EU Clinical Trials Register

Clinical trial results:

A Randomized, Double-Blind, Placebo-Controlled, Multicenter, Phase 3 Study to Assess the Efficacy and Safety of Filgotinib Administered for 24 Weeks in Combination with Conventional Synthetic Disease-modifying Anti-rheumatic Drug(s) (csDMARDs) to Subjects with Moderately to Severely Active Rheumatoid Arthritis Who Have an Inadequate Response to Biologic DMARD(s) Treatment

Summary

EudraCT number	2016-000569-21
Trial protocol	BE GB DE FR HU ES PL NL
Global end of trial date	26 June 2018

Results information

Result version number	v2 (current)
This version publication date	08 May 2021
First version publication date	04 July 2019
Version creation reason	• New data added to full data set Added additional secondary endpoints.

Trial information

Trial identification

Sponsor protocol code	GS-US-417-0302

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02873936
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	26 June 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 March 2018
Global end of trial reached?	Yes
Global end of trial date	26 June 2018
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:

All participants continued to receive a stable dose of a permitted protocol-specified conventional synthetic disease-modifying antirheumatic drug (csDMARD(s)) (methotrexate (MTX), hydroxychloroquine, sulfasalazine, or leflunomide). MTX was not permitted to be used in combination with leflunomide.

Evidence for comparator: -

Actual start date of recruitment	27 July 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	Poland: 19
Country: Number of subjects enrolled	Spain: 16
Country: Number of subjects enrolled	United Kingdom: 10
Country: Number of subjects enrolled	Belgium: 13
Country: Number of subjects enrolled	France: 9
Country: Number of subjects enrolled	Germany: 15
Country: Number of subjects enrolled	Hungary: 16
Country: Number of subjects enrolled	United States: 255

Country: Number of subjects enrolled	Japan: 40
Country: Number of subjects enrolled	Mexico: 30
Country: Number of subjects enrolled	Argentina: 12
Country: Number of subjects enrolled	Korea, Republic of: 5
Country: Number of subjects enrolled	Australia: 4
Country: Number of subjects enrolled	Israel: 3
Country: Number of subjects enrolled	Switzerland: 2
Worldwide total number of subjects	449
EEA total number of subjects	98

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)	336
From 65 to 84 years	113
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled at study sites in Australia, Asia, Europe, North America, and South America. The first participant was screened on 27 July 2016. The last study visit occurred on 26 June 2018.

Pre-assignment

Screening details:

688 participants were screened. The enrolled participants continued to receive ongoing therapy with permitted protocol specified Conventional Synthetic Disease-Modifying Anti-Rheumatic Drugs (csDMARDs) (ie, methotrexate (MTX), hydroxychloroquine, sulfasalazine, or leflunomide). MTX was not permitted to be used in combination with leflunomide.

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 filgotinib 200 mg tablet orally, once daily + placebo to match (PTM) filgotinib 100 mg tablet orally, once daily + stable dose of permitted csDMARDs for median exposure of 24.1 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 tablet administered once daily

Investigational medicinal product name	Placebo to match (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

Arm title	Filgotinib 100 mg

Arm description:

Participants were administered filgotinib 100 mg tablet orally, once daily + PTM filgotinib 200 mg tablet orally, once daily + stable dose of permitted csDMARDs for median exposure of 24 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 tablet 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

Arm title	Placebo

Arm description:

Participants were administered PTM filgotinib 200 mg tablet orally, once daily + PTM filgotinib 100 mg tablet orally, once daily + stable dose of permitted csDMARDs for median exposure of 24 weeks.

Arm type	Placebo
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 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

Number of subjects in period 1[1]	Filgotinib 200 mg	Filgotinib 100 mg	Placebo
Started	147	153	148
Completed	135	130	116
Not completed	12	23	32
Withdrew Consent	4	11	20
Adverse Event	3	5	3
Non-Compliance with Study Drug	1	-	1
Investigator's Discretion	3	5	4
Protocol Violation	-	1	3
Lost to follow-up	1	1	1

Notes:

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

Justification: One participant who was randomized but did not receive the study drug was not included in analysis.

Baseline characteristics

Reporting groups

Reporting group title	Filgotinib 200 mg
Reporting group description:	
Participants were administered filgotinib 200 mg tablet orally, once daily + placebo to match (PTM) filgotinib 100 mg tablet orally, once daily + stable dose of permitted csDMARDs for median exposure of 24.1 weeks.	
Reporting group title	Filgotinib 100 mg
Reporting group description:	
Participants were administered filgotinib 100 mg tablet orally, once daily + PTM filgotinib 200 mg tablet orally, once daily + stable dose of permitted csDMARDs for median exposure of 24 weeks.	
Reporting group title	Placebo
Reporting group description:	
Participants were administered PTM filgotinib 200 mg tablet orally, once daily + PTM filgotinib 100 mg tablet orally, once daily + stable dose of permitted csDMARDs for median exposure of 24 weeks.	

Reporting group values	Filgotinib 200 mg	Filgotinib 100 mg	Placebo
Number of subjects	147	153	148
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	56	55	56
standard deviation	± 12.5	± 12.0	± 12.1
Gender categorical			
Units: Subjects			
Female	120	119	121
Male	27	34	27
Race			
Not Permitted = local regulators did not allow collection of race information.			
Units: Subjects			
American Indian or Alaska Native	7	9	10
Asian	15	20	15
Black or African American	14	12	21
White	110	109	97
Other	1	3	2
Not Permitted	0	0	3
Ethnicity			
Not Permitted = local regulators did not allow collection of ethnicity information.			
Units: Subjects			
Hispanic or Latino	26	40	41
Not Hispanic or Latino	120	112	107
Not Permitted	1	1	0

Reporting group values	Total		
Number of subjects	448		

Age categorical			
Units: Subjects			

Age continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical			
Units: Subjects			
Female	360		
Male	88		
Race			
Not Permitted = local regulators did not allow collection of race information.			
Units: Subjects			
American Indian or Alaska Native	26		
Asian	50		
Black or African American	47		
White	316		
Other	6		
Not Permitted	3		
Ethnicity			
Not Permitted = local regulators did not allow collection of ethnicity information.			
Units: Subjects			
Hispanic or Latino	107		
Not Hispanic or Latino	339		
Not Permitted	2		

End points

End points reporting groups

Reporting group title	Filgotinib 200 mg
Reporting group description:	
Participants were administered filgotinib 200 mg tablet orally, once daily + placebo to match (PTM) filgotinib 100 mg tablet orally, once daily + stable dose of permitted csDMARDs for median exposure of 24.1 weeks.	
Reporting group title	Filgotinib 100 mg
Reporting group description:	
Participants were administered filgotinib 100 mg tablet orally, once daily + PTM filgotinib 200 mg tablet orally, once daily + stable dose of permitted csDMARDs for median exposure of 24 weeks.	
Reporting group title	Placebo
Reporting group description:	
Participants were administered PTM filgotinib 200 mg tablet orally, once daily + PTM filgotinib 100 mg tablet orally, once daily + stable dose of permitted csDMARDs for median exposure of 24 weeks.	

