Clinical trial results:
A Phase 3, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of Filgotinib in Subjects with Active Psoriatic Arthritis Who Have an Inadequate Response or are Intolerant to Biologic DMARD Therapy

Summary

EudraCT number	2019-002021-29
Trial protocol	DE GB BE HU PL ES CZ IT
Global end of trial date	18 March 2021

Results information

Result version number	v2 (current)
This version publication date	08 March 2022
First version publication date	15 January 2022
Version creation reason	• Correction of full data set Update to the statistical information provided along with the outcome measures 14, 70, 72 and 76 . Updates to the time frames of the outcome measures 46 an 51. Update to the overall number of participants analysed in outcome measures 67 and 69.

Trial information

Trial identification

Sponsor protocol code	GS-US-431-4567

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04115839
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	18 March 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 January 2021
Global end of trial reached?	Yes
Global end of trial date	18 March 2021
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to evaluate the effect of filgotinib compared to placebo as assessed by the American College of Rheumatology 20% improvement (ACR20) response in participants with active psoriatic arthritis who have an inadequate response or are intolerant to biologic disease-modifying anti-rheumatic drugs (DMARD) therapy.

Protection of trial subjects:

The protocol and consent/assent forms were submitted by each investigator to a duly constituted Independent Ethics Committee (IEC) or Institutional Review Board (IRB) for review and approval before study initiation. All revisions to the consent/assent forms (if applicable) after initial IEC/IRB approval were submitted by the investigator to the IEC/IRB for review and approval before implementation in accordance with regulatory requirements. This study was conducted in accordance with recognized international scientific and ethical standards, including but not limited to the International Conference on Harmonization guideline for Good Clinical Practice (ICH GCP) and the original principles embodied in the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	13 November 2019
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	Australia: 2
Country: Number of subjects enrolled	Canada: 3
Country: Number of subjects enrolled	Czechia: 6
Country: Number of subjects enrolled	Hungary: 2
Country: Number of subjects enrolled	Japan: 2
Country: Number of subjects enrolled	Poland: 27
Country: Number of subjects enrolled	Korea, Republic of: 1
Country: Number of subjects enrolled	Spain: 17
Country: Number of subjects enrolled	Taiwan: 1
Country: Number of subjects enrolled	United States: 45
Worldwide total number of subjects	106
EEA total number of subjects	52

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)	91
From 65 to 84 years	15
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled at study sites in the United States, Europe, Canada, Australia, and Asia. The first participant was screened on 13 November 2019. The last study visit occurred on 18 March 2021.

Pre-assignment

Screening details:

170 participants were screened.

Period 1

Period 1 title	Main Study (Up to 16 Weeks)
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 (Main Study)

Arm description:

Filgotinib 200 milligrams (mg) tablet orally once daily + placebo to match (PTM) filgotinib 100 mg tablet orally once daily for 16 weeks.

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

Dosage and administration details:

Administered once daily with or without food.

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 tablets administered once daily with or without food.

Arm title	Filgotinib 100 mg (Main Study)

Arm description:

Filgotinib 100 mg tablet orally once daily + PTM filgotinib 200 mg tablet orally once daily for 16 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 tablets administered once daily with or without food.

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

Dosage and administration details:

Administered once daily with or without food.

Arm title	Placebo (Main Study)

Arm description:

PTM filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily for 16 weeks.

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

Dosage and administration details:

Administered once daily with or without food.

Number of subjects in period 1	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)
Started	36	34	36
Completed	18	20	18
Not completed	18	14	18
Withdrew Consent	2	1	3
Adverse Event	2	-	-
Investigator's Discretion	-	-	1
Study Terminated by Sponsor	14	13	14

Period 2

Period 2 title	LTE Phase (After Week 16 to Week 63)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes

Arm title	Filgotinib 200 mg From Filgotinib 200 mg (LTE)

Arm description:

Long term extension (LTE):
Filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily for up to 44.3 weeks. Participants received filgotinib 200 mg in the Main Study.

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 tablets administered once daily with or without food.

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

Dosage and administration details:

Administered once daily with or without food.

Arm title	Filgotinib 100 mg From Filgotinib 100 mg (LTE)

Arm description:

Filgotinib 100 mg tablet orally once daily + PTM filgotinib 200 mg tablet orally once daily for up to 43.9 weeks. Participants received filgotinib 100 mg in the Main Study.

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 tablets administered once daily with or without food.

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

Dosage and administration details:

Administered once daily with or without food.

Arm title	Filgotinib 200 mg From Placebo (LTE)

Arm description:

Filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily for up to 44.1 weeks. Participants received placebo in the Main Study.

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 tablets administered once daily with or without food.

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

Dosage and administration details:

Administered once daily with or without food.

Arm title	Filgotinib 100 mg From Placebo (LTE)

Arm description:

Filgotinib 100 mg tablet orally once daily + PTM filgotinib 200 mg tablet orally once daily for up to 44 weeks. Participants received placebo in the Main Study.

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 tablets administered once daily with or without food.

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

Dosage and administration details:

Administered once daily with or without food.

Number of subjects in period 2	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)
Started	18	20	10
Completed	0	0	0
Not completed	18	20	10
Adverse Event	1	1	-
Study Terminated by Sponsor	17	19	10

Number of subjects in period 2	Filgotinib 100 mg From Placebo (LTE)
Started	8
Completed	0
Not completed	8
Adverse Event	-
Study Terminated by Sponsor	8

Baseline characteristics

Reporting groups	
Reporting group title	Filgotinib 200 mg (Main Study)
Reporting group description:	
Filgotinib 200 milligrams (mg) tablet orally once daily + placebo to match (PTM) filgotinib 100 mg tablet orally once daily for 16 weeks.	
Reporting group title	Filgotinib 100 mg (Main Study)
Reporting group description:	
Filgotinib 100 mg tablet orally once daily + PTM filgotinib 200 mg tablet orally once daily for 16 weeks.	
Reporting group title	Placebo (Main Study)
Reporting group description:	
PTM filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily for 16 weeks.	

Reporting group values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)
Number of subjects	36	34	36
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	56	54	54
standard deviation	± 10.5	± 9.3	± 10.5
Gender categorical Units: Subjects			
Female	12	15	18
Male	24	19	18
Race Units: Subjects			
Asian	1	1	2
Black or African American	0	1	0
White	35	32	34
Ethnicity Units: Subjects			
Hispanic or Latino	1	3	1
Not Hispanic or Latino	35	31	35
Psoriatic Arthritis Disease Activity Score (PASDAS)			
PASDAS is a composite disease activity measure for psoriatic arthritis. The score of PASDAS range from 0 -10, lower score indicates better function.			
Units: score on a scale			
arithmetic mean	5.9	5.7	5.6
standard deviation	± 0.97	± 1.07	± 0.93
Disease Activity in Psoriatic Arthritis (DAPSA)			
DAPSA score is the sum of swollen joint count (66 joints), tender joint count (68 joints), CRP (mg/dL), patient's global assessment of PsA pain intensity (PGAPI) [using visual analogue scale (VAS) on a scale of 0-100, 0 = no pain and 100 = serious pain), and patient's global assessment of disease activity (PGADA) (using VAS on a scale of 0-100, 0 = very well and 10 = very poor). DAPSA scores 0-4 = remission, 5-14 = low disease activity, 15-28 = moderate disease activity, and >28 = high disease			

activity. Lower scores indicate better function.			
Units: score on a scale			
arithmetic mean	45.9	42.8	43.1
standard deviation	± 22.64	± 22.05	± 23.26
Physician's Global Assessment of Psoriasis (PhGAP)			
The PhGAP is used to determine the participant's psoriasis lesions overall at a given time point. The participant's psoriasis disease activity is assessed by a physician according to the grades of induration, erythema and scaling on a scale of 0 to 5. The sum of the three grades will be used to obtain the total average score. PhGAP is based on the total average score on a scale of 0-5, where, 0=cleared, 1=minimal, 2=mild, 3=moderate, 4=marked and 5=severe. Lower scores indicates better function. Participants in the FAS with ≥ 3% BSA at baseline were analyzed (N=16, 17, 16).			
Units: score on a scale			
arithmetic mean	2.7	2.8	2.9
standard deviation	± 0.79	± 0.95	± 0.81
Modified Nail Psoriasis Severity Index (mNAPSI)			
mNAPSI is used to assess each nail abnormality for each of the participant's nails. Each finger has a score between 0 and 13. The total mNAPSI score is the sum of all abnormalities of individual score across all fingers, and the total mNAPSI score ranges from 0 to 130. Lower numbers indicate fewer nail abnormalities. Participants in the FAS with Psoriatic Nail Involvement at Baseline were analyzed (N=25, 25, 30).			
Units: score on a scale			
arithmetic mean	11	15	10
standard deviation	± 9.7	± 21.4	± 7.1
Leeds Enthesitis Index (LEI)			
Enthesitis is assessed using LEI. The enthesitis examination by LEI evaluated the presence or absence of pain by applying local pressure on 6 anatomical sites: medial femoral condyle (left and right), lateral epicondyle (left and right) and the achilles tendon insertion (left and right). Enthesitis at each site was scored as 0 = enthesitis absent and 1 = enthesitis present. The total score ranges from 0 to 6, higher scores indicates greater degree of enthesitis. Participants in the FAS with enthesitis at baseline were analyzed (N=22, 22, 24).			
Units: score on a scale			
arithmetic mean	2	2	1
standard deviation	± 1.7	± 1.6	± 1.2
12-Item Psoriatic Arthritis Impact of Disease (PsAID-12)			
The PsAID questionnaire assesses the impact of PsA on people's lives. The PsAID is calculated based on 12 numerical rating scales (NRS) questions. Each NRS is assessed as a number between 0 and 10. Total score is calculated as the sum of the individual scores, (some of which were multiplied by a weighting factor) divided by 20 for a total possible score of 0 to 10, where higher score indicates worse impact of disease.			
Units: score on a scale			
arithmetic mean	5.2	5.1	4.8
standard deviation	± 1.94	± 2.33	± 2.10
Tender Joint Count Based on 68 Joints (TJC68)			
TJC68 is an assessment of 68 joints. Each joint was evaluated as 'normal', 'tender', 'tender and swollen' or 'not able to evaluate'. It is derived as the sum of all tender joints. The overall tender joint count ranged from 0 to 68, with a higher score indicating a greater degree of tenderness.			
Units: tender joint count			
arithmetic mean	23	21	22
standard deviation	± 17.2	± 14.6	± 15.3
Swollen Joint Count Based on 66 Joints (SJC66)			
SJC66 is an assessment of 66 joints. Each joint was evaluated as 'normal', 'swollen', 'tender and swollen' or 'not able to evaluate'. It is derived as the sum of all swollen joints. The overall swollen joint count ranged from 0 to 66, with a higher score indicating a greater degree of swelling.			
Units: swollen joint count			
arithmetic mean	11	10	10

standard deviation	± 6.7	± 8.7	± 8.9
Patient's Global Assessment of Disease Activity (PGADA)			
PGADA was assessed by the participants using a VAS on a scale of 0 (very well) to 100 (very poor).			
Units: score on a scale			
arithmetic mean	56	55	53
standard deviation	± 22.4	± 24.7	± 21.1
Physician's Global Assessment of Disease Activity (PhGADA)			
PhGADA was assessed by the physician using a VAS on a scale of 0 (no disease activity) to 100 (maximum disease activity).			
Units: score on a scale			
arithmetic mean	63	63	59
standard deviation	± 13.8	± 14.0	± 14.5
Health Assessment Questionnaire Disability Index (HAQ-DI)'s Pain Assessment			
Participants assessed their pain severity using a VAS on a scale of 0 (no pain) to 100 (severe pain).			
Units: score on a scale			
arithmetic mean	61	56	57
standard deviation	± 19.3	± 23.3	± 23.4
High-Sensitivity CReactive Protein (hsCRP)			
Units: milligrams per liter (mg/L)			
arithmetic mean	8.03	7.58	8.20
standard deviation	± 18.347	± 10.361	± 12.707
Disease Activity Score 28 (DAS28) C-Reactive Protein (CRP)			
DAS28(CRP) is a measure of the participant's disease activity calculated using the tender joint count (28 joints), swollen joint count (28 joints), PGADA [using a VAS on a scale of 0 (very well) to 100 (very poor)] and hsCRP for a total possible score of 1 to 9.4. Higher values indicate higher disease activity.			
Units: score on a scale			
arithmetic mean	4.8	4.8	4.8
standard deviation	± 0.98	± 0.97	± 1.00
Psoriasis Area and Severity Index (PASI)			
PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. The PASI produces a numeric score that can range from 0 (no disease) to 72 (maximal disease). A higher score indicates more severe disease. Participants in the FAS with psoriasis covering >=3% of the BSA at baseline were analyzed (N=16, 17, 16).			
Units: score on a scale			
arithmetic mean	8.5	9.6	9.1
standard deviation	± 6.54	± 6.43	± 6.25
Spondyloarthritis Research Consortium of Canada (SPARCC) Enthesitis Index			
The enthesitis examination was based on the 16 anatomical sites. SPARCC enthesitis index has an overall total score ranging from 0 to 16. Higher score indicates a greater number of sites that are affected by enthesitis. Participants in FAS with Enthesitis at Baseline were analyzed (N=22, 22, 24).			
Units: score on a scale			
arithmetic mean	4	6	4
standard deviation	± 3.8	± 4.4	± 2.8
Leeds Dactylitis Index (LDI)			
LDI measures dactylitis using circumference of involved digits, control digits and tenderness of involved digits. LDI measures ratio of circumference of affected digit to circumference of digit on contralateral hand/foot using Leeds Dactylometer. LDI score is calculated based on circumference of dactylitic finger/toe (mm), circumference of contralateral digit (mm), tenderness score. Tenderness of affected digits is assessed on a scale from 0 [no tenderness] to 3 [tender and withdrawn]. Higher LDI=worse dactylitis. Participants in FAS with Dactylitis at Baseline were analyzed (N=15, 6, 9).			

Units: score on a scale			
arithmetic mean	54.8	21.9	22.1
standard deviation	± 83.24	± 26.26	± 12.91
Tender Dactylitis Count (TDC)			
Tender score (0 = no tenderness, 1 = tender, 2 = tender and wince, 3 = tender and withdraw) is collected for Dactylitis Assessments on the Dactylitis Score Sheet that was used for calculation of LDI total score. Tender dactylitis count (TDC) equals the number of tender fingers and toes (tendor score >0). For participants with dactylitis status absent for all the fingers and toes, the TDC will be set as 0. The total score range of TDC is from 0 to 60, higher scores indicate greater presence of dactylitis. Participants in the FAS with dactylitis at baseline were analyzed (N=15, 6, 9).			
Units: tender dactylitis count			
arithmetic mean	3	1	1
standard deviation	± 4.9	± 0.6	± 0.9
Health Assessment Questionnaire-Disability Index (HAQ-DI)			
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. The eight category scores are averaged into an overall HAQ-DI score on a scale from 0 (no disability) to 3 (completely disabled). When 6 or more categories are non-missing, total possible score is 3. If more than 2 categories are missing, the HAQ-DI score is set to missing.			
Units: score on a scale			
arithmetic mean	1.24	1.03	1.13
standard deviation	± 0.637	± 0.612	± 0.557
Functional Assessment of Chronic Illness Therapy (FACIT)- Fatigue			
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. Higher scores indicate less fatigue.			
Units: score on a scale			
arithmetic mean	25.9	30.9	31.0
standard deviation	± 12.98	± 10.08	± 10.66
36-item Short- Form Version 2 (SF-36v2): Mental Component Summary (MCS)			
The SF-36 is a health-related survey that assesses participant's quality of life and consists of 36 questions covering 8 health domains: physical functioning, bodily pain, role limitations due to physical problems and emotional problems, general health, mental health, social functioning, vitality, and 2 component scores (MCS and PCS). Each domain was scored by summing the individual items and transforming the scores into a 0 to 100 scale with higher scores indicating better health status or functioning.			
Units: score on a scale			
arithmetic mean	45.8	48.1	49.8
standard deviation	± 11.97	± 8.79	± 12.20
SF-36v2: Physical Component Summary (PCS)			
The SF-36 is a health-related survey that assesses participant's quality of life and consists of 36 questions covering 8 health domains: physical functioning, bodily pain, role limitations due to physical problems and emotional problems, general health, mental health, social functioning, vitality, and 2 component scores (MCS and PCS). Each domain was scored by summing the individual items and transforming the scores into a 0 to 100 scale with higher scores indicating better health status or functioning.			
Units: score on a scale			
arithmetic mean	33.7	35.5	35.7
standard deviation	± 8.13	± 9.41	± 9.05

Reporting group values	Total		
Number of subjects	106		

Age categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	- -		
Gender categorical Units: Subjects			
Female	45		
Male	61		
Race Units: Subjects			
Asian	4		
Black or African American	1		
White	101		
Ethnicity Units: Subjects			
Hispanic or Latino	5		
Not Hispanic or Latino	101		
Psoriatic Arthritis Disease Activity Score (PASDAS)			
PASDAS is a composite disease activity measure for psoriatic arthritis. The score of PASDAS range from 0 -10, lower score indicates better function.			
Units: score on a scale arithmetic mean standard deviation	 -		
Disease Activity in Psoriatic Arthritis (DAPSA)			
DAPSA score is the sum of swollen joint count (66 joints), tender joint count (68 joints), CRP (mg/dL), patient's global assessment of PsA pain intensity (PGAPI) [using visual analogue scale (VAS) on a scale of 0-100, 0 = no pain and 100 = serious pain), and patient's global assessment of disease activity (PGADA) (using VAS on a scale of 0-100, 0 = very well and 10 = very poor). DAPSA scores 0-4 = remission, 5-14 = low disease activity, 15-28 = moderate disease activity, and >28 = high disease activity. Lower scores indicate better function.			
Units: score on a scale arithmetic mean standard deviation	 -		
Physician's Global Assessment of Psoriasis (PhGAP)			
The PhGAP is used to determine the participant's psoriasis lesions overall at a given time point. The participant's psoriasis disease activity is assessed by a physician according to the grades of induration, erythema and scaling on a scale of 0 to 5. The sum of the three grades will be used to obtain the total average score. PhGAP is based on the total average score on a scale of 0-5, where, 0=cleared, 1=minimal, 2=mild, 3=moderate, 4=marked and 5=severe. Lower scores indicates better function. Participants in the FAS with ≥ 3% BSA at baseline were analyzed (N=16, 17, 16).			
Units: score on a scale arithmetic mean standard deviation	 -		
Modified Nail Psoriasis Severity Index (mNAPSI)			
mNAPSI is used to assess each nail abnormality for each of the participant's nails. Each finger has a score between 0 and 13. The total mNAPSI score is the sum of all abnormalities of individual score across all fingers, and the total mNAPSI score ranges from 0 to 130. Lower numbers indicate fewer nail abnormalities. Participants in the FAS with Psoriatic Nail Involvement at Baseline were analyzed (N=25, 25, 30).			
Units: score on a scale			

arithmetic mean standard deviation	- -		
Leeds Enthesitis Index (LEI)			
Enthesitis is assessed using LEI. The enthesitis examination by LEI evaluated the presence or absence of pain by applying local pressure on 6 anatomical sites: medial femoral condyle (left and right), lateral epicondyle (left and right) and the achilles tendon insertion (left and right). Enthesitis at each site was scored as 0 = enthesitis absent and 1 = enthesitis present. The total score ranges from 0 to 6, higher scores indicates greater degree of enthesitis. Participants in the FAS with enthesitis at baseline were analyzed (N=22, 22, 24).			
Units: score on a scale arithmetic mean standard deviation	 -		
12-Item Psoriatic Arthritis Impact of Disease (PsAID-12)			
The PsAID questionnaire assesses the impact of PsA on people's lives. The PsAID is calculated based on 12 numerical rating scales (NRS) questions. Each NRS is assessed as a number between 0 and 10. Total score is calculated as the sum of the individual scores, (some of which were multiplied by a weighting factor) divided by 20 for a total possible score of 0 to 10, where higher score indicates worse impact of disease.			
Units: score on a scale arithmetic mean standard deviation	 -		
Tender Joint Count Based on 68 Joints (TJC68)			
TJC68 is an assessment of 68 joints. Each joint was evaluated as 'normal', 'tender', 'tender and swollen' or 'not able to evaluate'. It is derived as the sum of all tender joints. The overall tender joint count ranged from 0 to 68, with a higher score indicating a greater degree of tenderness.			
Units: tender joint count arithmetic mean standard deviation	 -		
Swollen Joint Count Based on 66 Joints (SJC66)			
SJC66 is an assessment of 66 joints. Each joint was evaluated as 'normal', 'swollen', 'tender and swollen' or 'not able to evaluate'. It is derived as the sum of all swollen joints. The overall swollen joint count ranged from 0 to 66, with a higher score indicating a greater degree of swelling.			
Units: swollen joint count arithmetic mean standard deviation	 -		
Patient's Global Assessment of Disease Activity (PGADA)			
PGADA was assessed by the participants using a VAS on a scale of 0 (very well) to 100 (very poor).			
Units: score on a scale arithmetic mean standard deviation	 -		
Physician's Global Assessment of Disease Activity (PhGADA)			
PhGADA was assessed by the physician using a VAS on a scale of 0 (no disease activity) to 100 (maximum disease activity).			
Units: score on a scale arithmetic mean standard deviation	 -		
Health Assessment Questionnaire Disability Index (HAQ-DI)'s Pain Assessment			
Participants assessed their pain severity using a VAS on a scale of 0 (no pain) to 100 (severe pain).			
Units: score on a scale arithmetic mean standard deviation	 -		

