8)	46 (± 21.8)
Change from BL at Week 4 (N=465,470,316,455)	11 (± 24.4)	10 (± 25.2)	13 (± 24.4)	10 (± 25.1)
Change from BL at Week 12 (N=452,455,304,432)	18 (± 26.3)	17 (± 27.4)	17 (± 27.1)	13 (± 26.5)
Change from BL at Week 24 (N=413,417,273,369)	19 (± 30.5)	21 (± 28.9)	21 (± 28.8)	18 (± 29.3)

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 4; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not

imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	941
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.049 [201]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	5
Variability estimate	Standard error of the mean
Dispersion value	1.2

Notes:

[201] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 4; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.069 [202]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	5
Variability estimate	Standard error of the mean
Dispersion value	1.2

Notes:

[202] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 12; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo

Number of subjects included in analysis	941
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [203]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	7
Confidence interval	
level	95 %
sides	2-sided
lower limit	4
upper limit	9
Variability estimate	Standard error of the mean
Dispersion value	1.3

Notes:

[203] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 12; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [204]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	6
Confidence interval	
level	95 %
sides	2-sided
lower limit	4
upper limit	9
Variability estimate	Standard error of the mean
Dispersion value	1.3

Notes:

[204] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Week 24; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 200 mg v Placebo

Number of subjects included in analysis	941
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.06 [205]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	6
Variability estimate	Standard error of the mean
Dispersion value	1.5

Notes:

[205] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Statistical analysis title	Filgotinib 100 mg vs Placebo

Statistical analysis description:

Week 24; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	946
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003 [206]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2
upper limit	8
Variability estimate	Standard error of the mean
Dispersion value	1.5

Notes:

[206] - MMRM model included treatment, visit, treatment by visit, stratification factors, and baseline value as fixed effects, and participants being the random effect.

Secondary: Change From Baseline in EQ-5D Current Health VAS at Weeks 36 and 52

End point title	Change From Baseline in EQ-5D Current Health VAS at Weeks 36 and 52[207]

End point description:

The EQ-5D-5L is a standardized measure of health status of the participant at the visit (same day) that provides a simple, generic measure of health for clinical and economic appraisal. Participant rates their current health state on a 0-100 VAS. It gets recorded on a vertical VAS in which the endpoints are labeled best imaginable health state is 100 (on the top) and worst imaginable health state is 0 (on the bottom). Higher scores of EQ VAS indicate better health. Positive change indicates improvement (better health). Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 36, and 52

Notes:

[207] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	472	477	319	189
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	48 (± 22.5)	49 (± 22.8)	47 (± 21.8)	45 (± 21.6)
Change from BL at Week 36 (N=393,403,268,176,182)	21 (± 30.6)	23 (± 28.5)	20 (± 30.9)	28 (± 28.2)
Change from BL at Week 52 (N=384,376,254,166,172)	25 (± 29.3)	24 (± 28.5)	24 (± 29.2)	29 (± 28.6)

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	189			
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (BL)	47 (± 21.1)			
Change from BL at Week 36 (N=393,403,268,176,182)	24 (± 26.0)			
Change from BL at Week 52 (N=384,376,254,166,172)	23 (± 29.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Work Productivity and Activity Impairment-Rheumatoid Arthritis (WPAI-RA): Mean Percentage of Work Time Missed (Absenteeism) at Weeks 4, 12, and 24

End point title	Work Productivity and Activity Impairment-Rheumatoid Arthritis (WPAI-RA): Mean Percentage of Work Time Missed (Absenteeism) at Weeks 4, 12, and 24

End point description:

The WPAI is a questionnaire that measures impairments in work activities in participants with RA which consists of 6 questions: Q1-currently employed; Q2-work time missed due to RA; Q3-work time missed due to other reasons; Q4-hours actually worked; Q5-degree RA affected productivity while working (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant from working); Q6-degree RA affected productivity in regular unpaid activities (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant`s daily activities). Outcomes are expressed as impairment percentages: Absenteeism (work time missed) due to RA: 100×{Q2/(Q2+Q4)}. Higher numbers indicate greater impairment and less productivity. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: percentage of work time missed				
arithmetic mean (standard deviation)				
Week 4 (N=191,185,112,161)	8.5 (± 21.27)	6.6 (± 16.47)	9.2 (± 21.99)	9.4 (± 21.41)
Week 12 (N=189,177,111,153)	6.6 (± 17.06)	5.4 (± 14.56)	7.1 (± 18.46)	9.5 (± 22.66)
Week 24 (N=178,168,112,132)	4.4 (± 13.54)	3.6 (± 10.24)	7.2 (± 17.72)	10.5 (± 21.86)

Statistical analyses

No statistical analyses for this end point

Secondary: WPAI-RA: Mean Percentage of Work Time Missed (Absenteeism) at Weeks 36 and 52

End point title	WPAI-RA: Mean Percentage of Work Time Missed (Absenteeism) at Weeks 36 and 52[208]

End point description:

The WPAI is a questionnaire that measures impairments in work activities in participants with RA which consists of 6 questions: Q1-currently employed; Q2-work time missed due to RA; Q3-work time missed due to other reasons; Q4-hours actually worked; Q5-degree RA affected productivity while working (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant from working); Q6-degree RA affected productivity in regular unpaid activities (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant`s daily activities). Outcomes are expressed as impairment percentages: Absenteeism (work time missed) due to RA: 100×{Q2/(Q2+Q4)}. Higher numbers indicate greater impairment and less productivity. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 36 and 52

Notes:

[208] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	475	480	325	190
Units: percentage of work time missed				
arithmetic mean (standard deviation)				
Week 36 (N=178,169,106,72,63)	5.5 (± 16.17)	7.7 (± 19.46)	7.0 (± 19.65)	6.8 (± 19.79)
Week 52 (N=180,156,99,66,55)	4.8 (± 14.39)	5.4 (± 15.10)	7.4 (± 20.12)	5.5 (± 13.24)