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	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	153	148	
Units: percentage of participants				
number (confidence interval 95%)	66.0 (58.0 to 74.0)	57.5 (49.4 to 65.7)	31.1 (23.3 to 38.9)	

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo
Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [1]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	34.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	23.5
upper limit	46.3

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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [2]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	26.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	15
upper limit	37.9

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 28 C-Reactive Protein (DAS28(CRP)) ≤ 3.2 at Week 12

End point title	Percentage of Participants who Achieved Disease Activity Score 28 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 (CRP=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:

Week 12

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	153	148	
Units: percentage of participants				
number (confidence interval 95%)	40.8 (32.5 to 49.1)	37.3 (29.3 to 45.2)	15.5 (9.4 to 21.7)	

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo
Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [3]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	25.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	14.7
upper limit	35.8

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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [4]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	21.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.4
upper limit	32

Notes:

[4] - 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 0-3 [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, 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	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	153	148	
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	1.70 (± 0.656)	1.64 (± 0.683)	1.65 (± 0.633)	
Change from Baseline at Week 12 (N=137,140,129)	-0.55 (± 0.590)	-0.48 (± 0.602)	-0.23 (± 0.547)	

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo

Statistical analysis description:

Least squares (LS)-Mean, 95% confidence interval (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.

Comparison groups	Filgotinib 200 mg v Placebo
Number of subjects included in analysis	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [5]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.45
upper limit	-0.19
Variability estimate	Standard error of the mean
Dispersion value	0.066

Notes:

[5] - MMRM model included treatment, visit (as categorical), 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:

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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [6]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.4
upper limit	-0.14
Variability estimate	Standard error of the mean
Dispersion value	0.065

Notes:

[6] - MMRM model included treatment, visit (as categorical), 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 4, 12, and 24

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

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	153	148	
Units: percentage of participants				
number (confidence interval 95%)				
Week 4	22.4 (15.4 to 29.5)	21.6 (14.7 to 28.4)	7.4 (2.9 to 12.0)	

	Week 12	42.9 (34.5 to 51.2)	32.0 (24.3 to 39.7)	14.9 (8.8 to 20.9)	
	Week 24	45.6 (37.2 to 54.0)	35.3 (27.4 to 43.2)	18.9 (12.3 to 25.6)	

Statistical analyses

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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [7]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	15
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.4
upper limit	23.7

Notes:

[7] - 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [8]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	14.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.7
upper limit	22.6

Notes:

[8] - 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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [9]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	28
Confidence interval	
level	95 %
sides	2-sided
lower limit	17.5
upper limit	38.5

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 Placebo

Statistical analysis description:

Week 12

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [10]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	17.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.1
upper limit	27.2

Notes:

[10] - 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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [11]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	26.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	15.8
upper limit	37.6

Notes:

[11] - 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002 [12]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	16.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.9
upper limit	26.9

Notes:

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

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

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

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	153	148	
Units: percentage of participants				
number (confidence interval 95%)				
Week 4	6.1 (1.9 to 10.3)	8.5 (3.8 to 13.2)	2.7 (0.0 to 5.7)	
Week 12	21.8 (14.8 to 28.8)	14.4 (8.5 to 20.3)	6.8 (2.4 to 11.1)	
Week 24	32.0 (24.1 to 39.9)	20.3 (13.6 to 27.0)	8.1 (3.4 to 12.8)	

Statistical analyses

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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.16 [13]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	3.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	8.8

Notes:

[13] - 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.039 [14]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	5.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	11.6

Notes:

[14] - 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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [15]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	15
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.5
upper limit	23.5

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

Statistical analysis description:

Week 12

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.036 [16]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	7.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.1
upper limit	15.2

Notes:

[16] - 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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [17]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	23.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	14.5
upper limit	33.3

Notes:

[17] - 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004 [18]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	12.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.7
upper limit	20.6

Notes:

[18] - 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 4 and 24

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

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	153	148	
Units: percentage of participants				
number (confidence interval 95%)				
Week 4	51.7 (43.3 to 60.1)	44.4 (36.2 to 52.6)	25.7 (18.3 to 33.1)	
Week 24	69.4 (61.6 to 77.2)	54.9 (46.7 to 63.1)	34.5 (26.5 to 42.5)	

Statistical analyses

Statistical analysis title	Filgotinib 200 mg vs Placebo
Statistical analysis description:	
Week 4	
Comparison groups	Placebo v Filgotinib 200 mg
Number of subjects included in analysis	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [19]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	26
Confidence interval	
level	95 %
sides	2-sided
lower limit	14.6
upper limit	37.4

Notes:

[19] - 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [20]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	18.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.5
upper limit	30

Notes:

[20] - 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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [21]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	34.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	23.6
upper limit	46.3

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 24

Comparison groups	Filgotinib 100 mg v Placebo
Number of subjects included in analysis	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [22]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	20.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.8
upper limit	32.1

Notes:

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

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

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

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	146	153	148	
Units: tender joint count				
arithmetic mean (standard deviation)				
Baseline	28.0 (± 16.1)	26.0 (± 15.4)	27.0 (± 15.5)	
Change from Baseline at Week 4 (N=145,149,135)	-13.0 (± 13.5)	-11.0 (± 11.0)	-8.0 (± 13.8)	
Change from Baseline at Week 12 (N=136,139,129)	-18.0 (± 14.1)	-16.0 (± 11.8)	-12.0 (± 13.4)	
Change from Baseline at Week 24 (N=122,112,92)	-22.0 (± 14.2)	-19.0 (± 13.0)	-17.0 (± 13.3)	

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	294
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003 [23]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7
upper limit	-1
Variability estimate	Standard error of the mean
Dispersion value	1.4

Notes:

[23] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.027 [24]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6
upper limit	0
Variability estimate	Standard error of the mean
Dispersion value	1.4

Notes:

[24] - MMRM model included treatment, visit (as categorical), 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	294
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [25]
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	1.3

Notes:

[25] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [26]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-4
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:

[26] - MMRM model included treatment, visit (as categorical), 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	294
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [27]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10
upper limit	-4
Variability estimate	Standard error of the mean
Dispersion value	1.5

Notes:

[27] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.006 [28]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7
upper limit	-1
Variability estimate	Standard error of the mean
Dispersion value	1.5

Notes:

[28] - MMRM model included treatment, visit (as categorical), 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: Swollen Joint Count Based on 66 Joints (SJC66) at Weeks 4, 12, and 24

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

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	146	153	148	
Units: swollen joint count				
arithmetic mean (standard deviation)				
Baseline	18.0 (± 12.5)	17.0 (± 12.4)	17.0 (± 9.7)	
Change from Baseline at Week 4 (N=145,149,135)	-10.0 (± 10.6)	-7.0 (± 9.2)	-7.0 (± 8.8)	
Change from Baseline at Week 12 (N=136,139,129)	-12.0 (± 10.5)	-10.0 (± 8.6)	-8.0 (± 8.9)	
Change from Baseline at Week 24 (N=122,112,92)	-14.0 (± 10.3)	-13.0 (± 10.0)	-12.0 (± 8.7)	

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	294
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.008 [29]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5
upper limit	-1
Variability estimate	Standard error of the mean
Dispersion value	1

Notes:

[29] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.65 [30]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2
upper limit	1
Variability estimate	Standard error of the mean
Dispersion value	1

Notes:

[30] - MMRM model included treatment, visit (as categorical), 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	294
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [31]
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	0.9

Notes:

[31] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.008 [32]
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	0.9

Notes:

[32] - MMRM model included treatment, visit (as categorical), 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	294
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [33]
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	0.9

Notes:

[33] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.039 [34]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4
upper limit	0
Variability estimate	Standard error of the mean
Dispersion value	0.9

Notes:

[34] - MMRM model included treatment, visit (as categorical), 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 Global Assessment of Disease Activity (SGA) at Weeks 4, 12, and 24

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

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	153	148	
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	68.0 (± 20.6)	69.0 (± 20.2)	70.0 (± 18.0)	
Change from Baseline at Week 4 (N=146,149,138)	-21.0 (± 23.2)	-20.0 (± 26.1)	-10.0 (± 22.6)	
Change from Baseline at Week 12 (N=137,140,130)	-31.0 (± 25.9)	-27.0 (± 28.4)	-14.0 (± 26.3)	
Change from Baseline at Week 24 (N=123,112,92)	-38.0 (± 26.8)	-34.0 (± 28.1)	-24.0 (± 28.0)	

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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [35]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17
upper limit	-7
Variability estimate	Standard error of the mean
Dispersion value	2.7

Notes:

[35] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [36]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16
upper limit	-5
Variability estimate	Standard error of the mean
Dispersion value	2.7

Notes:

[36] - MMRM model included treatment, visit (as categorical), 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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [37]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24
upper limit	-12
Variability estimate	Standard error of the mean
Dispersion value	3

Notes:

[37] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [38]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19
upper limit	-7
Variability estimate	Standard error of the mean
Dispersion value	3

Notes:

[38] - MMRM model included treatment, visit (as categorical), 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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [39]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-25
upper limit	-12
Variability estimate	Standard error of the mean
Dispersion value	3.4

Notes:

[39] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [40]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19
upper limit	-6
Variability estimate	Standard error of the mean
Dispersion value	3.4

Notes:

[40] - MMRM model included treatment, visit (as categorical), 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: Physician's Global Assessment of Disease Activity (PGA) at Weeks 4, 12, and 24

End point title	Change From Baseline in Individual ACR Component: Physician's Global Assessment of Disease Activity (PGA) at Weeks 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 3 (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 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	153	148	
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	69.0 (± 17.6)	68.0 (± 18.7)	66.0 (± 16.7)	
Change from Baseline at Week 4 (N=145,146,136)	-32.0 (± 25.2)	-30.0 (± 24.3)	-19.0 (± 22.2)	
Change from Baseline at Week 12 (N=132,138,128)	-45.0 (± 25.2)	-41.0 (± 26.7)	-28.0 (± 26.9)	
Change from Baseline at Week 24 (N=122,111,92)	-53.0 (± 22.7)	-45.0 (± 23.8)	-41.0 (± 23.5)	

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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [41]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17
upper limit	-7
Variability estimate	Standard error of the mean
Dispersion value	2.6

Notes:

[41] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [42]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-10
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15
upper limit	-5
Variability estimate	Standard error of the mean
Dispersion value	2.6

Notes:

[42] - MMRM model included treatment, visit (as categorical), 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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [43]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22
upper limit	-11
Variability estimate	Standard error of the mean
Dispersion value	2.8

Notes:

[43] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [44]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18
upper limit	-7
Variability estimate	Standard error of the mean
Dispersion value	2.7

Notes:

[44] - MMRM model included treatment, visit (as categorical), 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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [45]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18
upper limit	-8
Variability estimate	Standard error of the mean
Dispersion value	2.7

Notes:

[45] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.052 [46]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11
upper limit	0
Variability estimate	Standard error of the mean
Dispersion value	2.7

Notes:

[46] - MMRM model included treatment, visit (as categorical), 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 4, 12, and 24

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

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	153	148	
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	66.0 (± 21.6)	67.0 (± 21.7)	68.0 (± 19.9)	
Change from Baseline at Week 4 (N=145,148,137)	-22.0 (± 24.2)	-20.0 (± 26.3)	-8.0 (± 22.6)	
Change from Baseline at Week 12 (N=137,140,129)	-30.0 (± 27.9)	-27.0 (± 30.9)	-14.0 (± 27.0)	
Change from Baseline at Week 24 (N=123,113,92)	-37.0 (± 28.1)	-35.0 (± 29.1)	-24.0 (± 28.3)	

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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [47]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-21
upper limit	-10
Variability estimate	Standard error of the mean
Dispersion value	2.7

Notes:

[47] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [48]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19
upper limit	-8
Variability estimate	Standard error of the mean
Dispersion value	2.7

Notes:

[48] - MMRM model included treatment, visit (as categorical), 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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [49]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-23
upper limit	-11
Variability estimate	Standard error of the mean
Dispersion value	3.1

Notes:

[49] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [50]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19
upper limit	-7
Variability estimate	Standard error of the mean
Dispersion value	3.1

Notes:

[50] - MMRM model included treatment, visit (as categorical), 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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [51]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-23
upper limit	-10
Variability estimate	Standard error of the mean
Dispersion value	3.4

Notes:

[51] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [52]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19
upper limit	-5
Variability estimate	Standard error of the mean
Dispersion value	3.4

Notes:

[52] - MMRM model included treatment, visit (as categorical), 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 4, and 24

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

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	153	148	
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	1.70 (± 0.656)	1.64 (± 0.683)	1.65 (± 0.633)	
Change from Baseline at Week 4 (N=145,148,137)	-0.39 (± 0.493)	-0.32 (± 0.539)	-0.18 (± 0.444)	
Change from Baseline at Week 24 (N=123,113,92)	-0.75 (± 0.620)	-0.60 (± 0.660)	-0.42 (± 0.600)	

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	Placebo v Filgotinib 200 mg
Number of subjects included in analysis	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [53]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.33
upper limit	-0.11
Variability estimate	Standard error of the mean
Dispersion value	0.055

Notes:

[53] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.006 [54]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.26
upper limit	-0.04
Variability estimate	Standard error of the mean
Dispersion value	0.055

Notes:

[54] - MMRM model included treatment, visit (as categorical), 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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [55]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.51
upper limit	-0.21
Variability estimate	Standard error of the mean
Dispersion value	0.075

Notes:

[55] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003 [56]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.37
upper limit	-0.08
Variability estimate	Standard error of the mean
Dispersion value	0.075

Notes:

[56] - MMRM model included treatment, visit (as categorical), 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: High-Sensitivity C-Reactive Protein (hsCRP) at Weeks 4, 12, and 24

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

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	153	148	
Units: mg/L				
arithmetic mean (standard deviation)				
Baseline	17.21 (± 18.275)	21.49 (± 28.206)	16.42 (± 18.321)	
Change from Baseline at Week 4 (N=144,145,132)	-9.55 (± 18.421)	-12.15 (± 25.502)	1.04 (± 13.942)	
Change from Baseline at Week 12 (N=137,138,129)	-11.86 (± 19.760)	-12.02 (± 26.226)	0.57 (± 15.178)	
Change from Baseline at Week 24 (N=121,113,88)	-10.87 (± 19.083)	-11.12 (± 27.766)	-1.50 (± 15.889)	

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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [57]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-10.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.61
upper limit	-7.41
Variability estimate	Standard error of the mean
Dispersion value	1.578

Notes:

[57] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [58]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-8.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.02
upper limit	-5.82
Variability estimate	Standard error of the mean
Dispersion value	1.577

Notes:

[58] - MMRM model included treatment, visit (as categorical), 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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [59]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-10.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.19
upper limit	-7.69
Variability estimate	Standard error of the mean
Dispersion value	1.652