High-Sensitivity CReactive Protein (hsCRP) Units: milligrams per liter (mg/L) arithmetic mean standard deviation	-		
Disease Activity Score 28 (DAS28) C-Reactive Protein (CRP)			
DAS28(CRP) is a measure of the participant's disease activity calculated using the tender joint count (28 joints), swollen joint count (28 joints), PGADA [using a VAS on a scale of 0 (very well) to 100 (very poor)] and hsCRP for a total possible score of 1 to 9.4. Higher values indicate higher disease activity.			
Units: score on a scale arithmetic mean standard deviation	-		
Psoriasis Area and Severity Index (PASI)			
PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. The PASI produces a numeric score that can range from 0 (no disease) to 72 (maximal disease). A higher score indicates more severe disease. Participants in the FAS with psoriasis covering >=3% of the BSA at baseline were analyzed (N=16, 17, 16).			
Units: score on a scale arithmetic mean standard deviation	-		
Spondyloarthritis Research Consortium of Canada (SPARCC) Enthesitis Index			
The enthesitis examination was based on the 16 anatomical sites. SPARCC enthesitis index has an overall total score ranging from 0 to 16. Higher score indicates a greater number of sites that are affected by enthesitis. Participants in FAS with Enthesitis at Baseline were analyzed (N=22, 22, 24).			
Units: score on a scale arithmetic mean standard deviation	-		
Leeds Dactylitis Index (LDI)			
LDI measures dactylitis using circumference of involved digits, control digits and tenderness of involved digits. LDI measures ratio of circumference of affected digit to circumference of digit on contralateral hand/foot using Leeds Dactylometer. LDI score is calculated based on circumference of dactylitic finger/toe (mm), circumference of contralateral digit (mm), tenderness score. Tenderness of affected digits is assessed on a scale from 0 [no tenderness] to 3 [tender and withdrawn]. Higher LDI=worse dactylitis. Participants in FAS with Dactylitis at Baseline were analyzed (N=15, 6, 9).			
Units: score on a scale arithmetic mean standard deviation	-		
Tender Dactylitis Count (TDC)			
Tender score (0 = no tenderness, 1 = tender, 2 = tender and wince, 3 = tender and withdraw) is collected for Dactylitis Assessments on the Dactylitis Score Sheet that was used for calculation of LDI total score. Tender dactylitis count (TDC) equals the number of tender fingers and toes (tendor score >0). For participants with dactylitis status absent for all the fingers and toes, the TDC will be set as 0. The total score range of TDC is from 0 to 60, higher scores indicate greater presence of dactylitis. Participants in the FAS with dactylitis at baseline were analyzed (N=15, 6, 9).			
Units: tender dactylitis count arithmetic mean standard deviation	-		
Health Assessment Questionnaire-Disability Index (HAQ-DI)			
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. The eight category scores are averaged into an overall HAQ-DI score on a scale from 0 (no disability) to 3 (completely disabled). When 6 or more categories are non-missing, total possible score is 3. If more than 2 categories are missing, the HAQ-DI score is set to missing.			
Units: score on a scale arithmetic mean			

standard deviation	-		
Functional Assessment of Chronic Illness Therapy (FACIT)- Fatigue			
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. Higher scores indicate less fatigue.			
Units: score on a scale arithmetic mean standard deviation	-		
36-item Short- Form Version 2 (SF-36v2): Mental Component Summary (MCS)			
The SF-36 is a health-related survey that assesses participant's quality of life and consists of 36 questions covering 8 health domains: physical functioning, bodily pain, role limitations due to physical problems and emotional problems, general health, mental health, social functioning, vitality, and 2 component scores (MCS and PCS). Each domain was scored by summing the individual items and transforming the scores into a 0 to 100 scale with higher scores indicating better health status or functioning.			
Units: score on a scale arithmetic mean standard deviation	-		
SF-36v2: Physical Component Summary (PCS)			
The SF-36 is a health-related survey that assesses participant's quality of life and consists of 36 questions covering 8 health domains: physical functioning, bodily pain, role limitations due to physical problems and emotional problems, general health, mental health, social functioning, vitality, and 2 component scores (MCS and PCS). Each domain was scored by summing the individual items and transforming the scores into a 0 to 100 scale with higher scores indicating better health status or functioning.			
Units: score on a scale arithmetic mean standard deviation	-		

End points

End points reporting groups

Reporting group title	Filgotinib 200 mg (Main Study)
Reporting group description:	
Filgotinib 200 milligrams (mg) tablet orally once daily + placebo to match (PTM) filgotinib 100 mg tablet orally once daily for 16 weeks.	
Reporting group title	Filgotinib 100 mg (Main Study)
Reporting group description:	
Filgotinib 100 mg tablet orally once daily + PTM filgotinib 200 mg tablet orally once daily for 16 weeks.	
Reporting group title	Placebo (Main Study)
Reporting group description:	
PTM filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily for 16 weeks.	
Reporting group title	Filgotinib 200 mg From Filgotinib 200 mg (LTE)
Reporting group description:	
Long term extension (LTE): Filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily for up to 44.3 weeks. Participants received filgotinib 200 mg in the Main Study.	
Reporting group title	Filgotinib 100 mg From Filgotinib 100 mg (LTE)
Reporting group description:	
Filgotinib 100 mg tablet orally once daily + PTM filgotinib 200 mg tablet orally once daily for up to 43.9 weeks. Participants received filgotinib 100 mg in the Main Study.	
Reporting group title	Filgotinib 200 mg From Placebo (LTE)
Reporting group description:	
Filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily for up to 44.1 weeks. Participants received placebo in the Main Study.	
Reporting group title	Filgotinib 100 mg From Placebo (LTE)
Reporting group description:	
Filgotinib 100 mg tablet orally once daily + PTM filgotinib 200 mg tablet orally once daily for up to 44 weeks. Participants received placebo in the Main Study.	

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

End point title	Percentage of Participants who Achieved an American College of Rheumatology (ACR) 20% Improvement 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: patient's global assessment of disease activity (PGADA) using a visual analogue scale (VAS) on a scale of 0 (very well) to 100 (very poor); physician's global assessment of disease activity (PHGADA) using a VAS on a scale of 0 (no disease activity) to 100 (maximum disease activity); health assessment questionnaire-disability index (HAQ-DI) inclusive of activities scored on a scale of 0 (no disability) to 3 (completely disabled); HAQ-DI pain assessment using VAS on a scale of 0 (no pain) to 100 (serious pain), and high-sensitivity C-reactive protein (hsCRP). Full Analysis Set (FAS) included all randomized participants who took at least 1 dose of study drug. Missing data was imputed using multiple imputation assuming missing at random.	
End point type	Primary
End point timeframe:	
Week 12	

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	34	36	
Units: percentage of participants				
number (confidence interval 95%)	60.0 (43.5 to 76.5)	35.3 (17.8 to 52.8)	33.1 (17.0 to 49.1)	

Statistical analyses

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Comparison groups	Placebo (Main Study) v Filgotinib 200 mg (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.022 [1]
Method	Multiple imputation method
Parameter estimate	Difference in response rates
Point estimate	26.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.3
upper limit	49.6

Notes:

[1] - The stratification factors (Geographic Region, Concurrent Use of csDMARD(s) and/or Apremilast at Randomization, Prior Use of bioDMARD(s)) and treatment groups were included in the imputation model as covariates.

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.89 [2]
Method	Multiple imputation method
Parameter estimate	Difference in response rates
Point estimate	2.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.5
upper limit	25

Notes:

[2] - The stratification factors (Geographic Region, Concurrent Use of csDMARD(s) and/or Apremilast at Randomization, Prior Use of bioDMARD(s)) and treatment groups were included in the imputation model as covariates.

Secondary: Change From Baseline in Psoriatic Arthritis Disease Activity Score (PASDAS) at Weeks 4 and 16

End point title	Change From Baseline in Psoriatic Arthritis Disease Activity Score (PASDAS) at Weeks 4 and 16

End point description:

PASDAS is a composite disease activity measure for psoriatic arthritis. The PASDAS includes the following components: PGADA [using a VAS on a scale of 0 (very well) to 100 (very poor)]; PhGADA [using a VAS on a scale of 0 (no disease activity) to 100 (maximum disease activity)]; 36-item short form survey (SF-36) [a questionnaire which measures quality of life across eight domains used to determine a physical component summary (PCS) with a score range of 0-100, higher scores indicates better health status]; TJC68; SJC66; leeds enthesitis index (LEI) [assessed at 6 sites with a score range of 0 to 6, higher scores indicates higher degree of enthesitis]; Tender dactylitis count (TDC) [with a score range of 0 to 60, higher score indicates higher degree of dactylitis]; C-reactive protein (CRP). The score of PASDAS ranges from 0-10, lower scores indicates better function. A negative change from baseline indicates improvement. Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline, 4, and 16 weeks

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	34	35	
Units: score on a scale				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 4 N=34,33,34	-1.2 (± 1.34)	-0.8 (± 0.73)	-0.6 (± 0.96)	
Change from Baseline at Wk 16 N=31,33,32	-2.1 (± 1.73)	-1.4 (± 1.19)	-0.9 (± 1.08)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in PASDAS at Week 48

End point title	Change From Baseline in PASDAS at Week 48

End point description:

PASDAS is a composite disease activity measure for psoriatic arthritis. The PASDAS includes the following components: PGADA [using a VAS on a scale of 0 (very well) to 100 (very poor)]; PhGADA [using a VAS on a scale of 0 (no disease activity) to 100 (maximum disease activity)]; 36-item short form survey (SF-36) [a questionnaire which measures quality of life across eight domains used to determine a physical component summary (PCS) with a score range of 0-100, higher scores indicates better health status]; TJC68; SJC66; leeds enthesitis index (LEI) [assessed at 6 sites with a score range of 0 to 6, higher scores indicates higher degree of enthesitis]; Tender dactylitis count (TDC) [with a score range of 0 to 60, higher score indicates higher degree of dactylitis]; C-reactive protein (CRP). The score of PASDAS ranges from 0-10, lower scores indicates better function. A negative change from baseline indicates improvement. Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline, Week 48

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	9	4	3
Units: score on a scale				
arithmetic mean (standard deviation)	-3.3 (± 1.69)	-2.0 (± 1.35)	-1.7 (± 0.57)	0.0 (± 0.30)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved Minimal Disease Activity (MDA) Response at Weeks 4, 8, 12, and 16

End point title	Percentage of Participants who Achieved Minimal Disease Activity (MDA) Response at Weeks 4, 8, 12, and 16

End point description:

MDA is a measure to indicate disease remission, and is based on a composite score of 7 domains. A participant is considered as having achieved the MDA if the participant fulfills at least 5 of the following 7 criteria: TJC68 ≤1; SJC66 ≤1; Psoriatic arthritis disease activity score (PASI) ≤1 for participants with psoriasis covering BSA <3% [PASI evaluates the severity and extent of psoriasis. In PASI, body is divided into four parts, head and neck, upper limb, trunk and lower limbs. Each area is assessed for erythema, induration and scaling, each rated on a scale of 0 to 4. The total score ranges from 0 (no disease) to 72 (maximal disease)]; PGAPI ≤15 [using VAS on a scale of 0 (no pain) to 100 (serious pain)]; PGADA ≤20 [using VAS on a scale of 0 (very well) to 100 (very poor)]; HAQ-DI score ≤0.5; LEI score ≤1 for participants with enthesitis at baseline. Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 12, and 16

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	34	36	
Units: percentage of participants				
number (confidence interval 95%)				
Wk 4 N=36,34,35	5.6 (0.0 to 14.4)	8.8 (0.0 to 19.8)	11.4 (0.0 to 23.4)	
Wk 8 N=32,34,34	15.6 (1.5 to 29.8)	11.8 (0.0 to 24.1)	14.7 (1.3 to 28.1)	
Wk 12 N=33,34,34	21.2 (5.7 to 36.7)	17.6 (3.4 to 31.9)	8.8 (0.0 to 19.8)	

Wk 16 N=32,33,33	34.4 (16.4 to 52.4)	24.2 (8.1 to 40.4)	12.1 (0.0 to 24.8)	

Statistical analyses

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 4	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.65 [3]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	-2.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.7
upper limit	14.5

Notes:

[3] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic Region, concurrent Use of csDMARD(s) and/or Apremilast at Randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 4	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.39 [4]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	-5.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-21.6
upper limit	9.9

Notes:

[4] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic Region, concurrent Use of csDMARD(s) and/or Apremilast at Randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 8	

Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7 [5]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	-2.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22
upper limit	16.1

Notes:

[5] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic Region, concurrent Use of csDMARD(s) and/or Apremilast at Randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 8

Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.86 [6]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.4
upper limit	21.3

Notes:

[6] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic Region, concurrent Use of csDMARD(s) and/or Apremilast at Randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 12

Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3 [7]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	8.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.1
upper limit	27.7

Notes:

[7] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic Region, concurrent Use of csDMARD(s) and/or Apremilast at Randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 12

Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.15 [8]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	12.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.5
upper limit	32.3

Notes:

[8] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic Region, concurrent Use of csDMARD(s) and/or Apremilast at Randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 16

Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.22 [9]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	12.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.3
upper limit	33.5

Notes:

[9] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic Region, concurrent Use of csDMARD(s) and/or Apremilast at Randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:	
Week 16	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.035 [10]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	22.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	45.2

Notes:

[10] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic Region, concurrent Use of csDMARD(s) and/or Apremilast at Randomization, prior use of bioDMARD(s)) in the model.

Secondary: Percentage of Participants who Achieved MDA Response at Weeks 20, 24, 28, 36, and 48

End point title	Percentage of Participants who Achieved MDA Response at Weeks 20, 24, 28, 36, and 48

End point description:

MDA is a measure to indicate disease remission, and is based on a composite score of 7 domains. A participant is considered as having achieved the MDA if the participant fulfills at least 5 of the following 7 criteria: TJC68 ≤1; SJC66 ≤1; Psoriatic arthritis disease activity score (PASI) ≤1 for participants with psoriasis covering BSA <3% [PASI evaluates the severity and extent of psoriasis. In PASI, body is divided into four parts, head and neck, upper limb, trunk and lower limbs. Each area is assessed for erythema, induration and scaling, each rated on a scale of 0 to 4. The total score ranges from 0 (no disease) to 72 (maximal disease)]; PGAPI ≤15 [using VAS on a scale of 0 (no pain) to 100 (serious pain)]; PGADA ≤20 [using VAS on a scale of 0 (very well) to 100 (very poor)]; HAQ-DI score ≤0.5; LEI score ≤1 for participants with enthesitis at baseline. Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 20, 24, 28, 36, and 48

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	20	10	8
Units: percentage of participants				
number (confidence interval 95%)				
Wk 20 N=13,19,10,8	30.8 (1.8 to 59.7)	21.1 (0.1 to 42.0)	40.0 (4.6 to 75.4)	0 (0.0 to 6.3)
Wk 24 N=13,16,7,7	38.5 (8.2 to 68.8)	43.8 (16.3 to 71.2)	71.4 (30.8 to 100.0)	28.6 (0.0 to 69.2)
Wk 28 N=8,11,4,5	37.5 (0.0 to 77.3)	36.4 (3.4 to 69.3)	50.0 (0.0 to 100.0)	20.0 (0.0 to 65.1)
Wk 36 N=9,10,4,5	55.6 (17.5 to 93.6)	30.0 (0.0 to 63.4)	50.0 (0.0 to 100.0)	20.0 (0.0 to 65.1)

Wk 48 N=8,9,4,3	62.5 (22.7 to 100.0)	11.1 (0.0 to 37.2)	75.0 (20.1 to 100.0)	0 (0.0 to 16.7)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved Very Low Disease Activity (VLDA) Response at Weeks 4, 8, 12, and 16

End point title	Percentage of Participants who Achieved Very Low Disease Activity (VLDA) Response at Weeks 4, 8, 12, and 16

End point description:

VLDA is a measure to indicate disease remission, and is based on a composite score of 7 domains. A participant is considered as having achieved the VLDA if the participant fulfills all the seven criteria: TJC68 ≤1; SJC66 ≤1; PASI score ≤1 for participants with psoriasis covering BSA <3% [PASI evaluates the severity and extent of psoriasis. In PASI, body is divided into four parts, head and neck, upper limb, trunk and lower limbs. Each area is assessed for erythema, induration and scaling, each rated on a scale of 0 to 4. The total score ranges from 0 (no disease) to 72 (maximal disease)]; PGAPI ≤15 [using VAS on a scale of 0 (no pain) to (serious pain)]; PGADA ≤20 [using VAS on a scale of 0 (very well) to 100 (very poor)]; HAQ-DI score ≤0.5; LEI score ≤1 with participants with enthesitis at baseline. Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 12, and 16

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	34	36	
Units: percentage of participants				
number (confidence interval 95%)				
Wk 4 N=36,34,35	0 (0.0 to 1.4)	0 (0.0 to 1.5)	0 (0.0 to 1.4)	
Wk 8 N=32,34,34	3.1 (0.0 to 10.7)	0 (0.0 to 1.5)	0 (0.0 to 1.5)	
Wk 12 N=33,34,34	3.0 (0.0 to 10.4)	5.9 (0.0 to 15.3)	0 (0.0 to 1.5)	
Wk 16 N=32,33,33	3.1 (0.0 to 10.7)	6.1 (0.0 to 15.7)	3.0 (0.0 to 10.4)	

Statistical analyses

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 4

Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)

Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.8
upper limit	2.8

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 4	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.9
upper limit	2.9

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 8	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.9
upper limit	2.9

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 8	

Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	3.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.9
upper limit	12.2

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 12	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	5.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5
upper limit	16.7

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 12	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.8
upper limit	11.9

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:	
Week 16	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10
upper limit	16.1

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 16	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.4
upper limit	11.6

Secondary: Percentage of Participants who Achieved VLDA Response at Weeks 20, 24, 28, 36, and 48

End point title	Percentage of Participants who Achieved VLDA Response at Weeks 20, 24, 28, 36, and 48

End point description:

VLDA is a measure to indicate disease remission, and is based on a composite score of 7 domains. A participant is considered as having achieved the VLDA if the participant fulfills all the seven criteria: TJC68 ≤1; SJC66 ≤1; PASI score ≤1 for participants with psoriasis covering BSA <3% [PASI evaluates the severity and extent of psoriasis. In PASI, body is divided into four parts, head and neck, upper limb, trunk and lower limbs. Each area is assessed for erythema, induration and scaling, each rated on a scale of 0 to 4. The total score ranges from 0 (no disease) to 72 (maximal disease)]; PGAPI ≤15 [using VAS on a scale of 0 (no pain) to (serious pain)]; PGADA ≤20 [using VAS on a scale of 0 (very well) to 100 (very poor)]; HAQ-DI score ≤0.5; LEI score ≤1 with participants with enthesitis at baseline. Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 20, 24, 28, 36, and 48

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	20	10	8
Units: percentage of participants				
number (confidence interval 95%)				
Wk 20 N=13,19,10,8	7.7 (0.0 to 26.0)	0 (0.0 to 2.6)	10.0 (0.0 to 33.6)	0 (0.0 to 6.3)
Wk 24 N=13,16,7,7	7.7 (0.0 to 26.0)	12.5 (0.0 to 31.8)	14.3 (0.0 to 47.4)	0 (0.0 to 7.1)
Wk 28 N=8,11,4,5	12.5 (0.0 to 41.7)	0 (0.0 to 4.5)	0 (0.0 to 12.5)	0 (0.0 to 10.0)
Wk 36 N=9,10,4,5	22.2 (0.0 to 54.9)	10.0 (0.0 to 33.6)	0 (0.0 to 12.5)	0 (0.0 to 10.0)
Wk 48 N=8,9,4,3	0 (0.0 to 6.3)	0 (0.0 to 5.6)	0 (0.0 to 12.5)	0 (0.0 to 16.7)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Disease Activity in Psoriatic Arthritis (DAPSA) at Weeks 2, 4, 8, 12, and 16

End point title	Change From Baseline in Disease Activity in Psoriatic Arthritis (DAPSA) at Weeks 2, 4, 8, 12, and 16

End point description:

DAPSA is calculated by summing the following components: TJC68; SJC66; PGADA [using VAS on a scale of 0 (very well) to 100 very poor)]; PGAPI [using a VAS on a scale of 0 (no pain) to 100 (serious pain)] and CRP. DAPSA scores 0-4 = remission, 5-14 = low disease activity, 15-28 = moderate disease activity, and >28 = high disease activity. A negative change from baseline indicates improvement. A negative change from baseline indicates improvement. Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline, 2, 4, 8, 12, and 16 weeks

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	34	36	
Units: score on a scale				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 2 N=34,33,35	-11.6 (± 19.12)	-9.4 (± 14.11)	-2.9 (± 16.01)	
Change from Baseline at Wk 4 N=35,34,34	-15.1 (± 18.48)	-11.5 (± 12.53)	-8.0 (± 19.32)	

Change from Baseline at Wk 8 N=32,34,33	-22.0 (± 21.73)	-14.4 (± 14.96)	-14.4 (± 20.15)	
Change from Baseline at Wk 12 N=33,34,33	-25.2 (± 24.43)	-15.8 (± 19.32)	-14.9 (± 16.43)	
Change from Baseline at Wk 16 N=31,33,32	-26.3 (± 23.48)	-19.4 (± 18.13)	-16.6 (± 15.61)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in DAPSA at Weeks 18, 20, 24, 28, 36, 48, and 60

End point title	Change From Baseline in DAPSA at Weeks 18, 20, 24, 28, 36, 48, and 60

End point description:

DAPSA is calculated by summing the following components: TJC68; SJC66; PGADA [using VAS on a scale of 0 (very well) to 100 very poor)]; PGAPI [using a VAS on a scale of 0 (no pain) to 100 (serious pain)] and CRP. DAPSA scores 0-4 = remission, 5-14 = low disease activity, 15-28 = moderate disease activity, and >28 = high disease activity. A negative change from baseline indicates improvement. Participants in the FAS with available data were analyzed. 9999=Standard deviation (SD) cannot be calculated for 1 participant.