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	191			
Units: percentage of work time missed				
arithmetic mean (standard deviation)				
Week 36 (N=178,169,106,72,63)	8.4 (± 19.97)			
Week 52 (N=180,156,99,66,55)	5.8 (± 14.29)			

Statistical analyses

No statistical analyses for this end point

Secondary: WPAI-RA: Mean Percentage of Impairment While Working Due to RA (Presenteeism) at Weeks 4, 12, and 24

End point title	WPAI-RA: Mean Percentage of Impairment While Working Due to RA (Presenteeism) at Weeks 4, 12, and 24

End point description:

The WPAI is a questionnaire that measures impairments in work activities in participants with RA which consists of 6 questions: Q1-currently employed; Q2-work time missed due to RA; Q3-work time missed due to other reasons; Q4-hours actually worked; Q5-degree RA affected productivity while working (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant from working); Q6-degree RA affected productivity in regular unpaid activities (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant`s daily activities). Outcomes are expressed as impairment percentages: Presenteeism (impairment while working) due to RA: 100×{Q5/10}. Higher numbers indicate greater impairment and less productivity. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: percentage of impairment while working				
arithmetic mean (standard deviation)				
Week 4 (N=185,182,108,156)	34.3 (± 22.69)	36.9 (± 24.01)	35.6 (± 22.39)	42.5 (± 23.54)
Week 12 (N=187,176,109,147)	26.3 (± 21.07)	26.9 (± 22.57)	27.6 (± 21.51)	34.0 (± 21.98)
Week 24 (N=177,168,110,128)	22.0 (± 21.28)	21.0 (± 20.74)	25.7 (± 21.99)	30.9 (± 23.11)

Statistical analyses

No statistical analyses for this end point

Secondary: WPAI-RA: Mean Percentage of Impairment While Working Due to RA (Presenteeism) at Weeks 36 and 52

End point title	WPAI-RA: Mean Percentage of Impairment While Working Due to RA (Presenteeism) at Weeks 36 and 52[209]

End point description:

The WPAI is a questionnaire that measures impairments in work activities in participants with RA which consists of 6 questions: Q1-currently employed; Q2-work time missed due to RA; Q3-work time missed due to other reasons; Q4-hours actually worked; Q5-degree RA affected productivity while working (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant from working); Q6-degree RA affected productivity in regular unpaid activities (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant`s daily activities). Outcomes are expressed as impairment percentages: Presenteeism (impairment while working) due to RA: 100×{Q5/10}. Higher numbers indicate greater impairment and less productivity. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 36 and 52

Notes:

[209] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	475	480	325	190
Units: percentage of impairment while working				
arithmetic mean (standard deviation)				
Week 36 (N=176,166,103,71,62)	20.2 (± 19.54)	19.6 (± 20.27)	21.2 (± 20.74)	21.5 (± 18.72)
Week 52 (N=179,155,97,66,55)	18.2 (± 18.83)	17.3 (± 19.25)	20.8 (± 21.78)	22.3 (± 21.82)

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	191			
Units: percentage of impairment while working				
arithmetic mean (standard deviation)				
Week 36 (N=176,166,103,71,62)	25.8 (± 23.51)			
Week 52 (N=179,155,97,66,55)	19.5 (± 20.04)			

Statistical analyses

No statistical analyses for this end point

Secondary: WPAI-RA: Mean Percentage of Overall Work Productivity Impairment Due to RA at Weeks 4, 12, and 24

End point title	WPAI-RA: Mean Percentage of Overall Work Productivity Impairment Due to RA at Weeks 4, 12, and 24

End point description:

The WPAI is a questionnaire that measures impairments in work activities in participants with RA which consists of 6 questions: Q1-currently employed; Q2-work time missed due to RA; Q3-work time missed due to other reasons; Q4-hours actually worked; Q5-degree RA affected productivity while working (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant from working); Q6-degree RA affected productivity in regular unpaid activities (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant`s daily activities). Outcomes are expressed as impairment percentages: Work productivity loss (overall work impairment) due to RA: 100×{Q2/(Q2+Q4) + [(1-Q2/(Q2+Q4) × (Q5/10)]}. Higher numbers indicate greater impairment and less productivity. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: percentage of work productivity loss				
arithmetic mean (standard deviation)				
Week 4 (N=185,182,108,156)	37.0 (± 24.64)	39.5 (± 25.17)	38.4 (± 24.59)	45.1 (± 25.18)
Week 12 (N=187,176,109,147)	29.5 (± 24.25)	29.3 (± 24.73)	30.7 (± 24.34)	36.7 (± 24.27)
Week 24 (N=177,168,110,128)	24.4 (± 23.06)	23.2 (± 22.64)	29.1 (± 23.88)	34.9 (± 26.04)

Statistical analyses

No statistical analyses for this end point

Secondary: WPAI-RA: Mean Percentage of Overall Work Productivity Impairment Due to RA at Weeks 36 and 52

End point title	WPAI-RA: Mean Percentage of Overall Work Productivity Impairment Due to RA at Weeks 36 and 52[210]

End point description:

The WPAI is a questionnaire that measures impairments in work activities in participants with RA which consists of 6 questions: Q1-currently employed; Q2-work time missed due to RA; Q3-work time missed due to other reasons; Q4-hours actually worked; Q5-degree RA affected productivity while working (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant from working); Q6-degree RA affected productivity in regular unpaid activities (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant`s daily activities). Outcomes are expressed as impairment percentages: Work productivity loss (overall work impairment) due to RA: 100×{Q2/(Q2+Q4) + [(1-Q2/(Q2+Q4) × (Q5/10)]}. Higher numbers indicate greater impairment and less productivity. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 36 and 52

Notes:

[210] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	475	480	325	190
Units: percentage of work productivity loss				
arithmetic mean (standard deviation)				
Week 36 (N=176,166,103,71,62)	23.3 (± 22.02)	23.9 (± 23.98)	23.8 (± 22.95)	24.0 (± 21.33)
Week 52 (N=179,155,97,66,55)	20.6 (± 21.74)	20.5 (± 22.15)	24.3 (± 24.77)	25.7 (± 24.32)