Notes:

[59] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [60]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-8.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.22
upper limit	-5.73
Variability estimate	Standard error of the mean
Dispersion value	1.651

Notes:

[60] - MMRM model included treatment, visit (as categorical), 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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [61]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-9.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.73
upper limit	-6
Variability estimate	Standard error of the mean
Dispersion value	1.964

Notes:

[61] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [62]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-6.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.8
upper limit	-2.98
Variability estimate	Standard error of the mean
Dispersion value	1.987

Notes:

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

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

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

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	153	148	
Units: percentage of participants				
number (confidence interval 95%)				
Week 4 (N=144,148,144)	60.4 (52.1 to 68.8)	54.7 (46.4 to 63.1)	40.3 (31.9 to 48.6)	
Week 12 (N=144,148,144)	66.7 (58.6 to 74.7)	66.2 (58.3 to 74.2)	44.4 (36.0 to 52.9)	
Week 24 (N=144,148,144)	68.8 (60.8 to 76.7)	54.1 (45.7 to 62.4)	35.4 (27.3 to 43.6)	

Statistical analyses

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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [63]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	20.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.1
upper limit	32.1

Notes:

[63] - 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.013 [64]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	14.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.4
upper limit	26.5

Notes:

[64] - 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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [65]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	22.2

Confidence interval	
level	95 %
sides	2-sided
lower limit	10.3
upper limit	34.1

Notes:

[65] - 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [66]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	21.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	10
upper limit	33.6

Notes:

[66] - 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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [67]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	33.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	21.8
upper limit	44.9

Notes:

[67] - 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001 [68]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	18.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.8
upper limit	30.5

Notes:

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

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

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

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	153	148	
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	5.9 (± 1.03)	5.9 (± 0.98)	5.9 (± 0.86)	
Change from Baseline at Week 4 (N=144,145,129)	-1.7 (± 1.16)	-1.5 (± 1.14)	-0.9 (± 1.14)	
Change from Baseline at Week 12 (N=136,137,128)	-2.4 (± 1.32)	-2.3 (± 1.38)	-1.3 (± 1.33)	
Change from Baseline at Week 24 (N=121,111,88)	-2.9 (± 1.29)	-2.6 (± 1.32)	-2.1 (± 1.28)	

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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [69]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	-0.6
Variability estimate	Standard error of the mean
Dispersion value	0.13

Notes:

[69] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [70]
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	-0.4
Variability estimate	Standard error of the mean
Dispersion value	0.13

Notes:

[70] - MMRM model included treatment, visit (as categorical), 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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [71]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.5
upper limit	-0.9
Variability estimate	Standard error of the mean
Dispersion value	0.15

Notes:

[71] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [72]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.3
upper limit	-0.7
Variability estimate	Standard error of the mean
Dispersion value	0.15

Notes:

[72] - MMRM model included treatment, visit (as categorical), 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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [73]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.5
upper limit	-0.8
Variability estimate	Standard error of the mean
Dispersion value	0.17

Notes:

[73] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [74]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	-0.4
Variability estimate	Standard error of the mean
Dispersion value	0.17

Notes:

[74] - MMRM model included treatment, visit (as categorical), 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) ≤ 3.2 at Weeks 4 and 24

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

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	153	148	
Units: percentage of participants				
number (confidence interval 95%)				
Week 4	21.8 (14.8 to 28.8)	22.2 (15.3 to 29.1)	9.5 (4.4 to 14.5)	
Week 24	48.3 (39.9 to 56.7)	37.9 (29.9 to 45.9)	20.9 (14.1 to 27.8)	

Statistical analyses

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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004 [75]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	12.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.5
upper limit	21.2

Notes:

[75] - 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003 [76]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	12.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	4
upper limit	21.5

Notes:

[76] - 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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [77]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	27.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	16.3
upper limit	38.4

Notes:

[77] - 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001 [78]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	17
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.2
upper limit	27.7

Notes:

[78] - 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 4, 12, and 24

End point title	Percentage of Participants Who Achieved DAS28 (CRP) < 2.6 at Weeks 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. 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 4, 12, and 24	

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	153	148	
Units: percentage of participants				
number (confidence interval 95%)				
Week 4	10.2 (5.0 to 15.4)	11.8 (6.3 to 17.2)	2.7 (0.0 to 5.7)	
Week 12	22.4 (15.4 to 29.5)	25.5 (18.3 to 32.7)	8.1 (3.4 to 12.8)	
Week 24	30.6 (22.8 to 38.4)	26.1 (18.9 to 33.4)	12.2 (6.6 to 17.8)	

Statistical analyses

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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.012 [79]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	7.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.3
upper limit	13.7

Notes:

[79] - 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.006 [80]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	9.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.7
upper limit	15.5

Notes:

[80] - 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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [81]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	14.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.6
upper limit	23.1

Notes:

[81] - 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [82]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	17.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.5
upper limit	26.2

[82] - 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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [83]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	18.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.6
upper limit	28.3

Notes:

[83] - 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003 [84]
Method	Regression, Logistic
Parameter estimate	Difference in Response Rates
Point estimate	14
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.6
upper limit	23.4

Notes:

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

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

End point title	American College of Rheumatology N Percent Improvement (ACR-N) at Weeks 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

scored on a scale of 0-3 [0 and 3 indicating without difficulty and 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 4, 12, and 24	

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	153	148	
Units: percent improvement				
arithmetic mean (standard deviation)				
Week 4 (N=139,141,125)	26.9 (± 24.58)	25.8 (± 27.09)	13.7 (± 19.42)	
Week 12 (N=128,135,123)	43.4 (± 29.26)	37.1 (± 30.29)	19.7 (± 25.44)	
Week 24 (N=117,109,86)	53.5 (± 27.52)	45.5 (± 32.16)	31.9 (± 29.52)	

Statistical analyses

No statistical analyses for this end point

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

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

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	153	148	
Units: participants				
Week 4: Good Response (N=144,145,129)	32	34	13	
Week 4: Moderate Response (N=144,145,129)	74	65	53	

Week 4: No Response (N=144,145,129)	38	46	63	
Week 12: Good Response (N=136,137,128)	58	56	23	
Week 12: Moderate Response (N=136,137,128)	65	58	51	
Week 12: No Response (N=136,137,128)	13	23	54	
Week 24: Good Response (N=121,111,88)	70	58	31	
Week 24: Moderate Response (N=121,111,88)	43	47	45	
Week 24: No Response (N=121,111,88)	8	6	12	

Statistical analyses

No statistical analyses for this end point

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

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

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	153	148	
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	41.7 (± 14.23)	40.4 (± 13.23)	41.4 (± 12.00)	
Change from Baseline at Week 4 (N=145,146,135)	-19.1 (± 13.06)	-16.8 (± 12.95)	-12.8 (± 13.71)	
Change from Baseline at Week 12 (N=132,137,128)	-26.2 (± 15.04)	-23.8 (± 14.33)	-17.3 (± 15.22)	
Change from Baseline at Week 24 (N=122,110,92)	-30.9 (± 13.77)	-27.8 (± 13.54)	-25.4 (± 14.40)	

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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [85]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-7.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10
upper limit	-4.2
Variability estimate	Standard error of the mean
Dispersion value	1.47

Notes:

[85] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [86]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.9
upper limit	-2.2
Variability estimate	Standard error of the mean
Dispersion value	1.46