End point type	Secondary

End point timeframe:

Baseline, 18, 20, 24, 28, 36, 48, and 60 weeks

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	20	10	8
Units: score on a scale				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 18 N=15,18,8,8	-27.0 (± 22.87)	-23.5 (± 18.80)	-9.3 (± 9.10)	-5.3 (± 9.72)
Change from Baseline at Wk 20 N=13,19,10,8	-32.1 (± 29.72)	-20.5 (± 15.12)	-9.6 (± 11.79)	1.1 (± 16.48)
Change from Baseline at Wk 24 N=13,16,7,7	-28.8 (± 37.40)	-22.1 (± 18.37)	-6.9 (± 6.51)	-5.4 (± 15.02)
Change from Baseline at Wk 28 N=8,11,4,4	-37.3 (± 26.49)	-24.1 (± 20.79)	-3.0 (± 7.61)	-5.3 (± 20.48)
Change from Baseline at Wk 36 N=9,10,4,5	-44.9 (± 27.81)	-23.6 (± 18.30)	-1.3 (± 10.75)	-9.9 (± 13.51)
Change from Baseline at Wk 48 N=8,9,4,3	-40.5 (± 31.97)	-28.5 (± 20.68)	-16.3 (± 21.00)	-2.3 (± 17.56)
Change from Baseline at Wk 60 N=1,1,2,2	-86.2 (± 9999)	-18.5 (± 9999)	-12.9 (± 11.80)	1.8 (± 23.75)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Physician's Global Assessment of Psoriasis (PhGAP) at Weeks 2, 4, 8, 12, and 16 in Participants With Psoriasis Covering ≥ 3% of the Body Surface Area (BSA) at Baseline

End point title	Change From Baseline in Physician's Global Assessment of Psoriasis (PhGAP) at Weeks 2, 4, 8, 12, and 16 in Participants With Psoriasis Covering ≥ 3% of the Body Surface Area (BSA) at Baseline

End point description:

The PhGAP is used to determine the participant's psoriasis lesions overall at a given time point. The participant's psoriasis disease activity is assessed by a physician according to the grades of induration, erythema, and scaling on a scale of 0 to 5. The sum of the three grades is used to obtain the total average score. PhGAP is based on the total average score on a scale of 0-5 where, 0 = cleared, 1 = minimal, 2 = mild, 3 = moderate, 4 = marked, and 5 = severe. A negative change from baseline indicates improvement. Participants in the FAS with psoriasis covering >=3% of the BSA at baseline and with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline, 2, 4, 8, 12, and 16 weeks

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	16	17	16	
Units: score on a scale				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 2	-1 (± 0.9)	0 (± 0.7)	0 (± 0.9)	
Change from Baseline at Wk 4 N=16,17,15	-1 (± 1.1)	0 (± 0.7)	0 (± 1.1)	
Change from Baseline at Wk 8 N=16,17,14	-1 (± 0.9)	0 (± 0.8)	-1 (± 1.1)	
Change from Baseline at Wk 12 N=16,17,13	-1 (± 1.0)	-1 (± 0.7)	-1 (± 0.8)	
Change from Baseline at Wk 16 N=15,17,14	-2 (± 1.0)	0 (± 0.7)	0 (± 0.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in PhGAP at Weeks 18, 20, 24, 28, 36, and 48 in Participants With Psoriasis Covering ≥ 3% of the BSA at Baseline

End point title	Change From Baseline in PhGAP at Weeks 18, 20, 24, 28, 36, and 48 in Participants With Psoriasis Covering ≥ 3% of the BSA at Baseline

End point description:

The PhGAP is used to determine the participant's psoriasis lesions overall at a given time point. The participant's psoriasis disease activity is assessed by a physician according to the grades of induration, erythema, and scaling on a scale of 0 to 5. The sum of the three grades is used to obtain the total average score. PhGAP is based on the total average score on a scale of 0-5 where, 0 = cleared, 1 =

minimal, 2 = mild, 3 = moderate, 4 = marked, and 5 = severe. A negative change from baseline indicates improvement. Participants in the FAS with psoriasis covering >=3% of the BSA at baseline and with available data were analyzed. 9999=SD cannot be calculated for 1 participant.

End point type	Secondary

End point timeframe:

Baseline, 18, 20, 24, 28, 36, and 48 weeks

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	17	5	2
Units: score on a scale				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 18 N=7,7,3,2	-2 (± 1.4)	-1 (± 0.5)	-1 (± 0.6)	0 (± 0.0)
Change from Baseline at Wk 20 N=6,8,5,2	-1 (± 0.9)	0 (± 0.9)	-1 (± 0.8)	0 (± 0.0)
Change from Baseline at Wk 24 N=7,7,4,2	-2 (± 1.1)	0 (± 0.5)	-2 (± 0.8)	-1 (± 0.7)
Change from Baseline at Wk 28 N=3,6,3,1	-1 (± 0.6)	-1 (± 0.4)	-1 (± 1.2)	-1 (± 9999)
Change from Baseline at Wk 36 N=4,5,4,1	-2 (± 0.6)	0 (± 0.5)	-1 (± 0.8)	0 (± 9999)
Change from Baseline at Wk 48 N=4,5,4,1	-1 (± 1.0)	0 (± 0.4)	-1 (± 0.8)	0 (± 9999)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Modified Nail Psoriasis Severity Index (mNAPSI) at Weeks 4, 8, 12, and 16 in Participants With Psoriatic Nail Involvement at Baseline

End point title	Change From Baseline in Modified Nail Psoriasis Severity Index (mNAPSI) at Weeks 4, 8, 12, and 16 in Participants With Psoriatic Nail Involvement at Baseline

End point description:

mNAPSI is used to assess each nail abnormality for each of the participant's nails. Three features or groups of features (pitting, onycholysis together with oil-drop dyschromia, and crumbling) of each fingernail are graded on a scale from 0 (no onycholysis together with oil-drop dyschromia, no pitting, no crumbling) to 3 (>30 onycholysis together with oil-drop dyschromia, >50 pitting, >50% crumbling). Four features (leukonychia, splinter, hemorrhages, hyperkeratosis, and red spots in the lunula) are graded with the score of 1 = present or 0 = absent for each fingernail. Each finger has a score between 0 and 13. The total mNAPSI score is the sum of all abnormalities individual score across all fingers, and the total mNAPSI score ranges from 0 to 130. Lower numbers indicate fewer nail abnormalities. A negative change from baseline indicates improvement. Participants in the FAS with psoriatic nail involvement at baseline and with available data were analysed.

End point type	Secondary

End point timeframe:

Baseline, 4, 8, 12, and 16 weeks

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	25	25	30	
Units: score on a scale				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 4 N=25,25,29	-6 (± 7.4)	-4 (± 8.5)	0 (± 9.7)	
Change from Baseline at Wk 8 N=23,25,28	-7 (± 9.9)	-5 (± 11.1)	0 (± 11.2)	
Change from Baseline at Wk 12 N=24,25,28	-7 (± 8.3)	-4 (± 11.7)	1 (± 14.0)	
Change from Baseline at Wk 16 N=24,25,27	-8 (± 9.3)	-6 (± 9.4)	-2 (± 8.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in mNAPSI at Weeks 20, 24, 28, 36, and 48 in Participants With Psoriatic Nail Involvement at Baseline

End point title	Change From Baseline in mNAPSI at Weeks 20, 24, 28, 36, and 48 in Participants With Psoriatic Nail Involvement at Baseline

End point description:

mNAPSI is used to assess each nail abnormality for each of the participant's nails. Three features or groups of features (pitting, onycholysis together with oil-drop dyschromia, and crumbling) of each fingernail are graded on a scale from 0 (no onycholysis together with oil-drop dyschromia, no pitting, no crumbling) to 3 (>30 onycholysis together with oil-drop dyschromia, >50 pitting, >50% crumbling). Four features (leukonychia, splinter, hemorrhages, hyperkeratosis, and red spots in the lunula) are graded with the score of 1 = present or 0 = absent for each fingernail. Each finger has a score between 0 and 13. The total mNAPSI score is the sum of all abnormalities individual score across all fingers, and the total mNAPSI score ranges from 0 to 130. Lower numbers indicate fewer nail abnormalities. A negative change from baseline indicates improvement. Participants in the FAS with psoriatic nail involvement at baseline and with available data were analysed.

End point type	Secondary

End point timeframe:

Baseline, 20, 24, 28, 36, and 48 weeks

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	20	8	5
Units: score on a scale				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 20 N=12,15,8,5	-11 (± 12.3)	-5 (± 10.1)	-1 (± 4.8)	-3 (± 5.5)

Change from Baseline at Wk 24 N=12,13,6,5	-10 (± 11.9)	-4 (± 7.5)	-2 (± 4.0)	-1 (± 1.4)
Change from Baseline at Wk 28 N=7,8,3,3	-13 (± 15.4)	-5 (± 11.4)	-3 (± 4.9)	-3 (± 2.3)
Change from Baseline at Wk 36 N=8,7,3,3	-13 (± 15.3)	-6 (± 8.4)	2 (± 2.1)	-2 (± 1.2)
Change from Baseline at Wk 48 N=7,6,3,2	-9 (± 16.6)	-3 (± 5.0)	1 (± 5.6)	-8 (± 10.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Leeds Enthesitis Index (LEI) at Weeks 4, 8, 12, and 16 in Participants With Enthesitis at Baseline

End point title	Change From Baseline in Leeds Enthesitis Index (LEI) at Weeks 4, 8, 12, and 16 in Participants With Enthesitis at Baseline

End point description:

Enthesitis is assessed using LEI. The enthesitis examination by LEI evaluates the presence or absence of pain by applying local pressure on 6 anatomical sites: medial femoral condyle (left and right), lateral epicondyle (left and right), and the achilles tendon insertion (left and right). Enthesitis at each site is scored as 0 (enthesitis absent) and 1 (enthesitis present). LEI is derived as the sum of the enthesitis score over the 6 sites mentioned above. The total score ranges from 0 to 6, higher scores indicates greater degree of enthesitis. A negative change from baseline indicates improvement. Participants in the FAS with enthesitis at baseline and with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline, 4, 8, 12, and 16 weeks

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	22	22	24	
Units: score on a scale				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 4	0 (± 1.3)	-1 (± 1.2)	0 (± 1.9)	
Change from Baseline at Wk 8 N=20,22,24	-1 (± 2.4)	0 (± 1.4)	0 (± 1.6)	
Change from Baseline at Wk 12 N=20,22,24	-1 (± 2.1)	0 (± 1.6)	0 (± 1.5)	
Change from Baseline at Wk 16 N=19,21,24	-1 (± 2.4)	-1 (± 1.3)	0 (± 1.4)	

Statistical analyses

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 4

Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.24 [11]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	0
Variability estimate	Standard error of the mean
Dispersion value	0.4

Notes:

[11] - P-value was provided from mixed-effects model for repeated measures (MMRM) having treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, participants being the random effect.

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 4

Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.22 [12]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	-1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	0
Variability estimate	Standard error of the mean
Dispersion value	0.4

Notes:

[12] - P-value was provided from MMRM having treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, participants being the random effect.

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 8

Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.43 [13]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	1
Variability estimate	Standard error of the mean
Dispersion value	0.5

Notes:

[13] - P-value was provided from MMRM having treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, participants being the random effect.

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 12

Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1 [14]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	-1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2
upper limit	0
Variability estimate	Standard error of the mean
Dispersion value	0.5

Notes:

[14] - P-value was provided from MMRM having treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, participants being the random effect.

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 8

Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7 [15]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	1
Variability estimate	Standard error of the mean
Dispersion value	0.5

Notes:

[15] - P-value was provided from MMRM having treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, participants being the random effect.

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 12	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9 [16]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	1
Variability estimate	Standard error of the mean
Dispersion value	0.5

Notes:

[16] - P-value was provided from MMRM having treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, participants being the random effect.

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 16	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.88 [17]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	1
Variability estimate	Standard error of the mean
Dispersion value	0.5

Notes:

[17] - P-value was provided from MMRM having treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, participants being the random effect.

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 16	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)

Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.89 [18]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	1
Variability estimate	Standard error of the mean
Dispersion value	0.5

Notes:

[18] - P-value was provided from MMRM having treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, participants being the random effect.

Secondary: Change From Baseline in LEI at Weeks 20, 24, 28, 36, and 48 in Participants With Enthesitis at Baseline

End point title	Change From Baseline in LEI at Weeks 20, 24, 28, 36, and 48 in Participants With Enthesitis at Baseline

End point description:

Enthesitis is assessed using LEI. The enthesitis examination by LEI evaluates the presence or absence of pain by applying local pressure on 6 anatomical sites: medial femoral condyle (left and right), lateral epicondyle (left and right), and the achilles tendon insertion (left and right). Enthesitis at each site is scored as 0 (enthesitis absent) and 1 (enthesitis present). LEI is derived as the sum of the enthesitis score over the 6 sites mentioned above. The total score ranges from 0 to 6, higher scores indicates greater degree of enthesitis. A negative change from baseline indicates improvement. Participants in the FAS with enthesitis at baseline and with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline, 20, 24, 28, 36, and 48 weeks

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	20	9	5
Units: score on a scale				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 20 N=10,13,9,5	-2 (± 2.2)	-1 (± 1.6)	0 (± 1.3)	0 (± 1.8)
Change from Baseline at Wk 24 N=11,11,7,5	-1 (± 2.0)	0 (± 1.4)	0 (± 0.8)	0 (± 0.4)
Change from Baseline at Wk 28 N=6,7,4,4	-2 (± 1.9)	-1 (± 2.2)	-1 (± 1.0)	0 (± 0.5)
Change from Baseline at Wk 36 N=7,7,4,4	-2 (± 1.8)	-2 (± 2.4)	0 (± 2.1)	0 (± 1.0)
Change from Baseline at Wk 48 N=6,6,4,4	-3 (± 1.4)	-2 (± 2.4)	-1 (± 1.0)	1 (± 1.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in 12-Item Psoriatic Arthritis Impact of Disease (PsAID-12) Score at Weeks 4 and 16

End point title	Change From Baseline in 12-Item Psoriatic Arthritis Impact of Disease (PsAID-12) Score at Weeks 4 and 16

End point description:

The PsAID questionnaire assesses the impact of PsA on people's lives. The PsAID is calculated based on 12 numerical rating scales (NRS) questions. The 12 NRS is focused on pain, fatigue, skin, work and/or leisure activities, function, discomfort, sleep, coping, anxiety, embarrassment, social life, and depression. Each NRS is assessed as a number between 0 and 10. Total score is calculated as the sum of the individual scores, (some of which were multiplied by a weighting factor) divided by 20 for a total possible score of 0 to 10, where higher score indicates worse impact of disease. A negative change from baseline indicates improvement. Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline, 4, and 16 weeks

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	34	36	
Units: score on a scale				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 4 N=36,34,35	-0.97 (± 1.876)	-0.66 (± 1.492)	-0.49 (± 1.139)	
Change from Baseline at Wk 16 N=32,33,34	-1.58 (± 2.263)	-1.04 (± 1.802)	-0.38 (± 1.543)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in PsAID-12 Score at Week 48

End point title	Change From Baseline in PsAID-12 Score at Week 48

End point description:

The PsAID questionnaire assesses the impact of PsA on people's lives. The PsAID is calculated based on 12 numerical rating scales (NRS) questions. The 12 NRS is focused on pain, fatigue, skin, work and/or leisure activities, function, discomfort, sleep, coping, anxiety, embarrassment, social life, and depression. Each NRS is assessed as a number between 0 and 10. Total score is calculated as the sum of the individual scores, (some of which were multiplied by a weighting factor) divided by 20 for a total

possible score of 0 to 10, where higher score indicates worse impact of disease. A negative change from baseline indicates improvement. Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline, Week 48

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	19	10	8
Units: score on a scale				
arithmetic mean (standard deviation)	-1.04 (± 2.441)	-1.44 (± 2.396)	-1.59 (± 1.807)	0.39 (± 1.123)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With PASDAS Low Disease Activity (LDA) at Weeks 4 and 16

End point title	Percentage of Participants With PASDAS Low Disease Activity (LDA) at Weeks 4 and 16

End point description:

PASDAS is a composite disease activity measure for psoriatic arthritis. The PASDAS includes the following components: PGADA [using a VAS on a scale of 0 (very well) to 100 (very poor)]; PhGADA [using a VAS on a scale of 0 (no disease activity) to 100 (maximum disease activity)]; 36-item short form survey (SF-36) [a questionnaire which measures quality of life across eight domains used to determine a PCS with a score range of 0-100, higher scores indicates better health status]; TJC68; SJC66; LEI [assessed at 6 sites with a score range of 0 to 6, higher scores indicates higher degree of enthesitis]; TDC [with a score range of 0 to 60, higher score indicates higher degree of dactylitis]; CRP. The score of PASDAS ranges from 0-10, lower score indicates better function. PASDAS LDA is defined as PASDAS ≤ 3.2. Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 4 and 16

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	34	36	
Units: percentage of participants				
number (confidence interval 95%)				
Wk 4 N=34,33,35	8.8 (0.0 to 19.8)	21.2 (5.7 to 36.7)	8.6 (0.0 to 19.3)	
Wk 16 N=31,33,33	38.7 (20.0 to 57.5)	30.3 (13.1 to 47.5)	12.1 (0.0 to 24.8)	

Statistical analyses

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 4	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.9
upper limit	16.5

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 16	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	18.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.1
upper limit	40.4

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 16	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)

Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	26.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	3
upper limit	50.2

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 4	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	12.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.1
upper limit	32.3

Secondary: Percentage of Participants With PASDAS LDA at Week 48

End point title	Percentage of Participants With PASDAS LDA at Week 48

End point description:

PASDAS is a composite disease activity measure for psoriatic arthritis. The PASDAS includes the following components: PGADA [using a VAS on a scale of 0 (very well) to 100 (very poor)]; PhGADA [using a VAS on a scale of 0 (no disease activity) to 100 (maximum disease activity)]; 36-item short form survey (SF-36) [a questionnaire which measures quality of life across eight domains used to determine a PCS with a score range of 0-100, higher scores indicates better health status]; TJC68; SJC66; LEI [assessed at 6 sites with a score range of 0 to 6, higher scores indicates higher degree of enthesitis]; TDC [with a score range of 0 to 60, higher score indicates higher degree of dactylitis]; CRP. The score of PASDAS ranges from 0-10, lower score indicates better function. PASDAS LDA is defined as PASDAS ≤ 3.2. Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Week 48

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	9	4	3
Units: percentage of participants				
number (confidence interval 95%)	50.0 (9.1 to 90.9)	33.3 (0.0 to 69.7)	50.0 (0.0 to 100.0)	0 (0.0 to 16.7)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved PASDAS Remission at Weeks 4 and 16

End point title	Percentage of Participants who Achieved PASDAS Remission at Weeks 4 and 16

End point description:

PASDAS is a composite disease activity measure for psoriatic arthritis. The PASDAS includes the following components: PGADA [using a VAS on a scale of 0 (very well) to 100 (very poor)]; PhGADA [using a VAS on a scale of 0 (no disease activity) to 100 (maximum disease activity)]; 36-item short form survey (SF-36) [a questionnaire which measures quality of life across eight domains used to determine a PCS with a score range of 0-100, higher scores indicates better health status]; TJC68; SJC66; LEI [assessed at 6 sites with a score range of 0 to 6, higher scores indicates higher degree of enthesitis]; TDC [with a score range of 0 to 60, higher score indicates higher degree of dactylitis]; CRP. The score of PASDAS ranges from 0-10, lower score indicates better function. PASDAS remission is defined as PASDAS ≤ 1.9. Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 4 and 16

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	34	36	
Units: percentage of participants				
number (confidence interval 95%)				
Wk 4 N=34,33,35	2.9 (0.0 to 10.1)	0 (0.0 to 1.5)	0 (0.0 to 1.4)	
Wk 16 N=31,33,33	12.9 (0.0 to 26.3)	9.1 (0.0 to 20.4)	0 (0.0 to 1.5)	

Statistical analyses

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 4

Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.9
upper limit	2.9

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 4	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	2.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.6
upper limit	11.5

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 16	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	9.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.7
upper limit	21.9

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:	
Week 16	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	12.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2
upper limit	27.8

Secondary: Percentage of Participants who Achieved PASDAS Remission at Week 48

End point title	Percentage of Participants who Achieved PASDAS Remission at Week 48

End point description:

PASDAS is a composite disease activity measure for psoriatic arthritis. The PASDAS includes the following components: PGADA [using a VAS on a scale of 0 (very well) to 100 (very poor)]; PhGADA [using a VAS on a scale of 0 (no disease activity) to 100 (maximum disease activity)]; 36-item short form survey (SF-36) [a questionnaire which measures quality of life across eight domains used to determine a PCS with a score range of 0-100, higher scores indicates better health status]; TJC68; SJC66; LEI [assessed at 6 sites with a score range of 0 to 6, higher scores indicates higher degree of enthesitis]; TDC [with a score range of 0 to 60, higher score indicates higher degree of dactylitis]; CRP. The score of PASDAS ranges from 0-10, lower score indicates better function. PASDAS remission is defined as PASDAS ≤ 1.9. Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Week 48

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	9	4	3
Units: percentage of participants				
number (confidence interval 95%)	25.0 (0.0 to 61.3)	11.1 (0.0 to 37.2)	25.0 (0.0 to 79.9)	0 (0.0 to 16.7)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved an American College of Rheumatology 20% Improvement Response at Weeks 2, 4, 8, 12, and 16

End point title	Percentage of Participants who Achieved an American College

	of Rheumatology 20% Improvement Response at Weeks 2, 4, 8, 12, and 16

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: PGADA using a VAS on a scale of 0 (very well) to 100 (very poor); PHGADA using a VAS on a scale of 0 (no disease activity) to 100 (maximum disease activity); HAQ-DI inclusive of activities scored on a scale of 0 (no disability) to 3 (completely disabled); HAQ-DI pain assessment using VAS on a scale of 0 (no pain) to 100 (serious pain); and hsCRP. Participants with missing outcomes were set as non-responders. Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 2, 4, 8, 12, and 16

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	34	36	
Units: percentage of participants				
number (confidence interval 95%)				
Wk 2 N=34,33,36	26.5 (10.2 to 42.8)	6.1 (0.0 to 15.7)	11.1 (0.0 to 22.8)	
Wk 4 N=35,34,34	31.4 (14.6 to 48.2)	29.4 (12.6 to 46.2)	20.6 (5.5 to 35.7)	
Wk 8 N=32,34,33	59.4 (40.8 to 78.0)	32.4 (15.2 to 49.5)	39.4 (21.2 to 57.6)	
Wk 12 N=33,34,34	60.6 (42.4 to 78.8)	35.3 (17.8 to 52.8)	32.4 (15.2 to 49.5)	
Wk 16 N=32,33,33	56.3 (37.5 to 75.0)	36.4 (18.4 to 54.3)	30.3 (13.1 to 47.5)	

Statistical analyses

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 2

Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.098 [19]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	15.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.5
upper limit	36.3

Notes:

[19] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic region, concurrent use of csDMARD(s) and/or apremilast at randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 4	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.26 [20]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.6
upper limit	34.3

Notes:

[20] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic region, concurrent use of csDMARD(s) and/or apremilast at randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 2	
Comparison groups	Placebo (Main Study) v Filgotinib 100 mg (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4 [21]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	-5.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-21.1
upper limit	11

Notes:

[21] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic region, concurrent use of csDMARD(s) and/or apremilast at randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 8	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)

Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.088 [22]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	20
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.9
upper limit	46.9

Notes:

[22] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic region, concurrent use of csDMARD(s) and/or apremilast at randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 4

Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.39 [23]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	8.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.6
upper limit	32.2

Notes:

[23] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic region, concurrent use of csDMARD(s) and/or apremilast at randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 12

Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.019 [24]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	28.3

Confidence interval	
level	95 %
sides	2-sided
lower limit	2.4
upper limit	54.2

Notes:

[24] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic region, concurrent use of csDMARD(s) and/or apremilast at randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 8

Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.49 [25]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	-7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-32.9
upper limit	18.9

Notes:

[25] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic region, concurrent use of csDMARD(s) and/or apremilast at randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 16

Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.036 [26]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	25.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.4
upper limit	52.3

Notes:

[26] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic region, concurrent use of csDMARD(s) and/or apremilast at randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 12

Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.85 [27]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	2.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.5
upper limit	28.4

Notes:

[27] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic region, concurrent use of csDMARD(s) and/or apremilast at randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 16

Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6 [28]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	6.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.7
upper limit	31.8

Notes:

[28] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic region, concurrent use of csDMARD(s) and/or apremilast at randomization, prior use of bioDMARD(s)) in the model.