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	191			
Units: percentage of work productivity loss				
arithmetic mean (standard deviation)				
Week 36 (N=176,166,103,71,62)	29.1 (± 26.79)			
Week 52 (N=179,155,97,66,55)	22.3 (± 24.10)			

Statistical analyses

No statistical analyses for this end point

Secondary: WPAI-RA: Mean Percentage of Activity Impairment Due to RA at Weeks 4, 12, and 24

End point title	WPAI-RA: Mean Percentage of Activity Impairment Due to RA at Weeks 4, 12, and 24

End point description:

The WPAI is a questionnaire that measures impairments in work activities in participants with RA which consists of 6 questions: Q1-currently employed; Q2-work time missed due to RA; Q3-work time missed due to other reasons; Q4-hours actually worked; Q5-degree RA affected productivity while working (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant from working); Q6-degree RA affected productivity in regular unpaid activities (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant`s daily activities). Outcomes are expressed as impairment percentages: Activity impairment due to RA: 100×{Q6/10}. If Question 1 (Are you currently employed?) is 'NO', then only the activity impairment score can be determined. Higher numbers indicate greater impairment and less productivity. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	475	480	325	475
Units: percentage of activity impairment				
arithmetic mean (standard deviation)				
Week 4 (N=468,471,319,457)	44.6 (± 24.18)	46.2 (± 24.05)	46.4 (± 23.84)	52.1 (± 23.41)
Week 12 (N=455,457,306,437)	35.1 (± 23.86)	36.6 (± 24.51)	38.3 (± 25.57)	44.3 (± 23.73)
Week 24 (N=416,419,277,372)	30.2 (± 24.69)	30.4 (± 23.07)	32.5 (± 24.40)	39.3 (± 23.69)

Statistical analyses

No statistical analyses for this end point

Secondary: WPAI-RA: Mean Percentage of Activity Impairment Due to RA at Weeks 36 and 52

End point title	WPAI-RA: Mean Percentage of Activity Impairment Due to RA at Weeks 36 and 52[211]

End point description:

The WPAI is a questionnaire that measures impairments in work activities in participants with RA which consists of 6 questions: Q1-currently employed; Q2-work time missed due to RA; Q3-work time missed due to other reasons; Q4-hours actually worked; Q5-degree RA affected productivity while working (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant from working); Q6-degree RA affected productivity in regular unpaid activities (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant`s daily activities). Outcomes are expressed as impairment percentages: Activity impairment due to RA: 100×{Q6/10}. If Question 1 (Are you currently employed?) is 'NO', then only the activity impairment score can be determined. Higher numbers indicate greater impairment and less productivity. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 36 and 52

Notes:

[211] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	475	480	325	190
Units: percentage of activity impairment				
arithmetic mean (standard deviation)				
Week 36 (N=395,404,270,177,184)	28.3 (± 23.30)	28.7 (± 23.47)	31.3 (± 25.44)	28.3 (± 22.47)
Week 52 (N=386,379,257,167,174)	26.0 (± 22.44)	26.3 (± 22.71)	28.1 (± 24.38)	28.6 (± 23.57)

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	191			
Units: percentage of activity impairment				
arithmetic mean (standard deviation)				
Week 36 (N=395,404,270,177,184)	32.3 (± 23.62)			
Week 52 (N=386,379,257,167,174)	28.9 (± 23.07)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in WPAI-RA: Mean Percentage of Work Time Missed (Absenteeism) at Weeks 4, 12, and 24

End point title	Change From Baseline in WPAI-RA: Mean Percentage of Work Time Missed (Absenteeism) at Weeks 4, 12, and 24

End point description:

The WPAI is a questionnaire that measures impairments in work activities in participants with RA which consists of 6 questions: Q1-currently employed; Q2-work time missed due to RA; Q3-work time missed due to other reasons; Q4-hours actually worked; Q5-degree RA affected productivity while working (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant from working); Q6-degree RA affected productivity in regular unpaid activities (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant`s daily activities). Outcomes are expressed as impairment percentages: Absenteeism (work time missed) due to RA: 100×{Q2/(Q2+Q4)}. Higher numbers indicate greater impairment and less productivity. A negative change from baseline indicates improvement. Participants in the Full Analysis Set with available data

End point type	Secondary

End point timeframe:

Baseline; Weeks 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	195	193	127	162
Units: percentage of work time missed				
arithmetic mean (standard deviation)				
Baseline (BL)	12.0 (± 25.77)	9.9 (± 20.91)	16.0 (± 27.57)	17.0 (± 29.52)
Change from BL at Week 4 (N=176,169,107,143)	-1.4 (± 21.24)	-2.1 (± 18.14)	-7.5 (± 24.26)	-5.7 (± 25.65)
Change from BL at Week 12 (N=167,160,103,129)	-4.3 (± 22.55)	-3.8 (± 18.37)	-7.5 (± 28.79)	-5.9 (± 27.94)
Change from BL at Week 24 (N=157,148,100,110)	-6.1 (± 24.77)	-3.8 (± 16.92)	-9.3 (± 28.99)	-1.5 (± 27.24)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in WPAI-RA: Mean Percentage of Work Time Missed (Absenteeism) at Weeks 36 and 52

End point title	Change From Baseline in WPAI-RA: Mean Percentage of Work Time Missed (Absenteeism) at Weeks 36 and 52[212]

End point description:

The WPAI is a questionnaire that measures impairments in work activities in participants with RA which consists of 6 questions: Q1-currently employed; Q2-work time missed due to RA; Q3-work time missed due to other reasons; Q4-hours actually worked; Q5-degree RA affected productivity while working (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant from working); Q6-degree RA affected productivity in regular unpaid activities (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant`s daily activities). Outcomes are expressed as impairment percentages: Absenteeism (work time missed) due to RA: 100×{Q2/(Q2+Q4)}. Higher numbers indicate greater impairment and less productivity. A negative change from baseline indicates improvement. Participants in the Full Analysis Set with available data

End point type	Secondary

End point timeframe:

Baseline; Weeks 36 and 52

Notes:

[212] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	195	193	127	76
Units: percentage of work time missed				
arithmetic mean (standard deviation)				
Baseline (BL)	12.0 (± 25.77)	9.9 (± 20.91)	16.0 (± 27.57)	18.3 (± 31.61)
Change from BL at Week 36 (N=149,143,94,63,48)	-4.4 (± 24.04)	-1.5 (± 24.41)	-8.7 (± 27.43)	-6.2 (± 30.25)
Change from BL at Week 52 (N=154,131,89,55,43)	-6.8 (± 26.27)	-1.7 (± 21.89)	-7.1 (± 24.00)	-7.4 (± 26.76)

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	62			
Units: percentage of work time missed				
arithmetic mean (standard deviation)				
Baseline (BL)	14.6 (± 26.88)			

Change from BL at Week 36 (N=149,143,94,63,48)	-7.5 (± 25.00)			
Change from BL at Week 52 (N=154,131,89,55,43)	-8.9 (± 27.90)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in WPAI-RA: Mean Percentage of Impairment While Working Due to RA (Presenteeism) at Weeks 4, 12, and 24

End point title	Change From Baseline in WPAI-RA: Mean Percentage of Impairment While Working Due to RA (Presenteeism) at Weeks 4, 12, and 24

End point description:

The WPAI is a questionnaire that measures impairments in work activities in participants with RA which consists of 6 questions: Q1-currently employed; Q2-work time missed due to RA; Q3-work time missed due to other reasons; Q4-hours actually worked; Q5-degree RA affected productivity while working (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant from working); Q6-degree RA affected productivity in regular unpaid activities (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant`s daily activities). Outcomes are expressed as impairment percentages: Presenteeism (impairment while working) due to RA: 100×{Q5/10}. Higher numbers indicate greater impairment and less productivity. A negative change from baseline indicates improvement. Participants in the Full Analysis Set with available data were

End point type	Secondary

End point timeframe:

Baseline; Weeks 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	184	187	119	150
Units: percentage of impairment while working				
arithmetic mean (standard deviation)				
Baseline (BL)	49.1 (± 25.23)	48.0 (± 24.61)	50.8 (± 22.98)	52.5 (± 25.89)
Change from BL at Week 4 (N=166,164,100,132)	-15.1 (± 23.19)	-10.2 (± 22.82)	-15.3 (± 24.84)	-9.5 (± 23.68)
Change from BL at Week 12 (N=160,156,96,118)	-24.1 (± 25.83)	-21.9 (± 23.22)	-22.9 (± 24.88)	-17.1 (± 27.24)
Change from BL at Week 24 (N=151,146,93,102)	-27.4 (± 26.37)	-25.9 (± 26.59)	-23.3 (± 27.56)	-21.2 (± 29.33)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in WPAI-RA: Mean Percentage of Impairment While Working Due to RA (Presenteeism) at Weeks 36 and 52

End point title	Change From Baseline in WPAI-RA: Mean Percentage of Impairment While Working Due to RA (Presenteeism) at Weeks 36 and 52[213]

End point description:

The WPAI is a questionnaire that measures impairments in work activities in participants with RA which consists of 6 questions: Q1-currently employed; Q2-work time missed due to RA; Q3-work time missed due to other reasons; Q4-hours actually worked; Q5-degree RA affected productivity while working (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant from working); Q6-degree RA affected productivity in regular unpaid activities (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant`s daily activities). Outcomes are expressed as impairment percentages: Presenteeism (impairment while working) due to RA: 100×{Q5/10}. Higher numbers indicate greater impairment and less productivity. A negative change from baseline indicates improvement. Participants in the Full Analysis Set with available data were

End point type	Secondary

End point timeframe:

Baseline; Weeks 36 and 52

Notes:

[213] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	184	187	119	69
Units: percentage of impairment while working				
arithmetic mean (standard deviation)				
Baseline (BL)	49.1 (± 25.23)	48.0 (± 24.61)	50.8 (± 22.98)	53.8 (± 26.35)
Change from BL at Week 36 (N=144,138,87,61,45)	-29.7 (± 26.73)	-27.5 (± 26.28)	-27.8 (± 29.90)	-32.0 (± 26.82)
Change from BL at Week 52 (N=144,128,84,52,40)	-31.7 (± 27.44)	-29.5 (± 24.66)	-29.4 (± 27.91)	-30.6 (± 28.24)

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	59			
Units: percentage of impairment while working				
arithmetic mean (standard deviation)				
Baseline (BL)	53.6 (± 23.40)			
Change from BL at Week 36 (N=144,138,87,61,45)	-26.4 (± 29.86)			
Change from BL at Week 52 (N=144,128,84,52,40)	-32.5 (± 28.17)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in WPAI-RA: Mean Percentage of Overall Work Productivity Impairment Due to RA at Weeks 4, 12, and 24

End point title	Change From Baseline in WPAI-RA: Mean Percentage of Overall Work Productivity Impairment Due to RA at Weeks 4, 12, and 24

End point description:

The WPAI is a questionnaire that measures impairments in work activities in participants with RA which consists of 6 questions: Q1-currently employed; Q2-work time missed due to RA; Q3-work time missed due to other reasons; Q4-hours actually worked; Q5-degree RA affected productivity while working (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant from working); Q6-degree RA affected productivity in regular unpaid activities (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant`s daily activities). Outcomes are expressed as impairment percentages: Work productivity loss (overall work impairment) due to RA: 100×{Q2/(Q2+Q4) + [(1-Q2/(Q2+Q4) × (Q5/10)]}. Higher numbers indicate greater impairment and less productivity. A negative change from baseline indicates improvement. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	184	187	119	150
Units: percentage of work productivity loss				
arithmetic mean (standard deviation)				
Baseline (BL)	51.3 (± 25.95)	50.6 (± 25.87)	54.3 (± 24.85)	55.8 (± 27.33)
Change from BL at Week 4 (N=166,164,100,132)	-14.6 (± 24.59)	-10.2 (± 23.71)	-16.8 (± 26.29)	-10.0 (± 24.06)
Change from BL at Week 12 (N=160,156,96,118)	-23.2 (± 28.18)	-22.3 (± 24.34)	-22.8 (± 26.61)	-17.5 (± 28.09)
Change from BL at Week 24 (N=151,146,93,102)	-27.1 (± 27.78)	-26.3 (± 27.29)	-23.6 (± 29.40)	-19.3 (± 30.81)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in WPAI-RA: Mean Percentage of Overall Work Productivity Impairment Due to RA at Weeks 36 and 52