Notes:

[86] - MMRM model included treatment, visit (as categorical), 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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [87]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-9.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.6
upper limit	-6.5
Variability estimate	Standard error of the mean
Dispersion value	1.56

Notes:

[87] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [88]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-7.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.6
upper limit	-4.5
Variability estimate	Standard error of the mean
Dispersion value	1.55

Notes:

[88] - MMRM model included treatment, visit (as categorical), 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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [89]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-8.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.9
upper limit	-5.5
Variability estimate	Standard error of the mean
Dispersion value	1.64

Notes:

[89] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003 [90]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-4.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.2
upper limit	-1.6
Variability estimate	Standard error of the mean
Dispersion value	1.66

Notes:

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

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

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

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	153	148	
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	43.4 (± 14.64)	42.6 (± 14.16)	43.0 (± 12.33)	
Change from Baseline at Week 4 (N=143,143,129)	-20.1 (± 13.73)	-18.1 (± 13.19)	-12.9 (± 14.01)	
Change from Baseline at Week 12 (N=131,135,127)	-27.6 (± 15.54)	-24.9 (± 15.01)	-17.2 (± 15.52)	
Change from Baseline at Week 24 (N=120,110,88)	-32.1 (± 14.41)	-28.8 (± 14.19)	-24.9 (± 14.84)	

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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [91]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.1
upper limit	-5.1
Variability estimate	Standard error of the mean
Dispersion value	1.52

Notes:

[91] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [92]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-5.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.9
upper limit	-2.9
Variability estimate	Standard error of the mean
Dispersion value	1.52

Notes:

[92] - MMRM model included treatment, visit (as categorical), 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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [93]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-10.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.8
upper limit	-7.5
Variability estimate	Standard error of the mean
Dispersion value	1.6

Notes:

[93] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [94]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-8.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.8
upper limit	-5.5
Variability estimate	Standard error of the mean
Dispersion value	1.59

Notes:

[94] - MMRM model included treatment, visit (as categorical), 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	295
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [95]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-10.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.5
upper limit	-6.8
Variability estimate	Standard error of the mean
Dispersion value	1.7

Notes:

[95] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [96]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	-6.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.4
upper limit	-2.7
Variability estimate	Standard error of the mean
Dispersion value	1.71

Notes:

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

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	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	153	148	
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 4 (N=147,149,146)	35.4 (± 8.72)	36.4 (± 9.29)	33.7 (± 8.67)	
Week 12 (N=142,144,133)	38.3 (± 10.14)	38.6 (± 9.39)	35.1 (± 9.90)	
Week 24 (N=123,112,92)	40.4 (± 9.64)	40.3 (± 10.31)	37.7 (± 9.09)	

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	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	146	153	148	
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	30.4 (± 7.75)	31.7 (± 7.76)	31.1 (± 8.17)	
Change from Baseline at Week 4 (N=146,149,146)	5.1 (± 6.34)	4.5 (± 6.53)	2.5 (± 5.91)	
Change from Baseline at Week 12 (N=141,144,133)	7.6 (± 7.68)	6.8 (± 8.22)	3.6 (± 8.16)	
Change from Baseline at Week 24 (N=122,112,92)	9.4 (± 8.23)	9.0 (± 8.44)	6.6 (± 7.95)	

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	Placebo v Filgotinib 200 mg
Number of subjects included in analysis	294
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [97]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	2.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.1
upper limit	3.9
Variability estimate	Standard error of the mean
Dispersion value	0.7

Notes:

[97] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005 [98]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	3.4
Variability estimate	Standard error of the mean
Dispersion value	0.7

Notes:

[98] - MMRM model included treatment, visit (as categorical), 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	294
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [99]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	4.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.5
upper limit	6.1
Variability estimate	Standard error of the mean
Dispersion value	0.92

Notes:

[99] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [100]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	3.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.6
upper limit	5.2
Variability estimate	Standard error of the mean
Dispersion value	0.92

Notes:

[100] - MMRM model included treatment, visit (as categorical), 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	294
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [101]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	3.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.9
upper limit	5.9
Variability estimate	Standard error of the mean
Dispersion value	1.02

Notes:

[101] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002 [102]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	3.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.1
upper limit	5.2
Variability estimate	Standard error of the mean
Dispersion value	1.03

Notes:

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

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	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	153	148	
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 4 (N=147,149,146)	48.0 (± 11.48)	47.3 (± 11.51)	45.5 (± 11.11)	
Week 12 (N=142,144,133)	50.2 (± 10.58)	48.8 (± 11.02)	47.9 (± 11.01)	
Week 24 (N=123,112,92)	50.6 (± 10.35)	49.5 (± 10.72)	49.1 (± 10.56)	

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	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	146	153	148	
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	44.5 (± 11.97)	44.2 (± 11.59)	44.3 (± 11.32)	
Change from Baseline at Week 4 (N=146,149,146)	3.5 (± 9.17)	3.0 (± 9.03)	1.2 (± 9.34)	
Change from Baseline at Week 12 (N=141,144,133)	5.3 (± 10.60)	4.6 (± 9.76)	3.7 (± 9.17)	
Change from Baseline at Week 24 (N=122,112,92)	6.5 (± 12.50)	4.6 (± 9.22)	4.3 (± 9.44)	

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	294
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.019 [103]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	2.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.4
upper limit	4.2
Variability estimate	Standard error of the mean
Dispersion value	0.97

Notes:

[103] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.073 [104]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	3.6
Variability estimate	Standard error of the mean
Dispersion value	0.97

Notes:

[104] - MMRM model included treatment, visit (as categorical), 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	294
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.045 [105]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	2.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	4.1
Variability estimate	Standard error of the mean
Dispersion value	1.03

Notes:

[105] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.32 [106]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	3
Variability estimate	Standard error of the mean
Dispersion value	1.02

Notes:

[106] - MMRM model included treatment, visit (as categorical), 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	294
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.12 [107]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	1.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.5
upper limit	4.2
Variability estimate	Standard error of the mean
Dispersion value	1.19

Notes:

[107] - MMRM model included treatment, visit (as categorical), 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	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.96 [108]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.3
upper limit	2.4
Variability estimate	Standard error of the mean
Dispersion value	1.2

Notes:

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

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	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	153	148	
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 4 (N=145,144,144)	30.4 (± 12.48)	30.3 (± 12.30)	27.9 (± 11.29)	
Week 12 (N=141,143,132)	34.0 (± 12.08)	32.1 (± 13.66)	30.4 (± 11.79)	
Week 24 (N=123,110,90)	36.3 (± 11.58)	34.4 (± 12.51)	33.3 (± 11.26)	

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	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	146	152	147	
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	24.2 (± 11.47)	23.7 (± 12.30)	25.4 (± 10.89)	
Change from Baseline at Week 4 (N=144,144,144)	6.2 (± 10.20)	6.4 (± 9.87)	2.2 (± 8.92)	
Change from Baseline at Week 12 (N=140,143,132)	9.6 (± 11.24)	8.3 (± 10.80)	4.5 (± 10.37)	
Change from Baseline at Week 24 (N=122,110,90)	11.6 (± 11.67)	9.8 (± 10.39)	7.0 (± 10.23)	

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	293
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [109]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	3.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.6
upper limit	5.7
Variability estimate	Standard error of the mean
Dispersion value	1.05

Notes:

[109] - MMRM model included treatment, visit (as categorical), 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	299
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002 [110]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	3.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.2
upper limit	5.4
Variability estimate	Standard error of the mean
Dispersion value	1.05

Notes:

[110] - MMRM model included treatment, visit (as categorical), 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	293
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [111]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	7.3
Variability estimate	Standard error of the mean
Dispersion value	1.19

Notes:

[111] - MMRM model included treatment, visit (as categorical), 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	299
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007 [112]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	3.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	5.5
Variability estimate	Standard error of the mean
Dispersion value	1.18

Notes:

[112] - MMRM model included treatment, visit (as categorical), 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	293
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [113]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	4.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.1
upper limit	7.1
Variability estimate	Standard error of the mean
Dispersion value	1.28

Notes:

[113] - MMRM model included treatment, visit (as categorical), 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	299
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.11 [114]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	2.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.5
upper limit	4.7
Variability estimate	Standard error of the mean
Dispersion value	1.3

Notes:

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

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	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	153	148	
Units: participants				
Mobility: Wk 4: No Problems (N=145,144,144)	34	45	32	
Mobility: Wk 4: Slight Problems (N=145,144,144)	58	49	49	
Mobility: Wk 4: Moderate Problems (N=145,144,144)	38	33	36	
Mobility: Wk 4: Severe Problems (N=145,144,144)	15	16	25	
Mobility: Wk 4: Extreme Problems (N=145,144,144)	0	1	2	
Mobility: Wk 12: No Problems (N=141,143,132)	47	57	38	

Mobility: Wk 12: Slight Problems (N=141,143,132)	55	48	46	
Mobility: Wk 12: Moderate Problems (N=141,143,132)	25	29	29	
Mobility: Wk 12: Severe Problems (N=141,143,132)	13	9	19	
Mobility: Wk 12: Extreme Problems (N=141,143,132)	1	0	0	
Mobility: Wk 24: No Problems (N=123,110,90)	51	38	32	
Mobility: Wk 24: Slight Problems (N=123,110,90)	38	45	29	
Mobility: Wk 24: Moderate Problems (N=123,110,90)	23	18	24	
Mobility: Wk 24: Severe Problems (N=123,110,90)	11	8	5	
Mobility: Wk 24: Extreme Problems (N=123,110,90)	0	1	0	
Self-care: Wk 4: No Problems (N=145,144,144)	67	67	49	
Self-care: Wk 4: Slight Problems (N=145,144,144)	45	43	52	
Self-care: Wk 4: Moderate Problems (N=145,144,144)	24	27	28	
Self-care: Wk 4: Severe Problems (N=145,144,144)	6	6	11	
Self-care: Wk 4: Extreme Problems (N=145,144,144)	3	1	4	
Self-care: Wk 12: No Problems (N=141,143,132)	79	78	56	
Self-care: Wk 12: Slight Problems (N=141,143,132)	38	46	44	
Self-care: Wk 12: Moderate Problems(N=141,143,132)	16	15	21	
Self-care: Wk 12: Severe Problems (N=141,143,132)	6	4	11	
Self-care: Wk 12: Extreme Problems (N=141,143,132)	2	0	0	
Self-care: Wk 24: No Problems (N=123,110,90)	83	58	45	
Self-care: Wk 24: Slight Problems (N=123,110,90)	23	31	31	
Self-care: Wk 24: Moderate Problems (N=123,110,90)	13	16	10	
Self-care: Wk 24: Severe Problems (N=123,110,90)	4	4	4	
Self-care: Wk 24: Extreme Problems (N=123,110,90)	0	1	0	
Usu Act: Wk 4: No Problems (N=145,144,144)	27	38	22	
Usu Act: Wk 4: Slight Problems (N=145,144,144)	65	50	44	
Usu Act: Wk 4: Moderate Problems (N=145,144,144)	26	38	49	
Usu Act: Wk 4: Severe Problems (N=145,144,144)	19	12	25	
Usu Act: Wk 4: Extreme Problems (N=145,144,144)	8	6	4	
Usu Act: Wk 12: No Problems (N=141,143,132)	47	51	26	
Usu Act: Wk 12: Slight Problems (N=141,143,132)	54	41	48	

Usu Act: Wk 12: Moderate Problems (N=141,143,132)	25	37	38	
Usu Act: Wk 12: Severe Problems (N=141,143,132)	15	11	20	
Usu Act: Wk 12: Extreme Problems (N=141,143,132)	0	3	0	
Usu Act: Wk 24: No Problems (N=123,110,90)	51	41	20	
Usu Act: Wk 24: Slight Problems (N=123,110,90)	45	32	41	
Usu Act: Wk 24: Moderate Problems (N=123,110,90)	18	28	24	
Usu Act: Wk 24: Severe Problems (N=123,110,90)	8	7	4	
Usu Act: Wk 24: Extreme Problems (N=123,110,90)	1	2	1	
Pai/Disc: Wk 4: No Problems (N=145,144,144)	8	11	3	
Pai/Disc: Wk 4: Slight Problems (N=145,144,144)	69	57	37	
Pai/Disc: Wk 4: Moderate Problems (N=145,144,144)	45	50	62	
Pai/Disc: Wk 4: Severe Problems (N=145,144,144)	19	22	36	
Pai/Disc: Wk 4: Extreme Problems (N=145,144,144)	4	4	6	
Pai/Disc: Wk 12: No Problems (N=141,143,132)	21	16	10	
Pai/Disc: Wk 12: Slight Problems (N=141,143,132)	68	56	36	
Pai/Disc: Wk 12: Moderate Problems (N=141,143,132)	34	56	57	
Pai/Disc: Wk 12: Severe Problems (N=141,143,132)	17	14	28	
Pai/Disc: Wk 12: Extreme Problems (N=141,143,132)	1	1	1	
Pai/Disc: Wk 24: No Problems (N=123,110,90)	18	20	10	
Pai/Disc: Wk 24: Slight Problems (N=123,110,90)	61	42	32	
Pai/Disc: Wk 24: Moderate Problems (N=123,110,90)	31	36	33	
Pai/Disc: Wk 24: Severe Problems (N=123,110,90)	12	10	14	
Pai/Disc: Wk 24: Extreme Problems (N=123,110,90)	1	2	1	
Anx/Dep: Wk 4: No Problems (N=145,144,144)	78	77	60	
Anx/Dep: Wk 4: Slight Problems (N=145,144,144)	33	41	43	
Anx/Dep: Wk 4: Moderate Problems (N=145,144,144)	25	21	34	
Anx/Dep: Wk 4: Severe Problems (N=145,144,144)	8	4	5	
Anx/Dep: Wk 4: Extreme Problems (N=145,144,144)	1	1	2	
Anx/Dep: Wk 12: No Problems (N=141,143,132)	79	84	71	
Anx/Dep: Wk 12: Slight Problems (N=141,143,132)	33	30	34	
Anx/Dep: Wk 12: Moderate Problems (N=141,143,132)	23	26	23	