Secondary: Percentage of Participants who Achieved an American College of Rheumatology 20% Improvement Response at Weeks 18, 20, 24, 28, 36, 48, and 60

End point title	Percentage of Participants who Achieved an American College of Rheumatology 20% Improvement Response at Weeks 18, 20, 24, 28, 36, 48, and 60

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: PGADA using a VAS on a scale of 0 (very well) to 100 (very poor); PHGADA using a VAS on a scale of 0 (no disease activity) to 100 (maximum disease activity); HAQ-DI inclusive of activities scored on a scale of 0 (no disability) to 3 (completely disabled); HAQ-DI pain assessment using VAS on a scale of 0 (no pain) to 100 (serious pain); and hsCRP. Participants with missing outcomes were set as non-responders. Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 18, 20, 24, 28, 36, 48, and 60

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	20	10	8
Units: percentage of participants				
number (confidence interval 95%)				
Wk 18 N=15,18,7,7	66.7 (39.5 to 93.9)	50.0 (24.1 to 75.9)	42.9 (0.0 to 86.7)	0 (0.0 to 7.1)
Wk 20 N=13,19,8,8	46.2 (15.2 to 77.1)	47.4 (22.3 to 72.5)	50.0 (9.1 to 90.9)	12.5 (0.0 to 41.7)
Wk 24 N=13,16,4,6	46.2 (15.2 to 77.1)	75.0 (50.7 to 99.3)	0 (0.0 to 12.5)	16.7 (0.0 to 54.8)
Wk 28 N=8,11,3,5	62.5 (22.7 to 100.0)	72.7 (41.9 to 100.0)	33.3 (0.0 to 100.0)	20.0 (0.0 to 65.1)
Wk 36 N=9,10,3,4	77.8 (45.1 to 100.0)	50.0 (14.0 to 86.0)	0 (0.0 to 16.7)	50.0 (0.0 to 100.0)
Wk 48 N=8,9,3,3	62.5 (22.7 to 100.0)	44.4 (6.4 to 82.5)	66.7 (0.0 to 100.0)	0 (0.0 to 16.7)
Wk 60 N=1,1,2,2	100.0 (50.0 to 100.0)	100.0 (50.0 to 100.0)	100.0 (75.0 to 100.0)	50.0 (0.0 to 100.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieve an American College of Rheumatology 50% Improvement Response at Weeks 2, 4, 8, 12, and 16

End point title	Percentage of Participants who Achieve an American College of Rheumatology 50% Improvement Response at Weeks 2, 4, 8, 12, and 16

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: PGADA using a VAS on a scale of 0 (very well) to 100 (very poor); PHGADA using a VAS on a scale of 0 (no disease activity) to 100 (maximum disease activity); HAQ-DI inclusive of activities scored on a scale of 0 (no disability) to 3 (completely disabled); HAQ-DI pain assessment using VAS on a scale of 0 (no pain) to 100 (serious pain); and hsCRP. Participants with missing outcomes were set as non-responders. Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 2, 4, 8, 12, and 16

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	34	36	
Units: percentage of participants				
number (confidence interval 95%)				
Wk 2 N=34,33,36	8.8 (0.0 to 19.8)	0 (0.0 to 1.5)	2.8 (0.0 to 9.5)	
Wk 4 N=36,34,35	11.1 (0.0 to 22.8)	0 (0.0 to 1.5)	8.6 (0.0 to 19.3)	
Wk 8 N=32,34,33	15.6 (1.5 to 29.8)	8.8 (0.0 to 19.8)	9.1 (0.0 to 20.4)	
Wk 12 N=33,34,34	36.4 (18.4 to 54.3)	8.8 (0.0 to 19.8)	17.6 (3.4 to 31.9)	
Wk 16 N=32,33,33	43.8 (25.0 to 62.5)	18.2 (3.5 to 32.9)	3.0 (0.0 to 10.4)	

Statistical analyses

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 2	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.48 [29]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	-2.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.1
upper limit	5.5

Notes:

[29] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic region, concurrent use of csDMARD(s) and/or apremilast at randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 2	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.31 [30]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	6

Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.8
upper limit	19.8

Notes:

[30] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic region, concurrent use of csDMARD(s) and/or apremilast at randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 4

Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7 [31]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	2.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.1
upper limit	19.2

Notes:

[31] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic region, concurrent use of csDMARD(s) and/or apremilast at randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 4

Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.17 [32]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	-8.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.7
upper limit	3.6

Notes:

[32] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic region, concurrent use of csDMARD(s) and/or apremilast at randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 8

Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.98 [33]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	-0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.9
upper limit	16.4

Notes:

[33] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic region, concurrent use of csDMARD(s) and/or apremilast at randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 8

Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.34 [34]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	6.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.5
upper limit	25.6

Notes:

[34] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic region, concurrent use of csDMARD(s) and/or apremilast at randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 12

Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.27 [35]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	-8.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.7
upper limit	10.1

Notes:

[35] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic region, concurrent use of csDMARD(s) and/or apremilast at randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 12

Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.071 [36]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	18.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.1
upper limit	42.5

Notes:

[36] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic region, concurrent use of csDMARD(s) and/or apremilast at randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 16

Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002 [37]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	40.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	19.5
upper limit	62

Notes:

[37] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic region, concurrent use of csDMARD(s) and/or apremilast at randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:	
Week 16	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.082 [38]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	15.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.3
upper limit	32.6

Notes:

[38] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic region, concurrent use of csDMARD(s) and/or apremilast at randomization, prior use of bioDMARD(s)) in the model.

Secondary: Percentage of Participants who Achieve an American College of Rheumatology 50% Improvement Response at Weeks 18, 20, 24, 28, 36, 48, and 60

End point title	Percentage of Participants who Achieve an American College of Rheumatology 50% Improvement Response at Weeks 18, 20, 24, 28, 36, 48, and 60

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: PGADA using a VAS on a scale of 0 (very well) to 100 (very poor); PHGADA using a VAS on a scale of 0 (no disease activity) to 100 (maximum disease activity); HAQ-DI inclusive of activities scored on a scale of 0 (no disability) to 3 (completely disabled); HAQ-DI pain assessment using VAS on a scale of 0 (no pain) to 100 (serious pain); and hsCRP. Participants with missing outcomes were set as non-responders. Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 18, 20, 24, 28, 36, 48, and 60

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	20	10	8
Units: percentage of participants				
number (confidence interval 95%)				
Wk 18 N=15,18,7,8	40.0 (11.9 to 68.1)	22.2 (0.2 to 44.2)	28.6 (0.0 to 69.2)	0 (0.0 to 6.3)
Wk 20 N=13,19,8,8	30.8 (1.8 to 59.7)	21.1 (0.1 to 42.0)	25.0 (0.0 to 61.3)	0 (0.0 to 6.3)
Wk 24 N=13,16,6,6	38.5 (8.2 to 68.8)	56.3 (28.8 to 83.7)	0 (0.0 to 8.3)	0 (0.0 to 8.3)
Wk 28 N=8,11,3,5	37.5 (0.0 to 77.3)	18.2 (0.0 to 45.5)	0 (0.0 to 16.7)	0 (0.0 to 10.0)
Wk 36 N=9,10,3,5	66.7 (30.3 to 100.0)	40.0 (4.6 to 75.4)	0 (0.0 to 16.7)	0 (0.0 to 10.0)

Wk 48 N=8,9,3,3	50.0 (9.1 to 90.9)	11.1 (0.0 to 37.2)	66.7 (0.0 to 100.0)	0 (0.0 to 16.7)
Wk 60 N=1,1,2,2	0 (0.0 to 50.0)	0 (0.0 to 50.0)	0 (0.0 to 25.0)	50.0 (0.0 to 100.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieve an American College of Rheumatology 70% Improvement Response at Weeks 2, 4, 8, 12, and 16

End point title	Percentage of Participants who Achieve an American College of Rheumatology 70% Improvement Response at Weeks 2, 4, 8, 12, and 16

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: PGADA using a VAS on a scale of 0 (very well) to 100 (very poor); PHGADA using a VAS on a scale of 0 (no disease activity) to 100 (maximum disease activity); HAQ-DI inclusive of activities scored on a scale of 0 (no disability) to 3 (completely disabled); HAQ-DI pain assessment using VAS on a scale of 0 (no pain) to 100 (serious pain); and hsCRP. Participants with missing outcomes were set as non-responders. Participants in the FAS with the available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 2, 4, 8, 12, and 16

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	34	36	
Units: percentage of participants				
number (confidence interval 95%)				
Wk 2 N=34,33,36	2.9 (0.0 to 10.1)	0 (0.0 to 1.5)	0 (0.0 to 1.4)	
Wk 4 N=36,34,35	2.8 (0.0 to 9.5)	0 (0.0 to 1.5)	0 (0.0 to 1.4)	
Wk 8 N=32,34,34	15.6 (1.5 to 29.8)	0 (0.0 to 1.5)	2.9 (0.0 to 10.1)	
Wk 12 N=33,34,34	21.2 (5.7 to 36.7)	5.9 (0.0 to 15.3)	2.9 (0.0 to 10.1)	
Wk 16 N=32,33,33	12.5 (0.0 to 25.5)	9.1 (0.0 to 20.4)	0 (0.0 to 1.5)	

Statistical analyses

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 2

Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)

Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	2.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.6
upper limit	11.5

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 2	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.9
upper limit	2.9

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 4	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	2.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.4
upper limit	11

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 4	

Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.9
upper limit	2.9

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 8	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	-2.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.6
upper limit	5.7

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 8	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	12.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.2
upper limit	29.5

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description: Week 12	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	2.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.7
upper limit	15.6

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 12	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	18.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.2
upper limit	36.3

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 16	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	12.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2
upper limit	27

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 16	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	9.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.7
upper limit	21.9

Secondary: Percentage of Participants who Achieve an American College of Rheumatology 70% Improvement Response at Weeks 18, 20, 24, 28, 36, 48, and 60

End point title	Percentage of Participants who Achieve an American College of Rheumatology 70% Improvement Response at Weeks 18, 20, 24, 28, 36, 48, and 60
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: PGADA using a VAS on a scale of 0 (very well) to 100 (very poor); PHGADA using a VAS on a scale of 0 (no disease activity) to 100 (maximum disease activity); HAQ-DI inclusive of activities scored on a scale of 0 (no disability) to 3 (completely disabled); HAQ-DI pain assessment using VAS on a scale of 0 (no pain) to 100 (serious pain); and hsCRP. Participants with missing outcomes were set as non-responders. Participants in the FAS with the available data were analyzed.	
End point type	Secondary
End point timeframe: Weeks 18, 20, 24, 28, 36, 48, and 60	

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	20	10	8
Units: percentage of participants				
number (confidence interval 95%)				
Wk 18 N=15,18,8,8	40.0 (11.9 to 68.1)	11.1 (0.0 to 28.4)	0 (0.0 to 6.3)	0 (0.0 to 6.3)
Wk 20 N=13,19,10,8	30.8 (1.8 to 59.7)	10.5 (0.0 to 27.0)	0 (0.0 to 5.0)	0 (0.0 to 6.3)
Wk 24 N=13,16,6,6	30.8 (1.8 to 59.7)	25.0 (0.7 to 49.3)	0 (0.0 to 8.3)	0 (0.0 to 8.3)
Wk 28 N=8,11,3,5	37.5 (0.0 to 77.3)	9.1 (0.0 to 30.6)	0 (0.0 to 16.7)	0 (0.0 to 10.0)
Wk 36 N=9,10,4,5	33.3 (0.0 to 69.7)	10.0 (0.0 to 33.6)	0 (0.0 to 12.5)	0 (0.0 to 10.0)

Wk 48 N=8,9,4,3	25.0 (0.0 to 61.3)	11.1 (0.0 to 37.2)	0 (0.0 to 12.5)	0 (0.0 to 16.7)
Wk 60 N=1,1,2,2	0 (0.0 to 50.0)	0 (0.0 to 50.0)	0 (0.0 to 25.0)	0 (0.0 to 25.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Individual ACR Component: Tender Joint Count Based on 68 Joints (TJC68) at Weeks 2, 4, 8, 12, and 16

End point title	Change From Baseline in Individual ACR Component: Tender Joint Count Based on 68 Joints (TJC68) at Weeks 2, 4, 8, 12, and 16

End point description:

TJC68 is an assessment of 68 joints. Each joint was evaluated as 'normal', 'tender', 'tender and swollen' or 'not able to evaluate'. It was derived as the sum of all tender joints. The overall tender joint count ranged from 0 to 68, with a higher score indicating a greater degree of tenderness. A negative change from baseline indicates improvement. Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline, 2, 4, 8, 12, and 16 weeks

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	34	36	
Units: tender joint count				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 2 N=34,33,36	-6 (± 10.3)	-5 (± 12.2)	-2 (± 11.9)	
Change from Baseline at Wk 4 N=36,34,35	-7 (± 10.7)	-7 (± 10.2)	-4 (± 13.9)	
Change from Baseline at Wk 8 N=32,34,34	-10 (± 13.2)	-8 (± 11.5)	-8 (± 13.2)	
Change from Baseline at Wk 12 N=33,34,34	-12 (± 15.4)	-10 (± 12.7)	-9 (± 10.7)	
Change from Baseline at Wk 16 N=32,33,33	-13 (± 15.7)	-11 (± 12.5)	-10 (± 10.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Individual ACR Component: TJC68 at Weeks 18, 20, 24, 28, 36, 48, and 60

End point title	Change From Baseline in Individual ACR Component: TJC68 at Weeks 18, 20, 24, 28, 36, 48, and 60

End point description:

TJC68 is an assessment of 68 joints. Each joint was evaluated as 'normal', 'tender', 'tender and swollen', or 'not able to evaluate'. It was derived as the sum of all tender joints. The overall tender joint count ranged from 0 to 68, with a higher score indicating a greater degree of tenderness. A negative change from baseline indicates improvement. Participants in the FAS with available data were analyzed. 9999=SD cannot be calculated for 1 participant.

End point type	Secondary

End point timeframe:

Baseline, 18, 20, 24, 28, 36, 48, and 60 weeks

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	20	10	8
Units: tender joint count				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 18 N=15,18,8,8	-12 (± 14.8)	-12 (± 9.9)	-4 (± 4.6)	-2 (± 6.4)
Change from Baseline at Wk 20 N=13,19,10,8	-18 (± 18.7)	-10 (± 12.2)	-4 (± 5.7)	1 (± 8.9)
Change from Baseline at Wk 24 N=13,16,7,7	-16 (± 25.6)	-11 (± 12.0)	-1 (± 2.3)	-1 (± 12.1)
Change from Baseline at Wk 28 N=8,11,4,5	-21 (± 20.0)	-14 (± 14.2)	0 (± 1.3)	-2 (± 13.4)
Change from Baseline at Wk 36 N=9,10,4,5	-25 (± 19.6)	-13 (± 12.3)	0 (± 1.9)	-5 (± 10.8)
Change from Baseline at Wk 48 N=8,9,4,3	-22 (± 21.6)	-17 (± 14.7)	-6 (± 9.9)	-3 (± 14.0)
Change from Baseline at Wk 60 N=1,1,2,2	-60 (± 9999)	-11 (± 9999)	-5 (± 3.5)	3 (± 17.7)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in ACR Component: Swollen Joint Count Based on 66 Joints (SJC66) at Weeks 2, 4, 8, 12, and 16

End point title	Change From Baseline in ACR Component: Swollen Joint Count Based on 66 Joints (SJC66) at Weeks 2, 4, 8, 12, and 16

End point description:

SJC66 is an assessment of 66 joints. Each joint was evaluated as 'normal', 'swollen', 'tender and swollen', or 'not able to evaluate'. It was derived as the sum of all swollen joints. The overall swollen joint count ranged from 0 to 66, with a higher score indicating a greater degree of swelling. A negative change from baseline indicates improvement. Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline, 2, 4, 8, 12, and 16 weeks

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	34	36	
Units: swollen joint count				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 2 N=34,33,36	-3 (± 7.4)	-3 (± 5.6)	0 (± 6.5)	
Change from Baseline at Wk 4 N=36,34,35	-6 (± 7.1)	-3 (± 4.4)	-3 (± 6.0)	
Change from Baseline at Wk 8 N=32,34,34	-7 (± 8.5)	-4 (± 5.0)	-4 (± 6.3)	
Change from Baseline at Wk 12 N=33,34,34	-8 (± 8.6)	-4 (± 7.2)	-4 (± 5.9)	
Change from Baseline at Wk 16 N=32,33,33	-7 (± 7.6)	-6 (± 6.9)	-5 (± 6.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in ACR Component: SJC66 at Weeks 18, 20, 24, 28, 36, 48, and 60

End point title	Change From Baseline in ACR Component: SJC66 at Weeks 18, 20, 24, 28, 36, 48, and 60

End point description:

SJC66 is an assessment of 66 joints. Each joint was evaluated as 'normal', 'swollen', 'tender and swollen' or 'not able to evaluate'. It was derived as the sum of all swollen joints. The overall swollen joint count ranged from 0 to 66, with a higher score indicating a greater degree of swelling. A negative change from baseline indicates improvement. Participants in the FAS with available data were analyzed. 9999=SD cannot be calculated for 1 participant.

End point type	Secondary

End point timeframe:

Baseline, 18, 20, 24, 28, 36, 48, and 60 weeks

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	20	10	8
Units: swollen joint count				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 18 N=15,18,8,8	-10 (± 7.7)	-8 (± 7.6)	-3 (± 3.2)	-1 (± 2.6)
Change from Baseline at Wk 20 N=13,19,10,8	-11 (± 9.5)	-6 (± 6.0)	-3 (± 4.2)	2 (± 6.6)

Change from Baseline at Wk 24 N=13,16,7,7	-10 (± 9.9)	-6 (± 4.0)	-2 (± 4.1)	-1 (± 2.1)
Change from Baseline at Wk 28 N=8,11,4,5	-14 (± 7.8)	-6 (± 4.2)	0 (± 0.5)	2 (± 6.9)
Change from Baseline at Wk 36 N=9,10,4,5	-14 (± 7.1)	-7 (± 4.3)	-2 (± 3.3)	-1 (± 3.4)
Change from Baseline at Wk 48 N=8,9,4,3	-13 (± 9.5)	-7 (± 4.1)	-6 (± 8.9)	2 (± 4.9)
Change from Baseline at Wk 60 N=1,1,2,2	-21 (± 9999)	-2 (± 9999)	-5 (± 2.8)	2 (± 7.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Individual ACR Component: Patient's Global Assessment of Disease Activity (PGADA) at Weeks 2, 4, 8, 12, and 16

End point title	Change From Baseline in Individual ACR Component: Patient's Global Assessment of Disease Activity (PGADA) at Weeks 2, 4, 8, 12, and 16

End point description:

PGADA was assessed by the participants using a VAS on a scale of 0 (very well) to 100 (very poor). A negative change from baseline indicates improvement. Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline, 2, 4, 8, 12, and 16 weeks

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	34	36	
Units: score on a scale				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 2 N=34,33,36	-13 (± 24.3)	-7 (± 18.6)	-4 (± 21.6)	
Change from Baseline at Wk 4 N=36,34,35	-9 (± 27.2)	-8 (± 19.2)	-9 (± 20.6)	
Change from Baseline at Wk 8 N=32,34,34	-20 (± 28.6)	-7 (± 21.9)	-11 (± 23.0)	
Change from Baseline at Wk 12 N=33,34,34	-24 (± 32.4)	-11 (± 19.4)	-8 (± 23.2)	
Change from Baseline at Wk 16 N=32,33,33	-21 (± 30.3)	-13 (± 24.2)	-5 (± 25.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Individual ACR Component: PGADA at Weeks 18, 20, 24, 28, 36, 48, and 60

End point title	Change From Baseline in Individual ACR Component: PGADA at Weeks 18, 20, 24, 28, 36, 48, and 60

End point description:

PGADA was assessed by the participants using a VAS on a scale of 0 (very well) to 100 (very poor). A negative change from baseline indicates improvement. Participants in the FAS with available data were analyzed. 9999=SD cannot be calculated for 1 participant.

End point type	Secondary

End point timeframe:

Baseline, 18, 20, 24, 28, 36, 48, and 60 weeks

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	20	10	8
Units: score on a scale				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 18 N=15,18,8,8	-24 (± 26.8)	-20 (± 25.4)	-13 (± 16.4)	-11 (± 21.5)
Change from Baseline at Wk 20 N=13,19,10,8	-16 (± 30.0)	-18 (± 31.0)	-15 (± 25.3)	-9 (± 25.1)
Change from Baseline at Wk 24 N=13,16,7,7	-12 (± 30.2)	-28 (± 34.3)	-19 (± 26.4)	-18 (± 9.8)
Change from Baseline at Wk 28 N=8,11,4,5	-19 (± 27.9)	-24 (± 30.4)	-10 (± 34.0)	-21 (± 9.5)
Change from Baseline at Wk 36 N=9,10,4,5	-26 (± 27.5)	-21 (± 30.6)	11 (± 34.9)	-24 (± 8.6)
Change from Baseline at Wk 48 N=8,9,4,3	-31 (± 17.0)	-23 (± 27.6)	-18 (± 21.6)	-6 (± 5.1)
Change from Baseline at Wk 60 N=1,1,2,2	-32 (± 9999)	-10 (± 9999)	-14 (± 18.4)	-6 (± 12.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Individual ACR Component: Physician's Global Assessment of Disease Activity (PhGADA) at Weeks 2, 4, 8, 12, and 16

End point title	Change From Baseline in Individual ACR Component: Physician's Global Assessment of Disease Activity (PhGADA) at Weeks 2, 4, 8, 12, and 16

End point description:

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

End point type	Secondary

End point timeframe:

Baseline, 2, 4, 8, 12, and 16 weeks

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	34	36	
Units: score on a scale				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 2 N=34,32,36	-14 (± 21.1)	-16 (± 14.5)	-8 (± 16.0)	
Change from Baseline at Wk 4 N=35,33,35	-20 (± 21.3)	-19 (± 15.8)	-12 (± 18.5)	
Change from Baseline at Wk 8 N=32,34,34	-31 (± 22.8)	-24 (± 14.1)	-17 (± 20.1)	
Change from Baseline at Wk 12 N=33,34,33	-34 (± 21.2)	-25 (± 17.9)	-15 (± 19.5)	
Change from Baseline at Wk 16 N=32,33,33	-35 (± 24.5)	-27 (± 20.3)	-18 (± 20.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Individual ACR Component: PhGADA at Weeks 18, 20, 24, 28, 36, 48, and 60

End point title	Change from Baseline in Individual ACR Component: PhGADA at Weeks 18, 20, 24, 28, 36, 48, and 60

End point description:

PhGADA was assessed by the physician using a VAS on a scale of 0 (no disease activity) to 100 (maximum disease activity). A negative change from baseline indicates improvement. Participants in the FAS with available data were analyzed. 9999=SD cannot be calculated for 1 participant.