End point title	Change From Baseline in WPAI-RA: Mean Percentage of Overall Work Productivity Impairment Due to RA at Weeks 36 and 52[214]

End point description:

The WPAI is a questionnaire that measures impairments in work activities in participants with RA which consists of 6 questions: Q1-currently employed; Q2-work time missed due to RA; Q3-work time missed due to other reasons; Q4-hours actually worked; Q5-degree RA affected productivity while working (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant from working); Q6-degree RA affected productivity in regular unpaid activities (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant`s daily activities). Outcomes are

expressed as impairment percentages: Work productivity loss (overall work impairment) due to RA: 100×{Q2/(Q2+Q4) + [(1-Q2/(Q2+Q4) × (Q5/10)]}. Higher numbers indicate greater impairment and less productivity. A negative change from baseline indicates improvement. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 36 and 52

Notes:

[214] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	184	187	119	69
Units: percentage of work productivity loss				
arithmetic mean (standard deviation)				
Baseline (BL)	51.3 (± 25.95)	50.6 (± 25.87)	54.3 (± 24.85)	56.6 (± 27.36)
Change from BL at Week 36 (N=144,138,87,61,45)	-28.9 (± 27.16)	-25.7 (± 29.54)	-28.6 (± 31.48)	-31.7 (± 30.53)
Change from BL at Week 52 (N=144,128,84,52,40)	-31.6 (± 29.17)	-28.4 (± 27.11)	-29.3 (± 29.38)	-30.3 (± 30.73)

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	59			
Units: percentage of work productivity loss				
arithmetic mean (standard deviation)				
Baseline (BL)	57.1 (± 25.14)			
Change from BL at Week 36 (N=144,138,87,61,45)	-26.9 (± 31.02)			
Change from BL at Week 52 (N=144,128,84,52,40)	-32.7 (± 29.65)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in WPAI-RA: Mean Percentage of Activity Impairment Due to RA at Weeks 4, 12, and 24

End point title	Change From Baseline in WPAI-RA: Mean Percentage of Activity Impairment Due to RA at Weeks 4, 12, and 24

End point description:

The WPAI is a questionnaire that measures impairments in work activities in participants with RA which consists of 6 questions: Q1-currently employed; Q2-work time missed due to RA; Q3-work time missed

due to other reasons; Q4-hours actually worked; Q5-degree RA affected productivity while working (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant from working); Q6-degree RA affected productivity in regular unpaid activities (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant`s daily activities). Outcomes are expressed as impairment percentages: Activity impairment due to RA: 100×{Q6/10}. If Question 1 (Are you currently employed?) is 'NO', then only the activity impairment score can be determined. Higher numbers indicate greater impairment and less productivity. A negative change from baseline indicates improvement. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	472	477	319	469
Units: percentage of activity impairment				
arithmetic mean (standard deviation)				
Baseline (BL)	61.5 (± 22.74)	60.5 (± 23.85)	61.3 (± 21.20)	62.2 (± 22.11)
Change from BL at Week 4 (N=465,470,316,455)	-17.0 (± 22.46)	-14.7 (± 22.07)	-14.8 (± 23.36)	-9.8 (± 20.98)
Change from BL at Week 12 (N=452,455,303,432)	-26.5 (± 25.17)	-24.1 (± 24.95)	-22.6 (± 24.93)	-16.9 (± 25.98)
Change from BL at Week 24 (N=413,417,273,369)	-30.7 (± 26.20)	-30.4 (± 25.45)	-28.6 (± 24.99)	-21.9 (± 27.78)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in WPAI-RA: Mean Percentage of Activity Impairment Due to RA at Weeks 36 and 52

End point title	Change From Baseline in WPAI-RA: Mean Percentage of Activity Impairment Due to RA at Weeks 36 and 52[215]

End point description:

The WPAI is a questionnaire that measures impairments in work activities in participants with RA which consists of 6 questions: Q1-currently employed; Q2-work time missed due to RA; Q3-work time missed due to other reasons; Q4-hours actually worked; Q5-degree RA affected productivity while working (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant from working); Q6-degree RA affected productivity in regular unpaid activities (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant`s daily activities). Outcomes are expressed as impairment percentages: Activity impairment due to RA: 100×{Q6/10}. If Question 1 (Are you currently employed?) is 'NO', then only the activity impairment score can be determined. Higher numbers indicate greater impairment and less productivity. A negative change from baseline indicates improvement. Participants in the Full Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 36 and 52

Notes:

[215] - 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: Not applicable for the arm 'Placebo never received Filgotinib' at the specified time points.

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Adalimumab	Placebo to Filgotinib 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	472	477	319	189
Units: percentage of activity impairment				
arithmetic mean (standard deviation)				
Baseline (BL)	61.5 (± 22.74)	60.5 (± 23.85)	61.3 (± 21.20)	62.9 (± 21.74)
Change from BL at Week 36 (N=393,402,268,176,182)	-32.6 (± 26.66)	-31.5 (± 25.66)	-30.2 (± 26.93)	-34.9 (± 26.60)
Change from BL at Week 52 (N=384,376,254,166,172)	-34.8 (± 26.74)	-33.7 (± 26.44)	-32.9 (± 26.03)	-35.2 (± 28.00)

End point values	Placebo to Filgotinib 100 mg			
Subject group type	Reporting group			
Number of subjects analysed	189			
Units: percentage of activity impairment				
arithmetic mean (standard deviation)				
Baseline (BL)	59.7 (± 22.10)			
Change from BL at Week 36 (N=393,402,268,176,182)	-27.5 (± 26.14)			
Change from BL at Week 52 (N=384,376,254,166,172)	-30.8 (± 25.99)			