Anx/Dep: Wk 12: Severe Problems (N=141,143,132)	5	3	3
Anx/Dep: Wk 12: Extreme Problems (N=141,143,132)	1	0	1
Anx/Dep: Wk 24: No Problems (N=123,110,90)	70	62	50
Anx/Dep: Wk 24: Slight Problems (N=123,110,90)	33	30	19
Anx/Dep: Wk 24: Moderate Problems (N=123,110,90)	16	13	15
Anx/Dep: Wk 24: Severe Problems (N=123,110,90)	4	4	6
Anx/Dep: Wk 24: Extreme Problems (N=123,110,90)	0	1	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 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 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	153	148	
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 4 (N=145,144,144)	59.0 (± 22.1)	60.0 (± 19.8)	52.0 (± 24.2)	
Week 12 (N=141,143,132)	66.0 (± 23.2)	65.0 (± 22.2)	58.0 (± 23.0)	
Week 24 (N=123,110,90)	70.0 (± 21.8)	69.0 (± 21.3)	62.0 (± 23.0)	

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	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	146	152	147	
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	49.0 (± 24.7)	46.0 (± 24.0)	46.0 (± 22.4)	
Change from Baseline at Week 4 (N=144,144,144)	10.0 (± 27.6)	14.0 (± 26.8)	6.0 (± 26.0)	
Change from Baseline at Week 12 (N=140,143,132)	17.0 (± 30.9)	19.0 (± 26.4)	12.0 (± 26.5)	
Change from Baseline at Week 24 (N=122,110,90)	22.0 (± 30.8)	25.0 (± 26.7)	17.0 (± 25.4)	

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	293
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.009 [115]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	6
Confidence interval	
level	95 %
sides	2-sided
lower limit	2
upper limit	11
Variability estimate	Standard error of the mean
Dispersion value	2.5

Notes:

[115] - MMRM model included treatment, visit (as categorical), 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	299
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003 [116]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	7
Confidence interval	
level	95 %
sides	2-sided
lower limit	3
upper limit	12
Variability estimate	Standard error of the mean
Dispersion value	2.5

Notes:

[116] - MMRM model included treatment, visit (as categorical), 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	293
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003 [117]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	8
Confidence interval	
level	95 %
sides	2-sided
lower limit	3
upper limit	13
Variability estimate	Standard error of the mean
Dispersion value	2.6

Notes:

[117] - MMRM model included treatment, visit (as categorical), 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	299
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.006 [118]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	7
Confidence interval	
level	95 %
sides	2-sided
lower limit	2
upper limit	12
Variability estimate	Standard error of the mean
Dispersion value	2.6

Notes:

[118] - MMRM model included treatment, visit (as categorical), 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	293
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002 [119]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	9
Confidence interval	
level	95 %
sides	2-sided
lower limit	3
upper limit	15
Variability estimate	Standard error of the mean
Dispersion value	2.9

Notes:

[119] - MMRM model included treatment, visit (as categorical), 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	299
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007 [120]
Method	MMRM
Parameter estimate	Least Squares Mean Difference
Point estimate	8
Confidence interval	
level	95 %
sides	2-sided
lower limit	2
upper limit	14
Variability estimate	Standard error of the mean
Dispersion value	2.9

Notes:

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

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: $100 \times \{Q2/(Q2+Q4)\}$. 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	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	153	148	
Units: percentage of work time missed				
arithmetic mean (standard deviation)				
Week 4 (N=39,53,46)	8.8 (± 21.01)	18.2 (± 30.93)	14.3 (± 27.52)	
Week 12 (N=38,48,45)	5.6 (± 13.79)	14.6 (± 27.13)	12.1 (± 24.39)	
Week 24 (N=40,38,30)	7.6 (± 16.37)	13.8 (± 26.23)	8.5 (± 18.08)	

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: $100 \times \{Q5/10\}$. 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	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	153	148	
Units: percentage of impairment while working				
arithmetic mean (standard deviation)				
Week 4 (N=38,49,43)	27.4 (± 22.50)	37.8 (± 25.43)	48.6 (± 29.81)	
Week 12 (N=38,46,43)	23.9 (± 20.99)	34.8 (± 27.22)	44.2 (± 29.21)	
Week 24 (N=40,36,30)	28.0 (± 27.57)	25.6 (± 22.10)	36.7 (± 26.95)	

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: $100 \times \{Q2/(Q2+Q4) + [(1-Q2/(Q2+Q4) \times (Q5/10)]\}$. 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	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	153	148	
Units: percentage of overall work productivity				
arithmetic mean (standard deviation)				
Week 4 (N=38,49,43)	30.8 (± 24.36)	43.1 (± 27.82)	51.3 (± 30.85)	
Week 12 (N=38,46,43)	26.9 (± 24.20)	39.5 (± 29.37)	46.9 (± 30.63)	
Week 24 (N=40,36,30)	31.7 (± 29.94)	31.4 (± 25.65)	39.8 (± 29.49)	

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	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	153	148	
Units: percentage of activity impairment				
arithmetic mean (standard deviation)				
Week 4 (N=145,144,144)	49.6 (± 26.56)	49.9 (± 27.43)	60.3 (± 25.49)	
Week 12 (N=141,143,132)	40.3 (± 26.75)	45.5 (± 28.23)	53.0 (± 27.26)	
Week 24 (N=123,110,90)	33.3 (± 24.61)	37.5 (± 27.00)	45.7 (± 25.57)	

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	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	35	54	48	
Units: percentage of work time missed				
arithmetic mean (standard deviation)				
Baseline	11.3 (± 16.31)	19.2 (± 28.57)	10.8 (± 25.65)	
Change from Baseline at Week 4 (N=34,48,43)	-4.3 (± 20.98)	-3.4 (± 24.57)	4.0 (± 20.75)	
Change from Baseline at Week 12 (N=31,46,40)	-3.6 (± 17.60)	-7.0 (± 30.93)	3.8 (± 18.40)	
Change from Baseline at Week 24 (N=29,34,25)	-4.6 (± 22.50)	-3.1 (± 34.28)	3.7 (± 25.13)	

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 analyzed.

End point type	Secondary

End point timeframe:

Baseline; Weeks 4, 12, and 24

End point values	Filgotinib 200 mg	Filgotinib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	35	51	46	
Units: percentage of impairment while working				
arithmetic mean (standard deviation)				
Baseline	46.9 (± 24.71)	51.0 (± 27.95)	55.7 (± 26.64)	
Change from Baseline at Week 4 (N=34,45,40)	-19.1 (± 25.63)	-13.1 (± 25.75)	-5.3 (± 25.52)	
Change from Baseline at Week 12 (N=31,42,38)	-20.0 (± 25.56)	-18.8 (± 28.64)	-10.8 (± 20.32)	
Change from Baseline at Week 24 (N=29,31,25)	-18.6 (± 22.48)	-28.7 (± 25.26)	-20.0 (± 31.36)	

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	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	35	51	46	
Units: percentage of overall work productivity				
arithmetic mean (standard deviation)				
Baseline	52.0 (± 24.02)	55.8 (± 30.53)	56.7 (± 27.60)	
Change from Baseline at Week 4 (N=34,45,40)	-20.9 (± 28.94)	-12.3 (± 28.05)	-3.4 (± 25.48)	
Change from Baseline at Week 12 (N=31,42,38)	-22.8 (± 29.20)	-19.5 (± 31.49)	-8.3 (± 20.16)	
Change from Baseline at Week 24 (N=29,31,25)	-20.5 (± 26.20)	-26.4 (± 29.87)	-16.7 (± 33.28)	

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	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	146	152	147	
Units: percentage of activity impairment				
arithmetic mean (standard deviation)				
Baseline	65.6 (± 22.16)	64.6 (± 23.07)	65.4 (± 23.33)	
Change from Baseline at Week 4 (N=144,144,144)	-16.0 (± 24.64)	-14.3 (± 22.89)	-4.7 (± 25.06)	
Change from Baseline at Week 12 (N=140,143,132)	-25.0 (± 26.81)	-19.2 (± 28.32)	-11.3 (± 25.75)	
Change from Baseline at Week 24 (N=122,110,90)	-32.5 (± 27.37)	-27.1 (± 27.97)	-18.4 (± 31.23)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

First dose date up to last dose date (Maximum 29.3 weeks) plus 30 days

Adverse event reporting additional description:

Safety Analysis Set included all participants who received at least 1 dose of study drug.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21.0

Reporting groups

Reporting group title	Filgotinib 200 mg

Reporting group description:

Participants were administered filgotinib 200 mg tablet orally, once daily + placebo to match (PTM) filgotinib 100 mg tablet orally, once daily + stable dose of permitted csDMARDs for median exposure of 24.1 weeks.

Reporting group title	Filgotinib 100 mg

Reporting group description:

Participants were administered filgotinib 100 mg tablet orally, once daily + PTM filgotinib 200 mg tablet orally, once daily + stable dose of permitted csDMARDs for median exposure of 24 weeks.

Reporting group title	Placebo

Reporting group description:

Participants were administered PTM filgotinib 200 mg tablet orally, once daily + PTM filgotinib 100 mg tablet orally, once daily + stable dose of permitted csDMARDs for median exposure of 24 weeks.

Serious adverse events	Filgotinib 200 mg	Filgotinib 100 mg	Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 147 (4.08%)	8 / 153 (5.23%)	5 / 148 (3.38%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	1 / 147 (0.68%)	0 / 153 (0.00%)	0 / 148 (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
Laceration			
subjects affected / exposed	1 / 147 (0.68%)	0 / 153 (0.00%)	0 / 148 (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
Lumbar vertebral fracture			

subjects affected / exposed	0 / 147 (0.00%)	0 / 153 (0.00%)	1 / 148 (0.68%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	1 / 147 (0.68%)	0 / 153 (0.00%)	0 / 148 (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
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 147 (0.00%)	0 / 153 (0.00%)	1 / 148 (0.68%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial ischaemia			
subjects affected / exposed	0 / 147 (0.00%)	1 / 153 (0.65%)	0 / 148 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 147 (0.00%)	1 / 153 (0.65%)	0 / 148 (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 / 147 (0.00%)	0 / 153 (0.00%)	1 / 148 (0.68%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 147 (0.00%)	0 / 153 (0.00%)	1 / 148 (0.68%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			

subjects affected / exposed	1 / 147 (0.68%)	0 / 153 (0.00%)	0 / 148 (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
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 147 (0.68%)	0 / 153 (0.00%)	0 / 148 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 147 (0.00%)	0 / 153 (0.00%)	1 / 148 (0.68%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 147 (0.00%)	0 / 153 (0.00%)	1 / 148 (0.68%)
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			
Uterine haemorrhage			
subjects affected / exposed	1 / 147 (0.68%)	0 / 153 (0.00%)	0 / 148 (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
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 147 (0.00%)	0 / 153 (0.00%)	1 / 148 (0.68%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	1 / 147 (0.68%)	0 / 153 (0.00%)	0 / 148 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			

subjects affected / exposed	0 / 147 (0.00%)	1 / 153 (0.65%)	0 / 148 (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			
Bursitis			
subjects affected / exposed	1 / 147 (0.68%)	0 / 153 (0.00%)	0 / 148 (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
Lumbar spinal stenosis			
subjects affected / exposed	0 / 147 (0.00%)	1 / 153 (0.65%)	0 / 148 (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
Osteitis			
subjects affected / exposed	0 / 147 (0.00%)	1 / 153 (0.65%)	0 / 148 (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
Rheumatoid arthritis			
subjects affected / exposed	0 / 147 (0.00%)	0 / 153 (0.00%)	1 / 148 (0.68%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	0 / 147 (0.00%)	0 / 153 (0.00%)	2 / 148 (1.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess oral			
subjects affected / exposed	0 / 147 (0.00%)	1 / 153 (0.65%)	0 / 148 (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
Bronchitis			
subjects affected / exposed	0 / 147 (0.00%)	1 / 153 (0.65%)	0 / 148 (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

Cellulitis	Filgotinib 200 mg	Filgotinib 100 mg	Placebo
subjects affected / exposed	1 / 147 (0.68%)	0 / 153 (0.00%)	0 / 148 (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
Gallbladder empyema			
subjects affected / exposed	0 / 147 (0.00%)	1 / 153 (0.65%)	0 / 148 (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
Vulval abscess			
subjects affected / exposed	0 / 147 (0.00%)	1 / 153 (0.65%)	0 / 148 (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	1 / 147 (0.68%)	0 / 153 (0.00%)	1 / 148 (0.68%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 147 (0.00%)	0 / 153 (0.00%)	1 / 148 (0.68%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lactic acidosis			
subjects affected / exposed	1 / 147 (0.68%)	0 / 153 (0.00%)	0 / 148 (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

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

Non-serious adverse events	Filgotinib 200 mg	Filgotinib 100 mg	Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	39 / 147 (26.53%)	35 / 153 (22.88%)	31 / 148 (20.95%)
Nervous system disorders			
Headache			
subjects affected / exposed	8 / 147 (5.44%)	9 / 153 (5.88%)	2 / 148 (1.35%)
occurrences (all)	8	11	2

Gastrointestinal disorders			
Nausea			
subjects affected / exposed	7 / 147 (4.76%)	8 / 153 (5.23%)	5 / 148 (3.38%)
occurrences (all)	9	8	5
Musculoskeletal and connective tissue disorders			
Rheumatoid arthritis			
subjects affected / exposed	2 / 147 (1.36%)	2 / 153 (1.31%)	8 / 148 (5.41%)
occurrences (all)	2	2	11
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	15 / 147 (10.20%)	9 / 153 (5.88%)	7 / 148 (4.73%)
occurrences (all)	15	11	7
Upper respiratory tract infection			
subjects affected / exposed	8 / 147 (5.44%)	9 / 153 (5.88%)	6 / 148 (4.05%)
occurrences (all)	9	9	6
Bronchitis			
subjects affected / exposed	8 / 147 (5.44%)	3 / 153 (1.96%)	8 / 148 (5.41%)
occurrences (all)	9	5	8

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
05 July 2016	• Updated to reflect the removal of radiologic assessments (including removal of modified Total Sharp Score [mTSS] objectives as a measure of joint structural damage derived from x-rays) • Added urine biomarker samples as an exploratory endpoint • Updated study procedures to collect body weight at all study visits • Updated study procedures to include Treatment Satisfaction Questionnaire for Medication (TSQM) collection at several study visits • Added a carotid artery ultrasound substudy • Added an assessment of quantitative immunoglobulin (Ig) at Day 1 and Week 24 (Early Termination) • Added assessments of hemoglobin A1c (HbA1c), leptin, low-density lipoprotein (LDL) particle, homocysteine, and Apo A1/B for subjects participating in the carotid artery ultrasound substudy • Removed peripheral blood mononuclear cell biomarker sampling • Clarified criteria for interruption of study drugs • Updated the definition of postmenopausal females

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

 None reported