End point type	Secondary

End point timeframe:

Baseline, 18, 20, 24, 28, 36, 48, and 60 weeks

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	20	10	8
Units: score on a scale				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 18 N=15,18,8,8	-36 (± 24.0)	-29 (± 17.7)	-7 (± 14.0)	-6 (± 10.7)

Change from Baseline at Wk 20 N=13,19,10,8	-32 (± 28.8)	-29 (± 15.4)	-14 (± 11.9)	-7 (± 8.9)
Change from Baseline at Wk 24 N=13,16,7,7	-40 (± 24.8)	-29 (± 15.1)	-21 (± 15.0)	-8 (± 5.0)
Change from Baseline at Wk 28 N=8,11,4,5	-43 (± 16.8)	-35 (± 14.4)	-27 (± 19.1)	-3 (± 22.3)
Change from Baseline at Wk 36 N=9,10,4,5	-47 (± 19.6)	-37 (± 13.2)	-20 (± 13.1)	-8 (± 7.2)
Change from Baseline at Wk 48 N=8,9,4,3	-46 (± 23.8)	-31 (± 12.9)	-25 (± 4.0)	-1 (± 2.3)
Change from Baseline at Wk 60 N=1,1,2,2	-77 (± 9999)	-33 (± 9999)	-18 (± 13.4)	-16 (± 4.2)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Individual ACR Component: Health Assessment Questionnaire Disability Index (HAQ-DI)'s Pain Assessment at Weeks 2, 4, 8, 12, and 16

End point title	Change From Baseline in Individual ACR Component: Health Assessment Questionnaire Disability Index (HAQ-DI)'s Pain Assessment at Weeks 2, 4, 8, 12, and 16

End point description:

HAQ-DI`s pain assessment was done using VAS on a scale of 0 (no pain) to 100 (serious pain). A negative change from baseline indicates improvement. Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline, 2, 4, 8, 12, and 16 weeks

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	34	36	
Units: score on a scale				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 2 N=34,33,36	-10 (± 20.4)	-3 (± 12.0)	-4 (± 14.7)	
Change from Baseline at Wk 4 N=36,34,35	-10 (± 23.0)	-4 (± 17.0)	-8 (± 19.1)	
Change from Baseline at Wk 8 N=32,34,34	-17 (± 22.7)	-8 (± 21.3)	-12 (± 20.0)	
Change from Baseline at Wk 12 N=33,34,34	-24 (± 30.0)	-12 (± 22.2)	-6 (± 21.9)	
Change from Baseline at Wk 16 N=32,33,33	-22 (± 26.4)	-13 (± 21.7)	-6 (± 23.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Individual ACR Component: Health Assessment Questionnaire Disability Index (HAQ-DI)'s Pain Assessment at Weeks 18, 20, 24, 28, 36, 48, and 60

End point title	Change From Baseline in Individual ACR Component: Health Assessment Questionnaire Disability Index (HAQ-DI)'s Pain Assessment at Weeks 18, 20, 24, 28, 36, 48, and 60

End point description:

HAQ-DI`s pain assessment was done using VAS on a scale of 0 (no pain) to 100 (serious pain). A negative change from baseline indicates improvement. Participants in the FAS with available data were analyzed. 9999=SD cannot be calculated for 1 participant.

End point type	Secondary

End point timeframe:

Baseline, 18, 20, 24, 28, 36, 48, and 60 weeks

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	20	10	8
Units: score on a scale				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 18 N=15,18,8,8	-26 (± 26.3)	-13 (± 24.7)	-18 (± 25.5)	-7 (± 8.5)
Change from Baseline at Wk 20 N=13,19,10,8	-13 (± 30.3)	-18 (± 24.5)	-19 (± 24.5)	-7 (± 23.5)
Change from Baseline at Wk 24 N=13,16,7,7	-18 (± 30.0)	-25 (± 29.4)	-17 (± 22.0)	-12 (± 12.7)
Change from Baseline at Wk 28 N=8,11,4,5	-23 (± 20.7)	-19 (± 26.6)	-21 (± 25.0)	-21 (± 4.2)
Change from Baseline at Wk 36 N=9,10,4,5	-27 (± 23.7)	-24 (± 23.4)	-2 (± 25.4)	-17 (± 8.4)
Change from Baseline at Wk 48 N=8,9,4,3	-30 (± 22.4)	-23 (± 28.0)	-24 (± 23.6)	-8 (± 5.5)
Change from Baseline at Wk 60 N=1,1,2,2	-22 (± 9999)	-35 (± 9999)	-20 (± 28.3)	-23 (± 2.8)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Individual ACR Component: High-Sensitivity C-Reactive Protein (hsCRP) at Weeks 2, 4, 8, 12, and 16

End point title	Change From Baseline in Individual ACR Component: High-Sensitivity C- Reactive Protein (hsCRP) at Weeks 2, 4, 8, 12, and 16

End point description:

The hsCRP is the ACR core set measure of acute phase reactant. It was measured at the central

laboratory to help assess the effect of filgotinib on the participant's psoriatic arthritis. A negative change from baseline indicates improvement. Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline, 2, 4, 8, 12, and 16 weeks

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	34	36	
Units: mg/L				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 2 N=34,33,35	-4.01 (± 6.669)	0.53 (± 14.972)	0.56 (± 8.836)	
Change from Baseline at Wk 4 N=35,34,34	-4.42 (± 10.769)	-1.20 (± 6.309)	0.05 (± 5.566)	
Change from Baseline at Wk 8 N=32,34,33	-5.21 (± 16.030)	-1.68 (± 5.085)	-1.35 (± 11.841)	
Change from Baseline at Wk 12 N=33,34,33	-4.57 (± 12.585)	-2.43 (± 6.248)	-1.09 (± 11.687)	
Change from Baseline at Wk 16 N=31,33,32	-4.96 (± 13.906)	-0.05 (± 7.210)	-0.37 (± 13.337)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Individual ACR Component: hsCRP at Weeks 18, 20, 24, 28, 36, 48, and 60

End point title	Change From Baseline in Individual ACR Component: hsCRP at Weeks 18, 20, 24, 28, 36, 48, and 60

End point description:

The hsCRP is the ACR core set measure of acute phase reactant. It was measured at the central laboratory to help assess the effect of filgotinib on the participant's psoriatic arthritis. A negative change from baseline indicates improvement. Participants in the FAS with available data were analyzed. 9999=SD cannot be calculated for 1 participant.

End point type	Secondary

End point timeframe:

Baseline, 18, 20, 24, 28, 36, 48, and 60 weeks

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	20	10	8
Units: mg/L				

arithmetic mean (standard deviation)				
Change from Baseline at Wk 18 N=15,18,8,8	-1.49 (± 5.017)	-0.70 (± 4.064)	-3.54 (± 6.980)	-3.05 (± 2.871)
Change from Baseline at Wk 20 N=14,19,10,8	-0.68 (± 4.040)	-1.36 (± 4.214)	-3.83 (± 6.244)	-2.49 (± 3.285)
Change from Baseline at Wk 24 N=14,16,7,7	-3.31 (± 5.963)	-2.21 (± 4.515)	-1.01 (± 5.187)	-1.72 (± 4.828)
Change from Baseline at Wk 28 N=8,11,4,4	1.56 (± 6.011)	-0.92 (± 5.460)	2.24 (± 7.159)	-2.33 (± 2.777)
Change from Baseline at Wk 36 N=9,10,4,5	-3.10 (± 5.507)	-0.84 (± 7.796)	-1.92 (± 1.217)	-2.38 (± 1.959)
Change from Baseline at Wk 48 N=8,9,4,3	-1.84 (± 6.262)	0.07 (± 6.378)	-2.08 (± 2.353)	-1.68 (± 1.992)
Change from Baseline at Wk 60 N=1,1,2,2	-1.65 (± 9999)	-12.32 (± 9999)	2.39 (± 4.851)	-2.73 (± 0.827)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Disease Activity Score 28 (DAS28) C-Reactive Protein (CRP) at Weeks 2, 4, 8, 12, and 16

End point title	Change From Baseline in Disease Activity Score 28 (DAS28) C-Reactive Protein (CRP) at Weeks 2, 4, 8, 12, and 16

End point description:

The DAS28(CRP) is a measure of the participant's disease activity calculated using the tender joint count (28 joints), swollen joint count (28 joints), PGADA [using a VAS on a scale of 0 (very well) to 100 (very poor)] 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 FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline, 2, 4, 8, 12, and 16 weeks

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	34	36	
Units: score on a scale				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 2 N=34,33,35	-1.0 (± 1.09)	-0.7 (± 0.69)	-0.2 (± 0.70)	
Change from Baseline at Wk 4 N=35,34,34	-1.2 (± 1.18)	-0.7 (± 0.78)	-0.7 (± 1.18)	
Change from Baseline at Wk 8 N=32,34,33	-1.5 (± 1.18)	-1.1 (± 0.99)	-1.1 (± 1.41)	
Change from Baseline at Wk 12 N=33,34,33	-1.8 (± 1.37)	-1.3 (± 1.21)	-1.0 (± 1.10)	
Change from Baseline at Wk 16 N=31,33,32	-1.7 (± 1.35)	-1.3 (± 1.04)	-1.0 (± 1.26)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in DAS28(CRP) at Weeks 18, 20, 24, 28, 36, 48 and 60

End point title	Change From Baseline in DAS28(CRP) at Weeks 18, 20, 24, 28, 36, 48 and 60

End point description:

The DAS28(CRP) is a measure of the participant's disease activity calculated using the tender joint count (28 joints), swollen joint count (28 joints), PGADA [using a VAS on a scale of 0 (very well) to 100 (very poor)] 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 FAS with available data were analyzed. 9999=SD cannot be calculated for 1 participant.

End point type	Secondary

End point timeframe:

Baseline, 18, 20, 24, 28, 36, 48 and 60 weeks

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	20	10	8
Units: score on a scale				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 18 N=15,18,8,8	-2.1 (± 1.37)	-1.8 (± 0.84)	-0.9 (± 0.70)	-0.4 (± 0.92)
Change from Baseline at Wk 20 N=13,19,10,8	-1.9 (± 1.34)	-1.7 (± 0.90)	-1.1 (± 0.71)	-0.2 (± 1.34)
Change from Baseline at Wk 24 N=13,16,7,7	-1.8 (± 1.75)	-1.9 (± 1.13)	-0.8 (± 0.66)	-0.7 (± 1.37)
Change from Baseline at Wk 28 N=8,11,4,4	-2.1 (± 1.10)	-2.2 (± 0.84)	-0.9 (± 0.73)	-0.5 (± 1.79)
Change from Baseline at Wk 36 N=9,10,4,5	-2.9 (± 1.38)	-2.1 (± 1.00)	-0.6 (± 1.30)	-0.5 (± 1.10)
Change from Baseline at Wk 48 N=8,9,4,3	-2.7 (± 1.37)	-2.2 (± 0.93)	-1.3 (± 0.67)	0.5 (± 1.62)
Change from Baseline at Wk 60 N=1,1,2,2	-4.9 (± 9999)	-0.4 (± 9999)	-0.7 (± 0.14)	0.1 (± 2.61)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved DAS28(CRP) LDA at Weeks 2, 4, 8, 12, and 16

End point title	Percentage of Participants who Achieved DAS28(CRP) LDA at Weeks 2, 4, 8, 12, and 16

End point description:

The DAS28(CRP) is a measure of the participant's disease activity calculated using the tender joint count (28 joints), swollen joint count (28 joints), PGADA (VAS; 0=very well to 100=very poor), and hsCRP for a total possible score of 1 to 9.4. Higher values indicate higher disease activity. DAS28(CRP) LDA is defined as DAS28(CRP) ≤ 3.2. Participants in FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 2, 4, 8, 12, and 16

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	34	36	
Units: percentage of participants				
number (confidence interval 95%)				
Wk 2 N=34,33,36	20.6 (5.5 to 35.7)	18.2 (3.5 to 32.9)	11.1 (0.0 to 22.8)	
Wk 4 N=35,34,35	40.0 (22.3 to 57.7)	26.5 (10.2 to 42.8)	20.0 (5.3 to 34.7)	
Wk 8 N=32,34,34	53.1 (34.3 to 72.0)	38.2 (20.4 to 56.0)	35.3 (17.8 to 52.8)	
Wk 12 N=33,34,34	51.5 (32.9 to 70.1)	41.2 (23.2 to 59.2)	26.5 (10.2 to 42.8)	
Wk 16 N=31,33,33	54.8 (35.7 to 74.0)	42.4 (24.0 to 60.8)	36.4 (18.4 to 54.3)	

Statistical analyses

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 2

Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	9.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.4
upper limit	29.4

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 2	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	7.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.5
upper limit	26.7

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 4	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	20
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.8
upper limit	43.8

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 4	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	6.5

Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.3
upper limit	29.3

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 8	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	17.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.8
upper limit	44.5

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 8	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	2.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.9
upper limit	28.8

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 12	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)

Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.5
upper limit	50.6

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 12	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	14.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.5
upper limit	39.9

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 16	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	18.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.7
upper limit	45.6

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 16	

Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	6.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.5
upper limit	32.6

Secondary: Percentage of Participants who Achieved DAS28(CRP) LDA at Weeks 18, 20, 24, 28, 36, 48, and 60

End point title	Percentage of Participants who Achieved DAS28(CRP) LDA at Weeks 18, 20, 24, 28, 36, 48, and 60

End point description:

The DAS28(CRP) is a measure of the participant's disease activity calculated using the tender joint count (28 joints), swollen joint count (28 joints), PGADA (VAS; 0=very well to 100=very poor), and hsCRP for a total possible score of 1 to 9.4. Higher values indicate higher disease activity. DAS28(CRP) LDA is defined as DAS28(CRP) ≤ 3.2. Participants in FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 18, 20, 24, 28, 36, 48, and 60

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	20	10	8
Units: percentage of participants				
number (confidence interval 95%)				
Wk 18 N=15,18,8,8	60.0 (31.9 to 88.1)	66.7 (42.1 to 91.2)	62.5 (22.7 to 100.0)	50.0 (9.1 to 90.9)
Wk 20 N=13,19,10,8	38.5 (8.2 to 68.8)	47.4 (22.3 to 72.5)	100.0 (95.0 to 100.0)	37.5 (0.0 to 77.3)
Wk 24 N=13,16,7,7	38.5 (8.2 to 68.8)	75.0 (50.7 to 99.3)	71.4 (30.8 to 100.0)	71.4 (30.8 to 100.0)
Wk 28 N=8,11,4,4	50.0 (9.1 to 90.9)	100.0 (95.5 to 100.0)	100.0 (87.5 to 100.0)	25.0 (0.0 to 79.9)
Wk 36 N=9,10,4,5	77.8 (45.1 to 100.0)	90.0 (66.4 to 100.0)	50.0 (0.0 to 100.0)	40.0 (0.0 to 92.9)
Wk 48 N=8,9,4,3	75.0 (38.7 to 100.0)	88.9 (62.8 to 100.0)	100.0 (87.5 to 100.0)	0 (0.0 to 16.7)
Wk 60 N=1,1,2,2	100.0 (50.0 to 100.0)	0 (0.0 to 50.0)	50.0 (0.0 to 100.0)	50.0 (0.0 to 100.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved DAS28(CRP) Remission at Weeks 2, 4, 8, 12, and 16

End point title	Percentage of Participants who Achieved DAS28(CRP) Remission at Weeks 2, 4, 8, 12, and 16

End point description:

The DAS28(CRP) is a measure of the participant's disease activity calculated using the tender joint count (28 joints), swollen joint count (28 joints), PGADA (VAS; 0=very well to 100=very poor), and hsCRP for a total possible score of 1 to 9.4. Higher values indicate higher disease activity. DAS28(CRP) remission is defined as DAS28(CRP) < 2.6. Missing outcomes were set as non-responders. Participants in FAS with the available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 2, 4, 8, 12, and 16

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	34	36	
Units: percentage of participants				
number (confidence interval 95%)				
Wk 2 N=34,33,36	11.8 (0.0 to 24.1)	6.1 (0.0 to 15.7)	2.8 (0.0 to 9.5)	
Wk 4 N=35,34,35	20.0 (5.3 to 34.7)	8.8 (0.0 to 19.8)	14.3 (1.3 to 27.3)	
Wk 8 N=32,34,34	21.9 (6.0 to 37.8)	20.6 (5.5 to 35.7)	20.6 (5.5 to 35.7)	
Wk 12 N=33,34,34	33.3 (15.7 to 50.9)	32.4 (15.2 to 49.5)	11.8 (0.0 to 24.1)	
Wk 16 N=31,33,33	38.7 (20.0 to 57.5)	24.2 (8.1 to 40.4)	21.2 (5.7 to 36.7)	

Statistical analyses

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 2

Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	9

Confidence interval	
level	95 %
sides	2-sided
lower limit	-6
upper limit	23.9

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 4	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	5.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.7
upper limit	26.2

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 2	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	3.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.4
upper limit	15.9

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 8	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)

Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-21.5
upper limit	24.1

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 4	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	-5.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-23.4
upper limit	12.4

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 12	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	21.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.8
upper limit	43.9

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 8	

Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.2
upper limit	22.2

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 16	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.2
upper limit	26.3

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 12	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	20.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	42.6

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:	
Week 16	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	17.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.7
upper limit	42.7

Secondary: Percentage of Participants who Achieved DAS28(CRP) Remission at Weeks 18, 20, 24, 28, 36, 48, and 60

End point title	Percentage of Participants who Achieved DAS28(CRP) Remission at Weeks 18, 20, 24, 28, 36, 48, and 60

End point description:

The DAS28(CRP) is a measure of the participant's disease activity calculated using the tender joint count (28 joints), swollen joint count (28 joints), PGADA (VAS; 0=very well to 100=very poor), and hsCRP for a total possible score of 1 to 9.4. Higher values indicate higher disease activity. DAS28(CRP) remission is defined as DAS28(CRP) < 2.6. Missing outcomes were set as non-responders. Participants in FAS with the available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 18, 20, 24, 28, 36, 48, and 60

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	20	10	8
Units: percentage of participants				
number (confidence interval 95%)				
Wk 18 N=15,18,8,8	53.3 (24.8 to 81.9)	44.4 (18.7 to 70.2)	62.5 (22.7 to 100.0)	25.0 (0.0 to 61.3)
Wk 20 N=13,19,10,8	30.8 (1.8 to 59.7)	31.6 (8.0 to 55.1)	60.0 (24.6 to 95.4)	25.0 (0.0 to 61.3)
Wk 24 N=13,16,7,7	38.5 (8.2 to 68.8)	62.5 (35.7 to 89.3)	57.1 (13.3 to 100.0)	42.9 (0.0 to 86.7)
Wk 28 N=8,11,4,4	50.0 (9.1 to 90.9)	63.6 (30.7 to 96.6)	75.0 (20.1 to 100.0)	25.0 (0.0 to 79.9)
Wk 36 N=9,10,4,5	55.6 (17.5 to 93.6)	50.0 (14.0 to 86.0)	50.0 (0.0 to 100.0)	20.0 (0.0 to 65.1)
Wk 48 N=8,9,4,3	62.5 (22.7 to 100.0)	55.6 (17.5 to 93.6)	100.0 (87.5 to 100.0)	0 (0.0 to 16.7)
Wk 60 N=1,1,2,2	100.0 (50.0 to 100.0)	0 (0.0 to 50.0)	50.0 (0.0 to 100.0)	50.0 (0.0 to 100.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Achieve DAS28(CRP) LDA

End point title	Time to Achieve DAS28(CRP) LDA

End point description:

The DAS28(CRP) is a measure of the participant's disease activity calculated using the TJC (28 joints), SJC (28 joints), PGADA (VAS; 0=very well to 100=very poor), and hsCRP for a total possible score of 1 to 9.4. Higher values indicate higher disease activity. DAS28(CRP) LDA is defined as DAS28(CRP) ≤ 3.2. Time to achieve DAS28(CRP) LDA is the number of days from the first dose date of study drug administration to the first time when a participant achieves DAS28(CRP) LDA. Participants in the FAS with available data were analyzed. 9999=Median and Upper Inter-Quartile Range was not estimable due to the low number of participants with DAS28(CRP) LDA.