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

First dose date up to last dose date (Maximum: 54 weeks) plus 30 days

Adverse event reporting additional description:

The Safety Analysis Set included all participants who received at least 1 dose of study drug. Treatment relatedness refers to study drug filgotinib, adalimumab and placebo to match, not other background treatment (MTX).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.0

Reporting groups

Reporting group title	Placebo to Filgotinib 100 mg

Reporting group description:

Participants in the placebo arm were administered a PTM filgotinib 200 mg tablet orally, once daily+ a PTM filgotinib 100 mg tablet orally, once daily + PTM adalimumab 40 mg SC injection, once every 2 weeks in addition to a weekly stable dose of MTX, orally for median exposure of 24 weeks. Then the participants in the placebo arm were rerandomized to filgotinib 100 mg and were administered a filgotinib 100 mg tablet orally, once daily + PTM filgotinib 200 mg tablet orally, once daily + PTM adalimumab 40 mg SC injection, once every 2 weeks in addition to a weekly stable dose of MTX, orally for median exposure of 28.1 weeks.

Reporting group title	Placebo

Reporting group description:

The Placebo arm included all participants who received placebo in the study. Participants were administered PTM filgotinib 200 mg tablets orally, once daily+ PTM filgotinib 100 mg tablets orally, once daily + PTM adalimumab 40 mg SC injection, once every 2 weeks in addition to a weekly stable dose of MTX, orally for median exposure of 24 weeks.

Reporting group title	Placebo to Filgotinib 200 mg

Reporting group description:

Participants in the placebo arm were administered a PTM filgotinib 200 mg tablet orally, once daily+ a PTM filgotinib 100 mg tablet orally, once daily + PTM adalimumab 40 mg SC injection, once every 2 weeks in addition to a weekly stable dose of MTX, orally for median exposure of 24 weeks. Then the participants in the placebo arm were rerandomized to filgotinib 200 mg and were administered a filgotinib 200 mg tablet orally, once daily + PTM filgotinib 100 mg tablet orally, once daily + PTM adalimumab 40 mg SC injection, once every 2 weeks in addition to a weekly stable dose of MTX, orally for median exposure of 28.1 weeks.

Reporting group title	Adalimumab

Reporting group description:

Participants were administered a PTM filgotinib 200 mg tablet orally, once daily + a PTM filgotinib 100 mg tablet orally, once daily + adalimumab 40 mg SC injection, once every 2 weeks in addition to a weekly stable dose of MTX, orally for median exposure of 52.1 weeks.

Reporting group title	Filgotinib 100 mg

Reporting group description:

Participants were administered a filgotinib 100 mg tablet orally, once daily + a PTM filgotinib 200 mg tablet orally, once daily + PTM adalimumab 40 mg SC injection, once every 2 weeks in addition to a weekly stable dose of MTX, orally for median exposure of 52.1 weeks.

Reporting group title	Filgotinib 200 mg

Reporting group description:

Participants were administered a filgotinib 200 mg tablet orally, once daily + a placebo to match (PTM) filgotinib 100 mg tablet orally, once daily + PTM adalimumab 40 mg subcutaneous (SC) injection, once every 2 weeks in addition to a weekly stable dose of MTX, orally for median exposure of 52.1 weeks.

Serious adverse events	Placebo to Filgotinib 100 mg	Placebo	Placebo to Filgotinib 200 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 191 (4.19%)	21 / 475 (4.42%)	7 / 190 (3.68%)
number of deaths (all causes)	1	2	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer stage I			
subjects affected / exposed	0 / 191 (0.00%)	1 / 475 (0.21%)	0 / 190 (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
Cervix carcinoma stage III			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leiomyosarcoma metastatic			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant glioma			
subjects affected / exposed	0 / 191 (0.00%)	1 / 475 (0.21%)	0 / 190 (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
Metastases to liver			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Prostate cancer			
subjects affected / exposed	0 / 191 (0.00%)	1 / 475 (0.21%)	0 / 190 (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
Uterine leiomyoma			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
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 / 191 (0.00%)	0 / 475 (0.00%)	1 / 190 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Hypotension			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
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 artery occlusion			
subjects affected / exposed	0 / 191 (0.00%)	1 / 475 (0.21%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	1 / 190 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Metrorrhagia			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatitis			

subjects affected / exposed	1 / 191 (0.52%)	0 / 475 (0.00%)	0 / 190 (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
Uterine haemorrhage			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal haemorrhage			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
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 failure			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	1 / 190 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Alveolitis			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiectasis			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Organising pneumonia			
subjects affected / exposed	0 / 191 (0.00%)	1 / 475 (0.21%)	0 / 190 (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
Pulmonary fibrosis			

subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
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 failure			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rheumatoid lung			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord polyp			
subjects affected / exposed	0 / 191 (0.00%)	1 / 475 (0.21%)	0 / 190 (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
Psychiatric disorders			
Adjustment disorder with depressed mood			
subjects affected / exposed	1 / 191 (0.52%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
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 creatinine increased			
subjects affected / exposed	0 / 191 (0.00%)	1 / 475 (0.21%)	0 / 190 (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
Lipase increased			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Femur fracture			
subjects affected / exposed	0 / 191 (0.00%)	1 / 475 (0.21%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery restenosis			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
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 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Road traffic accident			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	1 / 190 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scapula fracture			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	0 / 191 (0.00%)	1 / 475 (0.21%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 191 (0.00%)	1 / 475 (0.21%)	0 / 190 (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
Myocardial infarction			
subjects affected / exposed	0 / 191 (0.00%)	1 / 475 (0.21%)	0 / 190 (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
Angina unstable			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cor pulmonale chronic			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			

subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
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			
Dizziness			
subjects affected / exposed	0 / 191 (0.00%)	1 / 475 (0.21%)	0 / 190 (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
Ischaemic stroke			
subjects affected / exposed	1 / 191 (0.52%)	0 / 475 (0.00%)	1 / 190 (0.53%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Syncope			
subjects affected / exposed	0 / 191 (0.00%)	1 / 475 (0.21%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stenosis			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiplegia			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
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			
Pancytopenia			
subjects affected / exposed	0 / 191 (0.00%)	1 / 475 (0.21%)	0 / 190 (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
Anaemia			

subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 191 (0.00%)	1 / 475 (0.21%)	0 / 190 (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
Ear and labyrinth disorders			
Meniere's disease			
subjects affected / exposed	1 / 191 (0.52%)	0 / 475 (0.00%)	0 / 190 (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
Vertigo			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
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			
Cataract			
subjects affected / exposed	0 / 191 (0.00%)	1 / 475 (0.21%)	0 / 190 (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
Macular fibrosis			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitreous opacities			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
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			
Inguinal hernia			
subjects affected / exposed	1 / 191 (0.52%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pancreatitis acute			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer perforation			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
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 inflammation			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
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 haemorrhage			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mouth ulceration			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
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 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 191 (0.00%)	1 / 475 (0.21%)	0 / 190 (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
Peptic ulcer			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
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 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
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			
Cholelithiasis			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 191 (0.00%)	1 / 475 (0.21%)	0 / 190 (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
Cholecystitis acute			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			

Skin ulcer			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angioedema			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	1 / 190 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	1 / 190 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pustular psoriasis			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
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 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prerenal failure			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
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 cell dysplasia			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
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			
Rheumatoid arthritis			
subjects affected / exposed	1 / 191 (0.52%)	1 / 475 (0.21%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot deformity			
subjects affected / exposed	0 / 191 (0.00%)	1 / 475 (0.21%)	0 / 190 (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
Intervertebral disc disorder			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	1 / 190 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb asymmetry			
subjects affected / exposed	0 / 191 (0.00%)	1 / 475 (0.21%)	0 / 190 (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
Muscular weakness			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			

Pneumonia			
subjects affected / exposed	0 / 191 (0.00%)	1 / 475 (0.21%)	1 / 190 (0.53%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 191 (0.00%)	1 / 475 (0.21%)	0 / 190 (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 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
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 bacterial			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
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 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			
subjects affected / exposed	1 / 191 (0.52%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Abscess limb			

subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
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			
subjects affected / exposed	1 / 191 (0.52%)	0 / 475 (0.00%)	0 / 190 (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
Candida infection			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
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 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Helicobacter infection			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected skin ulcer			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious pleural effusion			
subjects affected / exposed	0 / 191 (0.00%)	1 / 475 (0.21%)	0 / 190 (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
Infective tenosynovitis			

subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
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 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paronychia			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
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 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
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 fungal			
subjects affected / exposed	0 / 191 (0.00%)	1 / 475 (0.21%)	0 / 190 (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
Pneumonia pneumococcal			
subjects affected / exposed	0 / 191 (0.00%)	1 / 475 (0.21%)	0 / 190 (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
Pneumonia viral			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
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 acute			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
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 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
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 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte imbalance			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypervitaminosis			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 191 (0.00%)	0 / 475 (0.00%)	0 / 190 (0.00%)
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	Adalimumab	Filgotinib 100 mg	Filgotinib 200 mg

Total subjects affected by serious adverse events			
subjects affected / exposed	22 / 325 (6.77%)	40 / 480 (8.33%)	35 / 475 (7.37%)
number of deaths (all causes)	1	1	3
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer			
subjects affected / exposed	1 / 325 (0.31%)	0 / 480 (0.00%)	0 / 475 (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
Breast cancer stage I			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	0 / 475 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervix carcinoma stage III			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (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
Leiomyosarcoma metastatic			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (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
Malignant glioma			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	0 / 475 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to liver			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			

subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	0 / 475 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine leiomyoma			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (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
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 325 (0.31%)	0 / 480 (0.00%)	0 / 475 (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
Hypotension			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery occlusion			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	0 / 475 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Metrorrhagia			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (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
Prostatitis			

subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	0 / 475 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine haemorrhage			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (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
Vaginal haemorrhage			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	2 / 475 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alveolitis			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Bronchiectasis			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Organising pneumonia			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	0 / 475 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary fibrosis			

subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pulmonary oedema			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
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 failure			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Rheumatoid lung			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Vocal cord polyp			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	0 / 475 (0.00%)
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			
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	0 / 475 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 325 (0.31%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 325 (0.31%)	0 / 480 (0.00%)	0 / 475 (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

Blood creatinine increased			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	0 / 475 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase increased			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Femur fracture			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	1 / 325 (0.31%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery restenosis			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus injury			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (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

Road traffic accident			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	0 / 475 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scapula fracture			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (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
Toxicity to various agents			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	0 / 475 (0.00%)
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			
Acute myocardial infarction			
subjects affected / exposed	1 / 325 (0.31%)	0 / 480 (0.00%)	0 / 475 (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
Myocardial infarction			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Angina unstable			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cor pulmonale chronic			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Coronary artery disease			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (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
Sinus tachycardia			

subjects affected / exposed	1 / 325 (0.31%)	0 / 480 (0.00%)	0 / 475 (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
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (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
Ischaemic stroke			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	0 / 475 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 325 (0.00%)	2 / 480 (0.42%)	0 / 475 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stenosis			
subjects affected / exposed	1 / 325 (0.31%)	0 / 480 (0.00%)	0 / 475 (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
Hemiplegia			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (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			
Pancytopenia			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			

subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	0 / 475 (0.00%)
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			
Meniere's disease			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	0 / 475 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (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
Eye disorders			
Cataract			
subjects affected / exposed	1 / 325 (0.31%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macular fibrosis			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitreous opacities			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Inguinal hernia			
subjects affected / exposed	0 / 325 (0.00%)	2 / 480 (0.42%)	0 / 475 (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

Pancreatitis acute			
subjects affected / exposed	1 / 325 (0.31%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (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
Duodenal ulcer perforation			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal inflammation			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
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 haemorrhage			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mouth ulceration			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (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
Obstructive pancreatitis			

subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (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
Pancreatitis			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	0 / 475 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (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
Vomiting			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	2 / 475 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (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
Cholecystitis acute			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			