End point type	Secondary

End point timeframe:

Approximately 16 weeks

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	34	32	35	
Units: days				
median (inter-quartile range (Q1-Q3))	57 (29 to 113)	9999 (30 to 9999)	115 (56 to 9999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved DAPSA LDA at Weeks 2, 4, 8, 12, and 16

End point title	Percentage of Participants who Achieved DAPSA LDA at Weeks 2, 4, 8, 12, and 16

End point description:

DAPSA is calculated by summing the following components: TJC68; SJC66; PGADA [using VAS on a scale of 0 (very well) to 100 very poor)]; PGAPI [using a VAS on a scale of 0 (no pain) to 100 (serious pain)] and CRP. DAPSA scores 0-4=remission, 5-14=low disease activity, 15-28=moderate disease activity, and >28=high disease activity. DAPSA LDA is defined as DAPSA ≤ 14. Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 2, 4, 8, 12, and 16

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	34	36	
Units: percentage of participants				
number (confidence interval 95%)				
Wk 2 N=34,33,36	17.6 (3.4 to 31.9)	12.1 (0.0 to 24.8)	8.3 (0.0 to 18.8)	
Wk 4 N=35,34,35	25.7 (9.8 to 41.6)	17.6 (3.4 to 31.9)	20.0 (5.3 to 34.7)	
Wk 8 N=32,34,34	40.6 (22.0 to 59.2)	29.4 (12.6 to 46.2)	35.3 (17.8 to 52.8)	
Wk 12 N=33,34,34	51.5 (32.9 to 70.1)	41.2 (23.2 to 59.2)	32.4 (15.2 to 49.5)	
Wk 16 N=31,33,33	54.8 (35.7 to 74.0)	39.4 (21.2 to 57.6)	36.4 (18.4 to 54.3)	

Statistical analyses

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 2	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	3.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.5
upper limit	21

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 2	
Comparison groups	Placebo (Main Study) v Filgotinib 200 mg (Main Study)

Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	9.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.2
upper limit	27.8

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 4	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	5.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.8
upper limit	28.2

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 4	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	-2.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-23.7
upper limit	19

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 8	

Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	-5.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-31
upper limit	19.3

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 8	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	5.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-21.1
upper limit	31.8

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 12	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	8.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.9
upper limit	34.6

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description: Week 12	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	19.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7
upper limit	45.3

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 16	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	18.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.7
upper limit	45.6

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 16	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-23.4
upper limit	29.5

Secondary: Percentage of Participants who Achieved DAPSA LDA at Weeks 18, 20, 24, 28, 36, 48, and 60

End point title	Percentage of Participants who Achieved DAPSA LDA at Weeks 18, 20, 24, 28, 36, 48, and 60

End point description:

DAPSA is calculated by summing the following components: TJC68; SJC66; PGADA [using VAS on a scale of 0 (very well) to 100 very poor)]; PGAPI [using a VAS on a scale of 0 (no pain) to 100 (serious pain)] and CRP. DAPSA scores 0-4=remission, 5-14=low disease activity, 15-28=moderate disease activity, and >28=high disease activity. DAPSA LDA is defined as DAPSA ≤ 14. Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 18, 20, 24, 28, 36, 48, and 60

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	20	10	8
Units: percentage of participants				
number (confidence interval 95%)				
Wk 18 N=15,18,8,8	53.3 (24.8 to 81.9)	50.0 (24.1 to 75.9)	75.0 (38.7 to 100.0)	50.0 (9.1 to 90.0)
Wk 20 N=13,19,10,8	30.8 (1.8 to 59.7)	47.4 (22.3 to 72.5)	80.0 (50.2 to 100.0)	37.5 (0.0 to 77.3)
Wk 24 N=13,16,7,7	38.5 (8.2 to 68.8)	75.0 (50.7 to 99.3)	71.4 (30.8 to 100.0)	42.9 (0.0 to 86.7)
Wk 28 N=8,11,4,4	62.5 (22.7 to 100.0)	72.7 (41.9 to 100.0)	100.0 (87.5 to 100.0)	50.0 (0.0 to 100.0)
Wk 36 N=9,10,4,5	66.7 (30.3 to 100.0)	60.0 (24.6 to 95.4)	50.0 (0.0 to 100.0)	60.0 (7.1 to 100.0)
Wk 48 N=8,9,4,3	62.5 (22.7 to 100.0)	77.8 (45.1 to 100.0)	75.0 (20.1 to 100.0)	33.3 (0.0 to 100.0)
Wk 60 N=1,1,2,2	0 (0.0 to 50.0)	0 (0.0 to 50.0)	50.0 (0.0 to 100.0)	50.0 (0.0 to 100.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved DAPSA Remission at Weeks 2, 4, 8, 12, and 16

End point title	Percentage of Participants who Achieved DAPSA Remission at Weeks 2, 4, 8, 12, and 16

End point description:

DAPSA is calculated by summing the following components: TJC68; SJC66; PGADA [using VAS on a scale of 0 (very well) to 100 very poor)]; PGAPI [using a VAS on a scale of 0 (no pain) to 100 (serious pain)] and CRP. DAPSA scores 0-4=remission, 5-14=low disease activity, 15-28=moderate disease activity, and >28=high disease activity. DAPSA remission is defined as DAPSA ≤ 4. Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe: Weeks 2, 4, 8, 12, and 16

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	34	36	
Units: percentage of participants				
number (confidence interval 95%)				
Wk 2 N=34,33,36	0 (0.0 to 1.5)	3.0 (0.0 to 10.4)	2.8 (0.0 to 9.5)	
Wk 4 N=35,34,35	2.9 (0.0 to 9.8)	0 (0.0 to 1.5)	5.7 (0.0 to 14.8)	
Wk 8 N=32,34,34	9.4 (0.0 to 21.0)	2.9 (0.0 to 10.1)	8.8 (0.0 to 19.8)	
Wk 12 N=33,34,34	15.2 (1.4 to 28.9)	5.9 (0.0 to 15.3)	2.9 (0.0 to 10.1)	
Wk 16 N=31,33,33	16.1 (1.6 to 30.7)	15.2 (1.4 to 28.9)	3.0 (0.0 to 10.4)	

Statistical analyses

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 2	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.6
upper limit	11.1

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 2	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)

Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	-2.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11
upper limit	5.4

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 4	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	-2.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.2
upper limit	9.5

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 4	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	-5.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.3
upper limit	4.9

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 8	

Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	-5.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.9
upper limit	8.2

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 8	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.4
upper limit	17.5

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 16	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	13.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.2
upper limit	30.4

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description: Week 12	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	12.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.3
upper limit	28.7

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 12	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	2.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.7
upper limit	15.6

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 16	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	12.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.5
upper limit	28.7

Secondary: Percentage of Participants who Achieved DAPSA Remission at Weeks 18, 20, 24, 28, 36, 48, and 60

End point title	Percentage of Participants who Achieved DAPSA Remission at Weeks 18, 20, 24, 28, 36, 48, and 60

End point description:

DAPSA is calculated by summing the following components: TJC68; SJC66; PGADA [using VAS on a scale of 0 (very well) to 100 very poor)]; PGAPI [using a VAS on a scale of 0 (no pain) to 100 (serious pain)] and CRP. DAPSA scores 0-4=remission, 5-14=low disease activity, 15-28=moderate disease activity, and >28=high disease activity. DAPSA remission is defined as DAPSA ≤ 4. Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 18, 20, 24, 28, 36, 48, and 60

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	20	10	8
Units: percentage of participants				
number (confidence interval 95%)				
Wk 18 N=15,18,8,8	46.7 (18.1 to 75.2)	16.7 (0.0 to 36.7)	50.0 (9.1 to 90.9)	12.5 (0.0 to 41.7)
Wk 20 N=13,19,10,8	23.1 (0.0 to 49.8)	15.8 (0.0 to 34.8)	20.0 (0.0 to 49.8)	0 (0.0 to 6.3)
Wk 24 N=13,16,7,7	30.8 (1.8 to 59.7)	43.8 (16.3 to 71.2)	28.6 (0.0 to 69.2)	14.3 (0.0 to 47.4)
Wk 28 N=8,11,4,4	37.5 (0.0 to 77.3)	18.2 (0.0 to 45.5)	50.0 (0.0 to 100.0)	0 (0.0 to 12.5)
Wk 36 N=9,10,4,5	55.6 (17.5 to 93.6)	10.0 (0.0 to 33.6)	25.0 (0.0 to 79.9)	0 (0.0 to 10.0)
Wk 48 N=8,9,4,3	50.0 (9.1 to 90.9)	22.2 (0.0 to 54.9)	75.0 (20.1 to 100.0)	0 (0.0 to 16.7)
Wk 60 N=1,1,2,2	0 (0.0 to 50.0)	0 (0.0 to 50.0)	50.0 (0.0 to 100.0)	0 (0.0 to 25.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Achieve DAPSA LDA

End point title	Time to Achieve DAPSA LDA

End point description:

DAPSA is calculated by summing following components: TJC68; SJC66; PGADA [using VAS on a scale of 0 (very well) to 100 very poor)]; PGAPI [using a VAS on a scale of 0 (no pain) to 100 (serious pain)] and CRP. DAPSA scores 0-4=remission, 5-14=low disease activity, 15-28=moderate disease activity, and >28=high disease activity. DAPSA LDA is defined as DAPSA ≤ 14. Time to achieve DAPSA LDA is number of days from first dose date of study drug administration to first time when a participant achieves DAPSA LDA. If DAPSA LDA is not achieved during main study phase, time to achieve DAPSA LDA was censored at last non-missing DAS28(CRP) assessment date during main study phase. If component scores of DAPSA LDA are at different dates for a visit, the latest date was used for derivation of time to achieve DAPSA LDA. Participants in the FAS with available data were analyzed. 9999=Median

and Upper Inter-Quartile Range was not estimable due to the low number of participants with DAPSA LDA.

End point type	Secondary

End point timeframe:

Approximately 16 weeks

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	33	35	
Units: days				
median (inter-quartile range (Q1-Q3))	84 (29 to 114)	9999 (58 to 9999)	9999 (55 to 9999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved Psoriatic Arthritis Response Criteria (PsARC) Response at Weeks 2, 4, 8, 12, and 16

End point title	Percentage of Participants who Achieved Psoriatic Arthritis Response Criteria (PsARC) Response at Weeks 2, 4, 8, 12, and 16

End point description:

The PsARC response was defined as improvement in at least 2 of the following 4 criteria; ≥ 30% decrease in SJC66, ≥ 30% decrease in TJC68, ≥ 20% decrease in PGADA (VAS; 0 = very well to 100 = very poor), ≥ 20% decrease in PhGADA (VAS; 0 = no disease activity to 100 = maximum disease activity) and with at least one of the 2 joint criteria, with no deterioration in any other criteria. Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 2, 4, 8, 12, and 16

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	34	36	
Units: percentage of participants				
number (confidence interval 95%)				
Wk 2 N=34,33,36	32.4 (15.2 to 49.5)	21.2 (5.7 to 36.7)	13.9 (1.2 to 26.6)	
Wk 4 N=36,34,35	41.7 (24.2 to 59.2)	41.2 (23.2 to 59.2)	25.7 (9.8 to 41.6)	
Wk 8 N=32,34,34	68.8 (51.1 to 86.4)	44.1 (26.0 to 62.3)	50.0 (31.7 to 68.3)	

Wk 12 N=33,34,34	75.8 (59.6 to 91.9)	58.8 (40.8 to 76.8)	35.3 (17.8 to 52.8)	
Wk 16 N=32,33,33	62.5 (44.2 to 80.8)	48.5 (29.9 to 67.1)	42.4 (24.0 to 60.8)	

Statistical analyses

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 2	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	18.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.8
upper limit	40.7

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 2	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	7.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.5
upper limit	28.2

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 4	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)

Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.5
upper limit	40.4

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 4	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	15.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.4
upper limit	40.3

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 8	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	-5.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-32.5
upper limit	20.7

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 8	

Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	18.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.5
upper limit	45

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 12	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	23.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	49.5

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 12	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	40.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	15.8
upper limit	65.2

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:	
Week 16	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	20.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.8
upper limit	46.9

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 16	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	6.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-21
upper limit	33.1

Secondary: Percentage of Participants who Achieved PsARC Response at Weeks 18, 20, 24, 28, 36, 48, and 60

End point title	Percentage of Participants who Achieved PsARC Response at Weeks 18, 20, 24, 28, 36, 48, and 60

End point description:

The PsARC response was defined as improvement in at least 2 of the following 4 criteria; ≥ 30% decrease in SJC66, ≥ 30% decrease in TJC68, ≥ 20% decrease in PGADA (VAS; 0 = very well to 100 = very poor), ≥ 20% decrease in PhGADA (VAS; 0 = no disease activity to 100 = maximum disease activity) and with at least one of the 2 joint criteria, with no deterioration in any other criteria. Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 18, 20, 24, 28, 36, 48, and 60

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	20	10	8
Units: percentage of participants				
number (confidence interval 95%)				
Wk 18 N=15,18,7,7	73.3 (47.6 to 99.0)	83.3 (63.3 to 100.0)	42.9 (0.0 to 86.7)	28.6 (0.0 to 69.2)
Wk 20 N=13,19,9,7	61.5 (31.2 to 91.8)	68.4 (44.9 to 92.0)	44.4 (6.4 to 82.5)	28.6 (0.0 to 69.2)
Wk 24 N=13,16,6,6	53.8 (22.9 to 84.8)	68.8 (42.9 to 94.6)	16.7 (0.0 to 54.8)	16.7 (0.0 to 54.8)
Wk 28 N=8,11,4,5	75.0 (38.7 to 100.0)	63.6 (30.7 to 96.6)	50.0 (0.0 to 100.0)	0 (0.0 to 10.0)
Wk 36 N=9,10,4,5	88.9 (62.8 to 100.0)	70.0 (36.6 to 100.0)	25.0 (0.0 to 79.9)	20.0 (0.0 to 65.1)
Wk 48 N=8,9,4,3	87.5 (58.3 to 100.0)	66.7 (30.3 to 100.0)	100.0 (87.5 to 100.0)	0 (0.0 to 16.7)
Wk 60 N=1,1,2,2	100.0 (50.0 to 100.0)	100.0 (50.0 to 100.0)	50.0 (0.0 to 100.0)	0 (0.0 to 25.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Psoriasis Area and Severity Index (PASI) at Weeks 4, 8, 12, and 16 in Participants With Psoriasis Covering ≥ 3% of the BSA at Baseline

End point title	Change From Baseline in Psoriasis Area and Severity Index (PASI) at Weeks 4, 8, 12, and 16 in Participants With Psoriasis Covering ≥ 3% of the BSA at Baseline

End point description:

PASI is assessed in participants with psoriasis covering ≥ 3% of the BSA at Baseline. PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body is divided into 4 regions: the head and neck, trunk, upper limbs, and lower limbs. Each of these areas are assessed separately for the percentage of the area involved and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4, where 0 = none, 1 = mild, 2 = moderate, 3 = severe and 4 = very severe, which translates to a numeric score that ranges from 0 (indicates no involvement) to 6 (90 percent [%] to 100% involvement). The PASI produces a numeric score that can range from 0 (no disease) to 72 (maximal disease). A higher score indicates more severe disease. A negative change from baseline indicates improvement. Participants in the FAS with psoriasis covering ≥ 3% of the BSA at baseline and with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline, 4, 8, 12, and 16 weeks

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	16	17	16	
Units: score on a scale				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 4 N=16,17,15	-1.8 (± 2.79)	-2.0 (± 3.70)	-1.5 (± 7.87)	
Change from Baseline at Wk 8 N=16,17,14	-3.6 (± 4.82)	-1.7 (± 5.27)	-4.3 (± 6.30)	
Change from Baseline at Wk 12 N=16,17,14	-4.5 (± 6.79)	-2.3 (± 5.28)	-4.9 (± 7.10)	
Change from Baseline at Wk 16 N=15,17,14	-5.5 (± 6.90)	-1.0 (± 7.34)	-5.4 (± 6.10)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in PASI at Weeks 20, 24, 28, 36, and 48 in Participants With Psoriasis Covering ≥ 3% of the BSA at Baseline

End point title	Change From Baseline in PASI at Weeks 20, 24, 28, 36, and 48 in Participants With Psoriasis Covering ≥ 3% of the BSA at Baseline

End point description:

PASI is assessed in participants with psoriasis covering ≥ 3% of the BSA at Baseline. PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body is divided into 4 regions: the head and neck, trunk, upper limbs, and lower limbs. Each of these areas are assessed separately for the percentage of the area involved and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4, where 0 = none, 1 = mild, 2 = moderate, 3 = severe and 4 = very severe, which translates to a numeric score that ranges from 0 (indicates no involvement) to 6 (90 percent [%] to 100% involvement). The PASI produces a numeric score that can range from 0 (no disease) to 72 (maximal disease). A higher score indicates more severe disease. A negative change from baseline indicates improvement. Participants in the FAS with psoriasis covering ≥ 3% of the BSA at baseline and with available data were analyzed. 9999=SD can

End point type	Secondary

End point timeframe:

Baseline, 20, 24, 28, 36, and 48 weeks

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	17	5	2
Units: score on a scale				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 20 N=8,7,5,2	-0.4 (± 7.20)	-2.9 (± 3.83)	-2.0 (± 2.21)	-1.3 (± 1.84)
Change from Baseline at Wk 24 N=7,7,4,2	-2.9 (± 3.25)	-2.6 (± 3.06)	-2.9 (± 2.45)	-1.9 (± 2.69)

Change from Baseline at Wk 28 N=3,6,3,1	-2.5 (± 2.37)	-4.4 (± 3.65)	-2.0 (± 2.62)	-4.0 (± 9999)
Change from Baseline at Wk 36 N=4,5,4,1	-2.3 (± 2.34)	-1.0 (± 4.68)	-2.4 (± 2.30)	-3.8 (± 9999)
Change from Baseline at Wk 48 N=4,5,4,1	-1.7 (± 1.54)	-2.0 (± 3.77)	-1.8 (± 1.41)	-2.6 (± 9999)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved Psoriasis Area and Severity Index 50% Improvement (PASI50) Response at Weeks 4, 8, 12, and 16 in Participants With Psoriasis Covering ≥ 3% of the BSA at Baseline

End point title	Percentage of Participants who Achieved Psoriasis Area and Severity Index 50% Improvement (PASI50) Response at Weeks 4, 8, 12, and 16 in Participants With Psoriasis Covering ≥ 3% of the BSA at Baseline

End point description:

PASI is assessed in participants with psoriasis covering ≥ 3% of the BSA at Baseline. PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body is divided into 4 regions: the head and neck, trunk, upper limbs, and lower limbs. Each of these areas are assessed separately for the percentage of the area involved and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4, which translates to a numeric score that ranges from 0 (indicates no involvement) to 6 (90 percent [%] to 100% involvement). The PASI produces a numeric score that can range from 0 (no disease) to 72 (maximal disease). For PASI50, the improvement threshold from baseline in PASI score is 50%. A higher score indicates more severe disease. Participants in the FAS with psoriasis covering ≥ 3% of the BSA at baseline and with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 12, and 16

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	16	17	16	
Units: percentage of participants				
number (confidence interval 95%)				
Wk 4 N=15,17,15	13.3 (0.0 to 33.9)	35.3 (9.6 to 61.0)	13.3 (0.0 to 33.9)	
Wk 8 N=15,17,14	40.0 (11.9 to 68.1)	41.2 (14.8 to 67.5)	35.7 (7.0 to 64.4)	
Wk 12 N=15,17,14	60.0 (31.9 to 88.1)	29.4 (4.8 to 54.0)	42.9 (13.4 to 72.4)	
Wk 16 N=14,17,14	64.3 (35.6 to 93.0)	35.3 (9.6 to 61.0)	35.7 (7.0 to 64.4)	

Statistical analyses

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 4	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.8
upper limit	56.7

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 4	
Comparison groups	Placebo (Main Study) v Filgotinib 200 mg (Main Study)
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-31
upper limit	31

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 8	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	4.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-37.9
upper limit	46.5

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 8	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	5.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-35.4
upper limit	46.3

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 16	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	28.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.1
upper limit	71.2

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 12	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	17.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.6
upper limit	59.9

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 12	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	-13.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-53.7
upper limit	26.8

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 16	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	-0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-40.8
upper limit	39.9

Secondary: Percentage of Participants who Achieved PASI50 Response at Weeks 20, 24, 28, 36, and 48 in Participants with Psoriasis Covering ≥ 3% of the BSA at Baseline

End point title	Percentage of Participants who Achieved PASI50 Response at Weeks 20, 24, 28, 36, and 48 in Participants with Psoriasis Covering ≥ 3% of the BSA at Baseline

End point description:

PASI was assessed in participants with psoriasis covering ≥ 3% of the BSA at Baseline. PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the

PASI system, the body is divided into 4 regions: the head and neck, trunk, upper limbs, and lower limbs. Each of these areas are assessed separately for the percentage of the area involved and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4, which translates to a numeric score that ranges from 0 (indicates no involvement) to 6 (90% to 100% involvement). The PASI produces a numeric score that can range from 0 (no disease) to 72 (maximal disease). A higher score indicates more severe disease. A negative change from baseline indicates improvement. A PASI50 response represents at least a 50% improvement from baseline in the PASI score. Participants in the FAS with psoriasis covering ≥ 3% of the BSA at baseline and with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 20, 24, 28, 36, and 48

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	17	5	2
Units: percentage of participants				
number (confidence interval 95%)				
Wk 20 N=7,7,5,2	57.1 (13.3 to 100.0)	57.1 (13.3 to 100.0)	40.0 (0.0 to 92.9)	0 (0.0 to 25.0)
Wk 24 N=6,7,4,2	83.3 (45.2 to 100.0)	57.1 (13.3 to 100.0)	75.0 (20.1 to 100.0)	50.0 (0.0 to 100.0)
Wk 28 N=2,6,3,1	100.0 (75.0 to 100.0)	66.7 (20.6 to 100.0)	66.7 (0.0 to 100.0)	100.0 (50.0 to 100.0)
Wk 36 N=3,5,4,1	66.7 (0.0 to 100.0)	60.0 (7.1 to 100.0)	75.0 (20.1 to 100.0)	100.0 (50.0 to 100.0)
Wk 48 N=3,5,4,1	66.7 (0.0 to 100.0)	60.0 (7.1 to 100.0)	50.0 (0.0 to 100.0)	0 (0.0 to 50.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved Psoriasis Area and Severity Index 75% Improvement (PASI75) Response at Weeks 4, 8, 12, and 16 in Participants With Psoriasis Covering ≥ 3% of the BSA at Baseline

End point title	Percentage of Participants who Achieved Psoriasis Area and Severity Index 75% Improvement (PASI75) Response at Weeks 4, 8, 12, and 16 in Participants With Psoriasis Covering ≥ 3% of the BSA at Baseline

End point description:

PASI is assessed in participants with psoriasis covering ≥ 3% of the BSA at Baseline. PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body is divided into 4 regions: the head and neck, trunk, upper limbs, and lower limbs. Each of these areas are assessed separately for the percentage of the area involved and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4, which translates to a numeric score that ranges from 0 (indicates no involvement) to 6 (90% to 100% involvement). The PASI produces a numeric score that can range from 0 (no disease) to 72 (maximal disease). For PASI75, the improvement threshold from baseline in PASI score is 75%. A higher score indicates more severe disease. Participants in the FAS with psoriasis covering ≥ 3% of the BSA at baseline and with available data were analyzed.

End point type	Secondary

End point timeframe:
Weeks 4, 8, 12, and 16

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	16	17	16	
Units: percentage of participants				
number (confidence interval 95%)				
Wk 4 N=15,17,15	13.3 (0.0 to 33.9)	17.6 (0.0 to 38.7)	6.7 (0.0 to 22.6)	
Wk 8 N=15,17,14	13.3 (0.0 to 33.9)	17.6 (0.0 to 38.7)	7.1 (0.0 to 24.2)	
Wk 12 N=15,17,14	40.0 (11.9 to 68.1)	17.6 (0.0 to 38.7)	21.4 (0.0 to 46.5)	
Wk 16 N=14,17,14	42.9 (13.4 to 72.4)	23.5 (0.4 to 46.6)	21.4 (0.0 to 46.5)	

Statistical analyses

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 4	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.55 [39]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	6.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-21.3
upper limit	34.7

Notes:

[39] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic region, concurrent use of csDMARD(s) and/or apremilast at randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 4	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)

Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.24 [40]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.4
upper limit	39.3

Notes:

[40] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic region, concurrent use of csDMARD(s) and/or apremilast at randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 8

Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.25 [41]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	10.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.6
upper limit	39.6

Notes:

[41] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic region, concurrent use of csDMARD(s) and/or apremilast at randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 8

Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.47 [42]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	6.2

Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.6
upper limit	35

Notes:

[42] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic region, concurrent use of csDMARD(s) and/or apremilast at randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 12

Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.68 [43]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	-3.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-38.4
upper limit	30.8

Notes:

[43] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic region, concurrent use of csDMARD(s) and/or apremilast at randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 12

Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.44 [44]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	18.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-21.1
upper limit	58.3

Notes:

[44] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic region, concurrent use of csDMARD(s) and/or apremilast at randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 16

Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.98 [45]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	2.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-33.9
upper limit	38.1

Notes:

[45] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic region, concurrent use of csDMARD(s) and/or apremilast at randomization, prior use of bioDMARD(s)) in the model.

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 16

Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.33 [46]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	21.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.4
upper limit	62.2

Notes:

[46] - P-value was calculated from the logistic regression with treatment groups and stratification factors (geographic region, concurrent use of csDMARD(s) and/or apremilast at randomization, prior use of bioDMARD(s)) in the model.

Secondary: Percentage of Participants who Achieved PASI75 Response at Weeks 20, 24, 28, 36, and 48 in Participants With Psoriasis Covering ≥ 3% of the BSA at Baseline

End point title	Percentage of Participants who Achieved PASI75 Response at Weeks 20, 24, 28, 36, and 48 in Participants With Psoriasis Covering ≥ 3% of the BSA at Baseline

End point description:

PASI is assessed in participants with psoriasis covering ≥ 3% of the BSA at Baseline. PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body is divided into 4 regions: the head and neck, trunk, upper limbs, and lower limbs. Each of these areas are assessed separately for the percentage of the area involved and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4, which translates to a numeric score that ranges from 0 (indicates no involvement) to 6 (90% to 100% involvement). The PASI produces a numeric score that can range from 0 (no disease) to 72 (maximal disease). For PASI75, the improvement threshold from baseline in PASI score is 75%. A higher score indicates more severe

disease. Participants in the FAS with psoriasis covering ≥ 3% of the BSA at baseline and with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 20, 24, 28, 36, and 48

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	17	5	2
Units: percentage of participants				
number (confidence interval 95%)				
Wk 20 N=7,7,5,2	14.3 (0.0 to 47.4)	42.9 (0.0 to 86.7)	0 (0.0 to 10.0)	0 (0.0 to 25.0)
Wk 24 N=6,7,4,2	50.0 (1.7 to 98.3)	42.9 (0.0 to 86.7)	75.0 (20.1 to 100.0)	0 (0.0 to 25.0)
Wk 28 N=2,6,3,1	0 (0.0 to 25.0)	50.0 (1.7 to 98.3)	66.7 (0.0 to 100.0)	0 (0.0 to 50.0)
Wk 36 N=3,5,4,1	66.7 (0.0 to 100.0)	40.0 (0.0 to 92.9)	50.0 (0.0 to 100.0)	0 (0.0 to 50.0)
Wk 48 N=3,5,4,1	0 (0.0 to 16.7)	20.0 (0.0 to 65.1)	25.0 (0.0 to 79.9)	0 (0.0 to 50.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved Psoriasis Area and Severity Index 90% Improvement (PASI90) Response at Weeks 4, 8, 12, and 16 in Participants With Psoriasis Covering ≥ 3% of the BSA at Baseline

End point title	Percentage of Participants who Achieved Psoriasis Area and Severity Index 90% Improvement (PASI90) Response at Weeks 4, 8, 12, and 16 in Participants With Psoriasis Covering ≥ 3% of the BSA at Baseline

End point description:

PASI is assessed in participants with psoriasis covering ≥ 3% of the BSA at Baseline. PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body is divided into 4 regions: the head and neck, trunk, upper limbs, and lower limbs. Each of these areas are assessed separately for the percentage of the area involved and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4, which translates to a numeric score that ranges from 0 (indicates no involvement) to 6 (90 percent [%] to 100% involvement). The PASI produces a numeric score that can range from 0 (no disease) to 72 (maximal disease). For PASI90, the improvement threshold from baseline in PASI score is 90%. A higher score indicates more severe disease. Participants in the FAS with psoriasis covering ≥ 3% of the BSA at baseline with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 12, and 16

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	16	17	16	
Units: percentage of participants				
number (confidence interval 95%)				
Wk 4 N=15,17,15	6.7 (0.0 to 22.6)	5.9 (0.0 to 20.0)	6.7 (0.0 to 22.6)	
Wk 8 N=15,17,14	13.3 (0.0 to 33.9)	5.9 (0.0 to 20.0)	0 (0.0 to 3.6)	
Wk 12 N=15,17,14	6.7 (0.0 to 22.6)	5.9 (0.0 to 20.0)	21.4 (0.0 to 46.5)	
Wk 16 N=14,17,14	28.6 (1.3 to 55.8)	11.8 (0.0 to 30.0)	7.1 (0.0 to 24.2)	

Statistical analyses

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 4	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	-0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-23.9
upper limit	22.4

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 4	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.5
upper limit	24.5

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 8	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	13.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.8
upper limit	37.4

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 8	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	5.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.8
upper limit	23.6

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 16	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)

Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	21.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13
upper limit	55.8

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 12	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	-14.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-46.6
upper limit	17.1

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 12	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	-15.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-46.3
upper limit	15.2

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 16	

Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	4.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.3
upper limit	31.5

Secondary: Percentage of Participants who Achieved PASI90 Response at Weeks 20, 24, 28, 36, and 48 in Participants With Psoriasis Covering ≥ 3% of the BSA at Baseline

End point title	Percentage of Participants who Achieved PASI90 Response at Weeks 20, 24, 28, 36, and 48 in Participants With Psoriasis Covering ≥ 3% of the BSA at Baseline

End point description:

PASI is assessed in participants with psoriasis covering ≥ 3% of the BSA at Baseline. PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body is divided into 4 regions: the head and neck, trunk, upper limbs, and lower limbs. Each of these areas are assessed separately for the percentage of the area involved and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4, which translates to a numeric score that ranges from 0 (indicates no involvement) to 6 (90 percent [%] to 100% involvement). The PASI produces a numeric score that can range from 0 (no disease) to 72 (maximal disease). For PASI90, the improvement threshold from baseline in PASI score is 90%. A higher score indicates more severe disease. Participants in the FAS with psoriasis covering ≥ 3% of the BSA at baseline with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 20, 24, 28, 36, and 48

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	17	5	2
Units: percentage of participants				
number (confidence interval 95%)				
Wk 20 N=7,7,5,2	0 (0.0 to 7.1)	14.3 (0.0 to 47.4)	0 (0.0 to 10.0)	0 (0.0 to 25.0)
Wk 24 N=6,7,4,2	33.3 (0.0 to 79.4)	14.3 (0.0 to 47.4)	0 (0.0 to 12.5)	0 (0.0 to 25.0)
Wk 28 N=2,6,3,1	0 (0.0 to 25.0)	16.7 (0.0 to 54.8)	0 (0.0 to 16.7)	0 (0.0 to 50.0)
Wk 36 N=3,5,4,1	0 (0.0 to 16.7)	0 (0.0 to 10.0)	0 (0.0 to 12.5)	0 (0.0 to 50.0)
Wk 48 N=3,5,4,1	0 (0.0 to 16.7)	0 (0.0 to 10.0)	25.0 (0.0 to 79.9)	0 (0.0 to 50.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved Psoriasis Area and Severity Index 100% Improvement (PASI100) Response at Weeks 4, 8, 12, and 16 in Participants With Psoriasis Covering ≥ 3% of the BSA at Baseline

End point title	Percentage of Participants who Achieved Psoriasis Area and Severity Index 100% Improvement (PASI100) Response at Weeks 4, 8, 12, and 16 in Participants With Psoriasis Covering ≥ 3% of the BSA at Baseline

End point description:

PASI is assessed in participants with psoriasis covering ≥ 3% of the BSA at Baseline. PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body is divided into 4 regions: the head and neck, trunk, upper limbs, and lower limbs. Each of these areas are assessed separately for the percentage of the area involved and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4, which translates to a numeric score that ranges from 0 (indicates no involvement) to 6 (90 percent [%] to 100% involvement). The PASI produces a numeric score that can range from 0 (no disease) to 72 (maximal disease). For PASI100, the improvement threshold from baseline in PASI score is 100%. A higher score indicates more severe disease. Participants in the FAS with psoriasis covering ≥ 3% of the BSA at baseline with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 12, and 16

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	16	17	16	
Units: percentage of participants				
number (confidence interval 95%)				
Wk 4 N=15,17,15	0 (0.0 to 3.3)	5.9 (0.0 to 20.0)	0 (0.0 to 3.3)	
Wk 8 N=15,17,14	6.7 (0.0 to 22.6)	5.9 (0.0 to 20.0)	0 (0.0 to 3.6)	
Wk 12 N=15,17,14	0 (0.0 to 3.3)	5.9 (0.0 to 20.0)	0 (0.0 to 3.6)	
Wk 16 N=14,17,14	0 (0.0 to 3.6)	5.9 (0.0 to 20.0)	0 (0.0 to 3.6)	

Statistical analyses

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 4	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	5.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.6
upper limit	23.3

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 4	
Comparison groups	Placebo (Main Study) v Filgotinib 200 mg (Main Study)
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.7
upper limit	6.7

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 8	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	5.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.8
upper limit	23.6

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 12	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.9
upper limit	6.9

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 8	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	6.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.9
upper limit	26.2

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 16	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.1
upper limit	7.1

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 12	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	5.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.8
upper limit	23.6

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 16	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	5.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.8
upper limit	23.6

Secondary: Percentage of Participants who Achieved PASI100 Response at Weeks 20, 24, 28, 36, and 48 in Participants With Psoriasis Covering ≥ 3% of the BSA at Baseline

End point title	Percentage of Participants who Achieved PASI100 Response at Weeks 20, 24, 28, 36, and 48 in Participants With Psoriasis Covering ≥ 3% of the BSA at Baseline

End point description:

PASI is assessed in participants with psoriasis covering ≥ 3% of the BSA at Baseline. PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the

PASI system, the body is divided into 4 regions: the head and neck, trunk, upper limbs, and lower limbs. Each of these areas are assessed separately for the percentage of the area involved and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4, which translates to a numeric score that ranges from 0 (indicates no involvement) to 6 (90 percent [%] to 100% involvement). The PASI produces a numeric score that can range from 0 (no disease) to 72 (maximal disease). For PASI100, the improvement threshold from baseline in PASI score is 100%. A higher score indicates more severe disease. Participants in the FAS with psoriasis covering ≥ 3% of the BSA at baseline with available data were analyzed.

End point type	Secondary

End point timeframe:

Weeks 20, 24, 28, 36, and 48

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	17	5	2
Units: percentage of participants				
number (confidence interval 95%)				
Wk 20 N=7,7,5,2	0 (0.0 to 7.1)	14.3 (0.0 to 47.4)	0 (0.0 to 10.0)	0 (0.0 to 25.0)
Wk 24 N=6,7,4,2	0 (0.0 to 8.3)	14.3 (0.0 to 47.4)	0 (0.0 to 12.5)	0 (0.0 to 25.0)
Wk 28 N=2,6,3,1	0 (0.0 to 25.0)	16.7 (0.0 to 54.8)	0 (0.0 to 16.7)	0 (0.0 to 50.0)
Wk 36 N=3,5,4,1	0 (0.0 to 16.7)	0 (0.0 to 10.0)	0 (0.0 to 12.5)	0 (0.0 to 50.0)
Wk 48 N=3,5,4,1	0 (0.0 to 16.7)	0 (0.0 to 10.0)	25.0 (0.0 to 79.9)	0 (0.0 to 50.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Spondyloarthritis Research Consortium of Canada (SPARCC) Enthesitis Index at Weeks 4, 8, 12, and 16 in Participants With Enthesitis at Baseline

End point title	Change From Baseline in Spondyloarthritis Research Consortium of Canada (SPARCC) Enthesitis Index at Weeks 4, 8, 12, and 16 in Participants With Enthesitis at Baseline

End point description:

The enthesitis examination is based on the 16 anatomical sites: the medial epicondyle (left and right), the lateral epicondyle (left and right), the supraspinatus insertion (left and right), the bilateral greater trochanter (left and right), the quadriceps tendon insertion into superior border of patella (left and right), the patellar ligament insertion into inferior pole of patella or tibial tuberosity (left and right), the achilles tendon insertion (left and right), and the plantar fascia insertion (left and right). Enthesitis at each site is scored as either 0 (enthesitis absent) and 1 (enthesitis present). SPARCC enthesitis index has an overall total score ranging from 0 to 16. Higher score indicates a greater number of sites that are affected by enthesitis. A negative change from baseline indicates improvement. Participants in the FAS with enthesitis at baseline and with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline, 4, 8, 12, and 16 weeks

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	22	22	24	
Units: score on a scale				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 4	-2 (± 3.8)	-2 (± 2.3)	0 (± 2.7)	
Change from Baseline at Wk 8 N=20,22,24	-2 (± 4.9)	-2 (± 3.2)	-1 (± 1.9)	
Change from Baseline at Wk 12 N=20,22,24	-2 (± 5.1)	-3 (± 3.2)	-1 (± 2.8)	
Change from Baseline at Wk 16 N=19,21,24	-2 (± 5.6)	-3 (± 2.9)	-2 (± 2.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in SPARCC Enthesitis Index at Weeks 20, 24, 28, 36, and 48 in Participants With Enthesitis at Baseline

End point title	Change From Baseline in SPARCC Enthesitis Index at Weeks 20, 24, 28, 36, and 48 in Participants With Enthesitis at Baseline

End point description:

The enthesitis examination is based on the 16 anatomical sites: the medial epicondyle (left and right), the lateral epicondyle (left and right), the supraspinatus insertion (left and right), the bilateral greater trochanter (left and right), the quadriceps tendon insertion into superior border of patella (left and right), the patellar ligament insertion into inferior pole of patella or tibial tuberosity (left and right), the achilles tendon insertion (left and right), and the plantar fascia insertion (left and right). Enthesitis at each site is scored as either 0 (enthesitis absent) and 1 (enthesitis present). SPARCC enthesitis index has an overall total score ranging from 0 to 16. Higher score indicates a greater number of sites that are affected by enthesitis. A negative change from baseline indicates improvement. Participants in the FAS with enthesitis at baseline and with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline, 20, 24, 28, 36, and 48 weeks

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	20	9	5
Units: score on a scale				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 20 N=10,13,9,5	-3 (± 5.2)	-4 (± 3.6)	0 (± 2.4)	0 (± 1.1)

Change from Baseline at Wk 24 N=11,11,7,5	-3 (± 5.3)	-3 (± 4.3)	0 (± 0.4)	-1 (± 0.8)
Change from Baseline at Wk 28 N=6,7,4,4	-3 (± 6.9)	-5 (± 5.4)	0 (± 1.7)	0 (± 0.8)
Change from Baseline at Wk 36 N=7,7,4,4	-4 (± 5.3)	-5 (± 5.3)	0 (± 2.1)	1 (± 1.7)
Change from Baseline at Wk 48 N=6,6,4,4	-6 (± 5.3)	-6 (± 5.8)	-1 (± 1.0)	0 (± 2.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Leeds Dactylitis Index (LDI) at Weeks 4, 8, 12, and 16 in Participants With Dactylitis at Baseline

End point title	Change From Baseline in Leeds Dactylitis Index (LDI) at Weeks 4, 8, 12, and 16 in Participants With Dactylitis at Baseline

End point description:

LDI measures dactylitis using circumference of involved digits and control digits and tenderness of involved digits. Digits affected by dactylitis are defined as those with an at least 10% difference in ratio of circumference of affected digit to contralateral digit. Control digit is either contralateral digit (digit on opposite hand/foot), or if contralateral digit is also affected, values from standard reference table. LDI score is calculated based on circumference of dactylitic finger/toe (mm), circumference of contralateral digit (mm), tenderness score (0=no tenderness, 1=tender). Tenderness of affected digits is assessed on a scale from 0 (no tenderness) to 3 (tender and withdrawn). Higher LDI=worse dactylitis. Negative change from baseline indicates improvement. Participants in FAS with dactylitis at baseline and with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline, 4, 8, 12, and 16 weeks

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	15	6	9	
Units: score on a scale				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 4	-18.8 (± 48.27)	-5.3 (± 15.36)	13.1 (± 70.34)	
Change from Baseline at Wk 8	-45.4 (± 88.15)	-14.4 (± 26.14)	23.3 (± 129.90)	
Change from Baseline at Wk 12	-49.8 (± 85.77)	-11.8 (± 11.82)	-15.8 (± 15.82)	
Change from Baseline at Wk 16 N=14,6,9	-42.1 (± 95.15)	-11.7 (± 6.30)	-16.2 (± 15.04)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in LDI at Weeks 20, 24, 28, 36, and 48 in Participants with Dactylitis at Baseline

End point title	Change from Baseline in LDI at Weeks 20, 24, 28, 36, and 48 in Participants with Dactylitis at Baseline

End point description:

LDI measures dactylitis using circumference of involved digits and control digits and tenderness of involved digits. Digits affected by dactylitis are defined as those with an at least 10% difference in ratio of circumference of affected digit to contralateral digit. Control digit is either contralateral digit (digit on opposite hand/foot), or if contralateral digit is also affected, values from standard reference table. LDI score is calculated based on circumference of dactylitic finger/toe (mm), circumference of contralateral digit (mm), tenderness score (0=no tenderness, 1=tender). Tenderness of affected digits is assessed on a scale from 0 (no tenderness) to 3 (tender and withdrawn). Higher LDI=worse dactylitis. Negative change from baseline indicates improvement. Participants in FAS with dactylitis at baseline and with available data were analyzed. 9999=SD cannot be calculated for 1 participant.

End point type	Secondary

End point timeframe:

Baseline, 20, 24, 28, 36, and 48 weeks

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	6	4	2
Units: score on a scale				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 20 N=7,4,4,2	-79.5 (± 120.99)	-9.7 (± 6.78)	0.0 (± 0.00)	0.0 (± 0.00)
Change from Baseline at Wk 24 N=6,3,2,2	-94.2 (± 125.41)	-13.0 (± 2.37)	0.0 (± 0.00)	0.0 (± 0.00)
Change from Baseline at Wk 28 N=3,2,2,1	-164.6 (± 147.22)	-11.8 (± 1.64)	0.0 (± 0.00)	0.0 (± 9999)
Change from Baseline at Wk 36 N=4,2,1,1	-123.4 (± 145.68)	-11.8 (± 1.64)	0.0 (± 9999)	0.0 (± 9999)
Change from Baseline at Wk 48 N=4,2,1,1	-123.4 (± 145.68)	-11.8 (± 1.64)	0.0 (± 9999)	0.0 (± 9999)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Tender Dactylitis Count (TDC) at Weeks 4, 8, 12, and 16 in Participants With Dactylitis at Baseline

End point title	Change From Baseline in Tender Dactylitis Count (TDC) at Weeks 4, 8, 12, and 16 in Participants With Dactylitis at Baseline

End point description:

Tender score (0 = no tenderness, 1 = tender, 2 = tender and wince, 3 = tender and withdraw) is collected for Dactylitis Assessments on the Dactylitis Score Sheet that was used for calculation of LDI total score. Tender dactylitis count (TDC) equals the number of tender fingers and toes (tender score >0). For participants with dactylitis status absent for all the fingers and toes, the TDC will be set as 0.

The total score range of TDC is from 0 to 60, higher scores indicate greater presence of dactylitis. A negative change from baseline indicates improvement. Participants in the FAS with dactylitis at baseline and with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline 4, 8, 12, and 16 weeks

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	15	6	9	
Units: tender dactylitis count				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 4	-1 (± 2.2)	1 (± 2.7)	0 (± 3.1)	
Change from Baseline at Wk 8	-3 (± 5.1)	1 (± 3.7)	1 (± 7.1)	
Change from Baseline at Wk 12	-3 (± 5.1)	-1 (± 0.8)	-1 (± 1.0)	
Change from Baseline at Wk 16 N=14,6,9	-3 (± 5.3)	-1 (± 0.5)	-1 (± 0.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in TDC at Weeks 20, 24, 28, 36, and 48 in Participants With Dactylitis at Baseline

End point title	Change From Baseline in TDC at Weeks 20, 24, 28, 36, and 48 in Participants With Dactylitis at Baseline

End point description:

Tender score (0 = no tenderness, 1 = tender, 2 = tender and wince, 3 = tender and withdraw) is collected for Dactylitis Assessments on the Dactylitis Score Sheet that was used for calculation of LDI total score. Tender dactylitis count (TDC) equals the number of tender fingers and toes (tendor score >0). For participants with dactylitis status absent for all the fingers and toes, the TDC will be set as 0. The total score range of TDC is from 0 to 60, higher scores indicate greater presence of dactylitis. A negative change from baseline indicates improvement. Participants in the FAS with dactylitis at baseline and with available data were analyzed. 9999=SD was not calculated for 1 participant.

End point type	Secondary

End point timeframe:

Baseline, 20, 24, 28, 36, and 48 weeks

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	6	4	2
Units: tender dactylitis count				
arithmetic mean (standard deviation)				

Change from Baseline at Wk 20 N=7,4,4,2	-5 (± 7.2)	-1 (± 0.5)	0 (± 0.0)	0 (± 0.0)
Change from Baseline at Wk 24 N=6,3,2,2	-6 (± 7.4)	-1 (± 0.0)	0 (± 0.0)	0 (± 0.0)
Change from Baseline at Wk 28 N=3,2,2,1	-10 (± 9.0)	-1 (± 0.0)	0 (± 0.0)	0 (± 9999)
Change from Baseline at Wk 36 N=4,2,1,1	-7 (± 8.8)	-1 (± 0.0)	0 (± 9999)	0 (± 9999)
Change from Baseline at Wk 48 N=4,2,1,1	-7 (± 8.8)	-1 (± 0.0)	0 (± 9999)	0 (± 9999)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Health Assessment Questionnaire - Disability Index (HAQ-DI) Score at Weeks 2, 4, 8, 12, and 16

End point title	Change From Baseline in Health Assessment Questionnaire - Disability Index (HAQ-DI) Score at Weeks 2, 4, 8, 12, and 16

End point description:

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

End point type	Secondary

End point timeframe:

Baseline, 2, 4, 8, 12, and 16 weeks

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	34	36	
Units: score on a scale				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 2 N=34,33,36	-0.13 (± 0.343)	-0.04 (± 0.277)	-0.03 (± 0.228)	
Change from Baseline at Wk 4 N=36,34,35	-0.16 (± 0.320)	-0.06 (± 0.364)	-0.07 (± 0.273)	
Change from Baseline at Wk 8 N=32,34,34	-0.29 (± 0.412)	-0.07 (± 0.471)	-0.10 (± 0.337)	
Change from Baseline at Wk 12 N=33,34,34	-0.38 (± 0.506)	-0.15 (± 0.401)	-0.14 (± 0.342)	
Change from Baseline at Wk 16 N=32,33,33	-0.38 (± 0.489)	-0.09 (± 0.456)	-0.08 (± 0.328)	

Statistical analyses

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 2	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.84 [47]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	-0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.15
upper limit	0.12
Variability estimate	Standard error of the mean
Dispersion value	0.067

Notes:

[47] - P-value was provided from MMRM including treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, participants being the random effect.

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 2	
Comparison groups	Placebo (Main Study) v Filgotinib 200 mg (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.19 [48]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	-0.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.22
upper limit	0.04
Variability estimate	Standard error of the mean
Dispersion value	0.066

Notes:

[48] - P-value was provided from MMRM including treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, participants being the random effect.

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 4	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)

Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3 [49]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	-0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.22
upper limit	0.07
Variability estimate	Standard error of the mean
Dispersion value	0.073

Notes:

[49] - P-value was provided from MMRM including treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, participants being the random effect.

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 4

Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.89 [50]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.14
upper limit	0.16
Variability estimate	Standard error of the mean
Dispersion value	0.074

Notes:

[50] - P-value was provided from MMRM including treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, participants being the random effect.

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 8

Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.88 [51]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	0.01

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.17
upper limit	0.2
Variability estimate	Standard error of the mean
Dispersion value	0.096

Notes:

[51] - P-value was provided from MMRM including treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, participants being the random effect.

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 8

Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.064 [52]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	-0.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.37
upper limit	0.01
Variability estimate	Standard error of the mean
Dispersion value	0.096

Notes:

[52] - P-value was provided from MMRM including treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, participants being the random effect.

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 12

Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.75 [53]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	-0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.23
upper limit	0.17
Variability estimate	Standard error of the mean
Dispersion value	0.099

Notes:

[53] - P-value was provided from MMRM including treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, participants being the random effect.

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 12	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.023 [54]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	-0.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.43
upper limit	-0.03
Variability estimate	Standard error of the mean
Dispersion value	0.099

Notes:

[54] - P-value was provided from MMRM including treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, participants being the random effect.

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 16	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005 [55]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	-0.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.51
upper limit	-0.1
Variability estimate	Standard error of the mean
Dispersion value	0.106

Notes:

[55] - P-value was provided from MMRM including treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, participants being the random effect.

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 16	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)

Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.54 [56]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	-0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.27
upper limit	0.14
Variability estimate	Standard error of the mean
Dispersion value	0.105

Notes:

[56] - P-value was provided from MMRM including treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, participants being the random effect.

Secondary: Change From Baseline in HAQ-DI Score at Weeks 18, 20, 24, 28, 36, 48, and 60

End point title	Change From Baseline in HAQ-DI Score at Weeks 18, 20, 24, 28, 36, 48, and 60

End point description:

The HAQ-DI score is defined as the average of the scores of eight functional categories (dressing and grooming, arising, eating, walking, hygiene, reach, grip, and other activities), usually completed by the participant. Responses in each functional category are collected as 0 (without any difficulty) to 3 (unable to do a task in that area), with or without aids or devices. The eight category scores are averaged into an overall HAQ-DI score on a scale from 0 (no disability) to 3 (completely disabled). When 6 or more categories are non-missing, total possible score is 3. If more than 2 categories are missing, the HAQ-DI score is set to missing. Negative change from baseline indicates improvement (less disability). Participants in the FAS with available data were analyzed. 9999=SD cannot be calculated for 1 participant.

End point type	Secondary

End point timeframe:

Baseline, 18, 20, 24, 28, 36, 48, and 60 weeks

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	20	10	8
Units: score on a scale				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 18 N=15,18,8,8	-0.42 (± 0.403)	-0.09 (± 0.481)	-0.11 (± 0.254)	-0.02 (± 0.156)
Change from Baseline at Wk 20 N=13,19,10,8	-0.38 (± 0.468)	-0.14 (± 0.573)	-0.28 (± 0.558)	-0.02 (± 0.356)
Change from Baseline at Wk 24 N=13,16,7,7	-0.21 (± 0.431)	-0.30 (± 0.546)	-0.29 (± 0.672)	-0.11 (± 0.168)
Change from Baseline at Wk 28 N=8,11,4,5	-0.23 (± 0.430)	-0.33 (± 0.485)	-0.63 (± 0.685)	-0.13 (± 0.234)
Change from Baseline at Wk 36 N=9,10,4,5	-0.36 (± 0.345)	-0.29 (± 0.417)	-0.25 (± 0.777)	-0.20 (± 0.259)

Change from Baseline at Wk 48 N=8,9,4,3	-0.41 (± 0.346)	-0.25 (± 0.428)	-0.44 (± 0.725)	-0.04 (± 0.191)
Change from Baseline at Wk 60 N=1,1,2,2	0.00 (± 9999)	-0.25 (± 9999)	-0.38 (± 0.000)	-0.19 (± 0.265)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Functional Assessment of Chronic Illness Therapy - Fatigue Scale (FACIT-Fatigue) Score at Weeks 4 and 16

End point title	Change From Baseline in Functional Assessment of Chronic Illness Therapy - Fatigue Scale (FACIT-Fatigue) Score at Weeks 4 and 16

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. Higher scores indicate less fatigue. Positive change in value indicates improvement (no or less severity of fatigue). Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline, 4 and 16 weeks

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	34	36	
Units: score on a scale				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 4 N=36,34,35	4.8 (± 6.80)	2.3 (± 5.94)	2.5 (± 8.23)	
Change from Baseline at Wk 16 N=32,33,34	6.9 (± 11.56)	1.9 (± 7.93)	0.6 (± 11.14)	

Statistical analyses

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 4

Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)

Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.81 [57]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	-0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.6
upper limit	2.9
Variability estimate	Standard error of the mean
Dispersion value	1.64

Notes:

[57] - P-value was provided from MMRM including treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, participants being the random effect.

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 4

Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.43 [58]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	4.5
Variability estimate	Standard error of the mean
Dispersion value	1.64

Notes:

[58] - P-value was provided from MMRM including treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, participants being the random effect.

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 16

Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.58 [59]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	1.4

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.4
upper limit	6.1
Variability estimate	Standard error of the mean
Dispersion value	2.41

Notes:

[59] - P-value was provided from MMRM including treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, participants being the random effect.

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 16

Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.04 [60]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	5.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.2
upper limit	9.9
Variability estimate	Standard error of the mean
Dispersion value	2.43

Notes:

[60] - P-value was provided from MMRM including treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, participants being the random effect.

Secondary: Change From Baseline in FACIT-Fatigue Scale Score at Week 48

End point title	Change From Baseline in FACIT-Fatigue Scale Score at Week 48

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. Higher scores indicate better quality of life. Positive change in value indicates improvement (no or less severity of fatigue). Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline, Week 48

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	19	10	8
Units: score on a scale				
arithmetic mean (standard deviation)	6.9 (± 11.27)	4.4 (± 11.76)	5.1 (± 9.09)	3.0 (± 7.63)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Mental Component Score (MCS) of the 36-Item Short-Form Version 2 (SF-36v2) at Weeks 4 and 16

End point title	Change From Baseline in Mental Component Score (MCS) of the 36-Item Short-Form Version 2 (SF-36v2) at Weeks 4 and 16

End point description:

The SF-36 is a health-related survey that assesses participant's quality of life and consists of 36 questions covering 8 health domains: physical functioning, bodily pain, role limitations due to physical problems and emotional problems, general health, mental health, social functioning, vitality, and 2 component scores (MCS and PCS). MCS consists of social functioning, vitality, mental health, and role-emotional scales. Each domain was scored by summing the individual items and transforming the scores into a 0 to 100 scale with higher scores indicating better health status or functioning. A positive change from baseline indicated improvement (better health status). Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline, 4 and 16 weeks

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	34	36	
Units: score on a scale				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 4 N=36,34,35	1.4 (± 7.91)	1.0 (± 5.07)	-0.2 (± 8.48)	
Change from Baseline at Wk 16 N=32,33,34	3.3 (± 9.84)	1.8 (± 8.12)	0.7 (± 9.43)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in MCS of the SF-36v2 at Week 48

End point title	Change From Baseline in MCS of the SF-36v2 at Week 48

End point description:

The SF-36 is a health-related survey that assesses participant's quality of life and consists of 36 questions covering 8 health domains: physical functioning, bodily pain, role limitations due to physical problems and emotional problems, general health, mental health, social functioning, vitality, and 2 component scores (MCS and PCS). MCS consists of social functioning, vitality, mental health, and role-emotional scales. Each domain was scored by summing the individual items and transforming the scores into a 0 to 100 scale with higher scores indicating better health status or functioning. A positive change from baseline indicated improvement (better health status). Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline, Week 48

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	19	10	8
Units: score on a scale				
arithmetic mean (standard deviation)	2.3 (± 10.55)	1.5 (± 8.74)	-0.5 (± 4.13)	-1.4 (± 7.51)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Physical Component Score (PCS) of the SF-36v2 at Weeks 4 and 16

End point title	Change From Baseline in Physical Component Score (PCS) of the SF-36v2 at Weeks 4 and 16

End point description:

The SF-36 is a health-related survey that assesses participant's quality of life and consists of 36 questions covering 8 health domains: physical functioning, bodily pain, role limitations due to physical problems and emotional problems, general health, mental health, social functioning, vitality, and 2 component scores (MCS and PCS). PCS consists of physical functioning, bodily pain, role-physical, and general health scales. Each domain will be scored by summing the individual items and transforming the scores into a 0 to 100 scale with higher scores indicating better health status or functioning. A positive change from baseline indicates improvement (better health status). Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline, 4 and 16 weeks

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	34	36	
Units: score on a scale				
arithmetic mean (standard deviation)				
Change from Baseline at Wk 4 N=36,34,35	2.1 (± 4.95)	2.2 (± 3.92)	0.8 (± 5.61)	
Change from Baseline at Wk 16 N=32,33,34	4.6 (± 6.43)	2.6 (± 5.80)	0.6 (± 5.95)	

Statistical analyses

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 4	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4 [61]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.2
upper limit	3.1
Variability estimate	Standard error of the mean
Dispersion value	1.09

Notes:

[61] - P-value was provided from MMRM including treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, participants being the random effect.

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 16	
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.011 [62]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	3.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	6.7
Variability estimate	Standard error of the mean
Dispersion value	1.46

Notes:

[62] - P-value was provided from MMRM including treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, participants being the random effect.

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 4

Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.28 [63]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	3.4
Variability estimate	Standard error of the mean
Dispersion value	1.1

Notes:

[63] - P-value was provided from MMRM including treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, participants being the random effect.

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 16

Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.14 [64]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	2.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	5
Variability estimate	Standard error of the mean
Dispersion value	1.45

Notes:

[64] - P-value was provided from MMRM including treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, participants being the random effect.

Secondary: Change From Baseline in PCS of the SF-36v2 at Week 48

End point title	Change From Baseline in PCS of the SF-36v2 at Week 48

End point description:

The SF-36 is a health-related survey that assesses participant's quality of life and consists of 36 questions covering 8 health domains: physical functioning, bodily pain, role limitations due to physical problems and emotional problems, general health, mental health, social functioning, vitality, and 2 component scores (MCS and PCS). PCS consists of physical functioning, bodily pain, role-physical, and general health scales. Each domain will be scored by summing the individual items and transforming the scores into a 0 to 100 scale with higher scores indicating better health status or functioning. A positive change from baseline indicates improvement (better health status). Participants in the FAS with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline, Week 48

End point values	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	19	10	8
Units: score on a scale				
arithmetic mean (standard deviation)	1.7 (± 7.27)	3.2 (± 7.54)	3.8 (± 8.51)	-1.9 (± 4.74)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse Events: First dose date up to 63 weeks plus 30 days; All-Cause Mortality: Randomization up to 63 weeks plus 30 days

Adverse event reporting additional description:

Adverse Events: Safety Analysis Set included all participants who took at least 1 dose of study drug. All-Cause Mortality: All Randomized Analysis Set included all participants who were randomized in the study.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.0

Reporting groups

Reporting group title	Filgotinib 200 mg (Main Study)

Reporting group description:

Filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily for 16 weeks.

Reporting group title	Filgotinib 100 mg (Main Study)

Reporting group description:

Filgotinib 100 mg tablet orally once daily + PTM filgotinib 200 mg tablet orally once daily for 16 weeks.

Reporting group title	Placebo (Main Study)

Reporting group description:

PTM filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily for 16 weeks.

Reporting group title	Filgotinib 100 mg From Placebo (LTE)

Reporting group description:

Filgotinib 100 mg tablet orally once daily + PTM filgotinib 200 mg tablet orally once daily for up to 44 weeks. Participants received placebo in the Main Study.

Reporting group title	Filgotinib 100 mg From Filgotinib 100 mg (LTE)

Reporting group description:

Filgotinib 100 mg tablet orally once daily + PTM filgotinib 200 mg tablet orally once daily for up to 43.9 weeks. Participants received filgotinib 100 mg in the Main Study.

Reporting group title	Filgotinib 200 mg From Placebo (LTE)

Reporting group description:

Filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily for up to 44.1 weeks. Participants received placebo in the Main Study.

Reporting group title	Filgotinib 200 mg From Filgotinib 200 mg (LTE)

Reporting group description:

Filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily for up to 44.3 weeks. Participants received filgotinib 200 mg in the Main Study.

Serious adverse events	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 36 (2.78%)	1 / 34 (2.94%)	0 / 36 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Cardiac disorders			
Angina unstable			
subjects affected / exposed	1 / 36 (2.78%)	0 / 34 (0.00%)	0 / 36 (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
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 36 (0.00%)	1 / 34 (2.94%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Localised infection			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Filgotinib 100 mg From Placebo (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 8 (25.00%)	1 / 20 (5.00%)	0 / 10 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Cardiac disorders			
Angina unstable			

subjects affected / exposed	0 / 8 (0.00%)	0 / 20 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 8 (0.00%)	0 / 20 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 8 (12.50%)	0 / 20 (0.00%)	0 / 10 (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
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 8 (0.00%)	1 / 20 (5.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Localised infection			
subjects affected / exposed	1 / 8 (12.50%)	0 / 20 (0.00%)	0 / 10 (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

Serious adverse events	Filgotinib 200 mg From Filgotinib 200 mg (LTE)		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 18 (5.56%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Cardiac disorders			
Angina unstable			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Localised infection			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Placebo (Main Study)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 36 (19.44%)	4 / 34 (11.76%)	9 / 36 (25.00%)
Investigations			
Blood pressure systolic increased			
subjects affected / exposed	1 / 36 (2.78%)	0 / 34 (0.00%)	1 / 36 (2.78%)
occurrences (all)	3	0	2
Liver function test increased			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Lymph node palpable			

subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Exposure to SARS-CoV-2			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Hypertensive crisis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Migraine			
subjects affected / exposed	2 / 36 (5.56%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences (all)	2	0	0
Carpal tunnel syndrome			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Ocular myasthenia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	2 / 36 (5.56%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences (all)	2	0	0
Diarrhoea			
subjects affected / exposed	1 / 36 (2.78%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Chronic gastritis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Hypoxia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Respiratory distress			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Mechanical acne			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Psoriatic arthropathy			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	3 / 36 (8.33%)
occurrences (all)	0	0	3
Arthralgia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			

subjects affected / exposed	1 / 36 (2.78%)	1 / 34 (2.94%)	0 / 36 (0.00%)
occurrences (all)	1	1	0
Pain in extremity			
subjects affected / exposed	2 / 36 (5.56%)	1 / 34 (2.94%)	0 / 36 (0.00%)
occurrences (all)	2	1	0
Osteoarthritis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Covid-19			
subjects affected / exposed	0 / 36 (0.00%)	1 / 34 (2.94%)	2 / 36 (5.56%)
occurrences (all)	0	1	2
Gastroenteritis			
subjects affected / exposed	0 / 36 (0.00%)	1 / 34 (2.94%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Cellulitis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	1 / 36 (2.78%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Sinusitis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Acarodermatitis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Skin candida			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0

Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Dyslipidaemia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Filgotinib 100 mg From Placebo (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 8 (25.00%)	7 / 20 (35.00%)	5 / 10 (50.00%)
Investigations			
Blood pressure systolic increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 20 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Liver function test increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 20 (5.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Lymph node palpable			
subjects affected / exposed	0 / 8 (0.00%)	0 / 20 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Exposure to SARS-CoV-2			
subjects affected / exposed	0 / 8 (0.00%)	0 / 20 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Foot fracture			

subjects affected / exposed	0 / 8 (0.00%)	0 / 20 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 8 (0.00%)	0 / 20 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 20 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 20 (5.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Hypertensive crisis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 20 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 8 (0.00%)	0 / 20 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 8 (0.00%)	0 / 20 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Carpal tunnel syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 20 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 8 (0.00%)	0 / 20 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 20 (5.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Ocular myasthenia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 20 (5.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			

Nausea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 20 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 8 (12.50%)	0 / 20 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Chronic gastritis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 20 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Hypoxia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 20 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Respiratory distress			
subjects affected / exposed	1 / 8 (12.50%)	0 / 20 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Mechanical acne			
subjects affected / exposed	0 / 8 (0.00%)	0 / 20 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Psoriatic arthropathy			
subjects affected / exposed	1 / 8 (12.50%)	1 / 20 (5.00%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Arthralgia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 20 (5.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Muscle spasms			
subjects affected / exposed	0 / 8 (0.00%)	0 / 20 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 8 (0.00%)	0 / 20 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 20 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1

Infections and infestations			
Covid-19			
subjects affected / exposed	2 / 8 (25.00%)	1 / 20 (5.00%)	1 / 10 (10.00%)
occurrences (all)	2	1	1
Gastroenteritis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 20 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 20 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Ear infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 20 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 20 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 20 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Acarodermatitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 20 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 8 (0.00%)	1 / 20 (5.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Skin candida			
subjects affected / exposed	1 / 8 (12.50%)	0 / 20 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	0 / 8 (0.00%)	1 / 20 (5.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Dyslipidaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 20 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Hypercholesterolaemia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 20 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 20 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 20 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1

Non-serious adverse events	Filgotinib 200 mg From Filgotinib 200 mg (LTE)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 18 (55.56%)		
Investigations			
Blood pressure systolic increased			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Liver function test increased			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Lymph node palpable			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Injury, poisoning and procedural complications			
Exposure to SARS-CoV-2			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Foot fracture			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Joint injury			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Ligament sprain			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Vascular disorders			

Deep vein thrombosis subjects affected / exposed occurrences (all) Hypertensive crisis subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0 0 / 18 (0.00%) 0		
Nervous system disorders Headache subjects affected / exposed occurrences (all) Migraine subjects affected / exposed occurrences (all) Carpal tunnel syndrome subjects affected / exposed occurrences (all) Neuropathy peripheral subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1 0 / 18 (0.00%) 0 1 / 18 (5.56%) 1 1 / 18 (5.56%) 1		
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0		
Eye disorders Ocular myasthenia subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0		
Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all) Diarrhoea subjects affected / exposed occurrences (all) Chronic gastritis subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1 0 / 18 (0.00%) 0 1 / 18 (5.56%) 1		

Respiratory, thoracic and mediastinal disorders			
Hypoxia			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Respiratory distress			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Mechanical acne			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Psoriatic arthropathy			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Arthralgia			
subjects affected / exposed	2 / 18 (11.11%)		
occurrences (all)	2		
Muscle spasms			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Pain in extremity			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Osteoarthritis			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Covid-19			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Gastroenteritis			
subjects affected / exposed	2 / 18 (11.11%)		
occurrences (all)	2		
Cellulitis			

subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Ear infection			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	2		
Pneumonia			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Sinusitis			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Acarodermatitis			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Herpes zoster			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Skin candida			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Dyslipidaemia			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		
Hypercholesterolaemia			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Hyperlipidaemia			
subjects affected / exposed	1 / 18 (5.56%)		
occurrences (all)	1		
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 18 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 August 2019	• Re-categorized secondary and exploratory endpoints • Clarified stratification at randomization • Added optional human leukocyte antigen B27 (HLA-B27) sample collection • Common terminology criteria for adverse events (CTCAE) version 4.03 was updated to version 5.0 • Added follicle stimulating hormone (FSH) testing post screening • Updated sample questionnaires for clinical and patient reported outcomes and corrected inconsistencies with nomenclature.
17 April 2020	• Removed restriction on use of Week 16 data • Corrected and clarified inclusion and exclusion criteria with respect to cyclosporine removal, region-specific age requirements, and total bilirubin at Screening • Removed CRP collection at Screening and updated CRP at Day 1 to be unblinded to the Sponsor • Updated key secondary, other secondary, and exploratory endpoints • Updated statistical methods to add description for graphical approach test procedures, safety estimands, and ACR20 response rate assumptions • Updated preclinical pharmacology and toxicology section to align with current Investigator Brochure • Added participant discontinuation requirement for thromboembolic events and for participants with active disease at Week 24 • Included biomarker collection visits in study procedures table footnotes and peripheral blood mononuclear cells (PBMC) collection clarification for North America only • Updated concomitant medications to include a note for medications that can cause dermatitis and exacerbate psoriasis • Revised psoriatic arthritis (PsA) rescue therapy language • Updated AE terminology, special situations reporting, SAE and death reporting • Added toxicity management for thromboembolic events • Added more detailed process language for data monitoring committee (DMC) • Updated major adverse cardiovascular events and thromboembolic events language to include/add more detailed description of adjudication process • Clarified when early termination and safety follow-up visits will occur • Clarified when clinical reported outcome collection was planned.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
19 March 2020	There was a temporary halt to recruitment following the declaration of the COVID-19 pandemic by WHO.	18 June 2020

Notes:

Limitations and caveats

None reported