Skin ulcer			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angioedema			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	0 / 475 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	0 / 475 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pustular psoriasis			
subjects affected / exposed	1 / 325 (0.31%)	0 / 480 (0.00%)	0 / 475 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (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
Prerenal failure			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
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 cell dysplasia			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (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			
Rheumatoid arthritis			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot deformity			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc disorder			
subjects affected / exposed	1 / 325 (0.31%)	1 / 480 (0.21%)	0 / 475 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	0 / 475 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (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
Limb asymmetry			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	0 / 475 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (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
Osteonecrosis			
subjects affected / exposed	1 / 325 (0.31%)	0 / 480 (0.00%)	0 / 475 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			

Pneumonia			
subjects affected / exposed	3 / 325 (0.92%)	4 / 480 (0.83%)	4 / 475 (0.84%)
occurrences causally related to treatment / all	2 / 3	3 / 4	4 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	2 / 2
Bronchitis			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	2 / 475 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cellulitis			
subjects affected / exposed	1 / 325 (0.31%)	1 / 480 (0.21%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	1 / 1	1 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
subjects affected / exposed	1 / 325 (0.31%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	1 / 325 (0.31%)	1 / 480 (0.21%)	0 / 475 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	2 / 475 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 2
Urinary tract infection			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (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
Abscess limb			

subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
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			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	0 / 475 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Candida infection			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (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
Erysipelas			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (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
Gastroenteritis			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Helicobacter infection			
subjects affected / exposed	1 / 325 (0.31%)	0 / 480 (0.00%)	0 / 475 (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
Infected skin ulcer			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (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
Infectious pleural effusion			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	0 / 475 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective tenosynovitis			

subjects affected / exposed	1 / 325 (0.31%)	0 / 480 (0.00%)	0 / 475 (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
Osteomyelitis			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (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
Paronychia			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	1 / 325 (0.31%)	0 / 480 (0.00%)	0 / 475 (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
Pneumonia fungal			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	0 / 475 (0.00%)
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 pneumococcal			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	0 / 475 (0.00%)
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 viral			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (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
Sepsis			

subjects affected / exposed	1 / 325 (0.31%)	0 / 480 (0.00%)	0 / 475 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (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
Tooth abscess			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (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
Electrolyte imbalance			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypervitaminosis			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 325 (0.00%)	1 / 480 (0.21%)	0 / 475 (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
Metabolic acidosis			
subjects affected / exposed	0 / 325 (0.00%)	0 / 480 (0.00%)	1 / 475 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Placebo to Filgotinib 100 mg	Placebo	Placebo to Filgotinib 200 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	23 / 191 (12.04%)	61 / 475 (12.84%)	36 / 190 (18.95%)
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	3 / 191 (1.57%)	11 / 475 (2.32%)	7 / 190 (3.68%)
occurrences (all)	3	11	7
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 191 (1.57%)	9 / 475 (1.89%)	8 / 190 (4.21%)
occurrences (all)	3	9	9
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	1 / 191 (0.52%)	7 / 475 (1.47%)	4 / 190 (2.11%)
occurrences (all)	1	7	4
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	6 / 191 (3.14%)	25 / 475 (5.26%)	7 / 190 (3.68%)
occurrences (all)	8	31	9
Upper respiratory tract infection			
subjects affected / exposed	6 / 191 (3.14%)	14 / 475 (2.95%)	8 / 190 (4.21%)
occurrences (all)	6	16	10
Urinary tract infection			
subjects affected / exposed	8 / 191 (4.19%)	6 / 475 (1.26%)	10 / 190 (5.26%)
occurrences (all)	8	6	10

Non-serious adverse events	Adalimumab	Filgotinib 100 mg	Filgotinib 200 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	82 / 325 (25.23%)	142 / 480 (29.58%)	128 / 475 (26.95%)
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	21 / 325 (6.46%)	25 / 480 (5.21%)	17 / 475 (3.58%)
occurrences (all)	24	31	24
Aspartate aminotransferase increased			

subjects affected / exposed	17 / 325 (5.23%)	20 / 480 (4.17%)	12 / 475 (2.53%)
occurrences (all)	19	29	16
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	6 / 325 (1.85%)	16 / 480 (3.33%)	26 / 475 (5.47%)
occurrences (all)	6	19	30
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	24 / 325 (7.38%)	48 / 480 (10.00%)	43 / 475 (9.05%)
occurrences (all)	27	58	53
Upper respiratory tract infection			
subjects affected / exposed	21 / 325 (6.46%)	49 / 480 (10.21%)	41 / 475 (8.63%)
occurrences (all)	27	65	49
Urinary tract infection			
subjects affected / exposed	17 / 325 (5.23%)	19 / 480 (3.96%)	18 / 475 (3.79%)
occurrences (all)	20	21	21

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
05 July 2016	• Terminology for the Open Label Extension study was changed to long-term extension (LTE) study • Updated study procedures to collect body weight at all study visits • Added urine biomarker samples as an exploratory endpoint • Updated study procedures to include Treatment Satisfaction Questionnaire for Medication (TSQM) collection at Day 1 and Week 12, 24, 36, and 52 visits. • Clarified eligibility criteria as needed • Updated Study Procedures, to reflect global protocol changes in study procedures and time points • Updated the Prior and Concomitant Medications section to clarify documentation of prior medications and restriction window on injectable corticosteroids • Updated to stipulate that viably frozen peripheral blood mononuclear cells and leukocyte subset samples would be drawn in the US and Canada only; removed peripheral blood mononuclear cell substudy • Clarified that the magnetic resonance imaging (MRI) substudy would be performed postrandomization within 7 days of first dose and at Week 12 within ± 7 days • Clarified that radiographs performed after randomization could be done ± 7 days of the scheduled visit • Added carotid artery ultrasound substudy at selected sites, when available • Updated Criteria for Interruption or Discontinuation of Study Treatment, to align across protocols

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported