Clinical trial results:
A Phase 3, Randomized, Double-blind, Placebo and Adalimumab-controlled Study to Evaluate the Efficacy and Safety of Filgotinib in Subjects with Active Psoriatic Arthritis Who Are Naive to Biologic DMARD Therapy

Summary

EudraCT number	2019-001996-35
Trial protocol	EE BE GB SK HU PL BG ES CZ NL IT
Global end of trial date	11 May 2021

Results information

Result version number	v2
This version publication date	23 March 2022
First version publication date	03 February 2022
Version creation reason	• Correction of full data set Update to the outcome measure descriptions of outcomes 10, 11, 25 and 35. Time frame will be updated for outcome measures 26 and 27.

Trial information

Trial identification

Sponsor protocol code	GS-US-431-4566

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04115748
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	11 May 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	19 January 2021
Global end of trial reached?	Yes
Global end of trial date	11 May 2021
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was 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 are naive to biologic disease-modifying anti-rheumatic drug (DMARD) therapy. The study consists of two parts, the Main Study and the Long Term Extension (LTE).

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	03 December 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: 4
Country: Number of subjects enrolled	Bulgaria: 7
Country: Number of subjects enrolled	Canada: 1
Country: Number of subjects enrolled	Japan: 2
Country: Number of subjects enrolled	New Zealand: 2
Country: Number of subjects enrolled	Poland: 34
Country: Number of subjects enrolled	Spain: 7
Country: Number of subjects enrolled	United States: 10
Worldwide total number of subjects	67
EEA total number of subjects	48

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)	57
From 65 to 84 years	10
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled at study sites in Poland, the United States, Bulgaria, Spain, Australia, Japan, New Zealand, and Canada. The first participant was screened on 03 December 2019. The last study visit occurred on 11 May 2021.

Pre-assignment

Screening details:

161 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 + PTM adalimumab subcutaneous (SC) injection every two weeks for 16 weeks.

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

Dosage and administration details:

200 mg administered once daily with or without food

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

Dosage and administration details:

PTM filgotinib 100 mg administered once daily with or without food

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

Dosage and administration details:

PTM adalimumab administered once every 2 weeks

Arm title	Filgotinib 100 mg (Main Study)

Arm description:

Filgotinib 100 mg tablet orally once daily + PTM filgotinib 200 mg tablet orally once daily + PTM Adalimumab SC injection every two weeks for 16 weeks.

Arm type	Experimental

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

Dosage and administration details:

100 mg administered orally once daily with or without food

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

Dosage and administration details:

PTM filgotinib 200 mg administered orally once daily with or without food

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

Dosage and administration details:

PTM adalimumab administered once every 2 weeks

Arm title	Adalimumab 40 mg (Main Study)

Arm description:

PTM filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily + Adalimumab 40 mg SC injection every two weeks for 16 weeks.

Arm type	Experimental
Investigational medicinal product name	PTM Filgotinib
Investigational medicinal product code	
Other name	GS-6034
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	Adalimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Adalimumab 40 mg administered once every 2 weeks

Arm title	Placebo (Main Study)

Arm description:

PTM filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily + PTM adalimumab SC injection every two weeks for 16 weeks.

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

Dosage and administration details:

Administered orally once daily with or without food

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

Dosage and administration details:

Injection administered subcutaneously once every 2 weeks

Number of subjects in period 1	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Adalimumab 40 mg (Main Study)
Started	19	19	9
Completed	4	3	2
Not completed	15	16	7
Study terminated by sponsor	15	16	7
Withdrew consent	-	-	-

Number of subjects in period 1	Placebo (Main Study)
Started	20
Completed	4
Not completed	16
Study terminated by sponsor	15
Withdrew consent	1

Period 2	
Period 2 title	LTE (After 16 Weeks to Week 50)
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 34 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
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

200 mg administered once daily with or without food

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

Dosage and administration details:

PTM filgotinib 100 mg administered orally 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 34 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
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

100 mg administered once daily with or without food

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

Dosage and administration details:

PTM filgotinib 200 mg administered orally once daily with or without food

Arm title	Filgotinib 200 mg From Adalimumab 40 mg (LTE)

Arm description:

Filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily for up to 34 weeks. Participants received adalimumab 40 mg in the Main Study.

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

Dosage and administration details:

200 mg administered once daily with or without food

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

Dosage and administration details:

PTM filgotinib 100 mg administered orally once daily with or without food

Arm title	Filgotinib 100 mg From Adalimumab 40 mg (LTE)

Arm description:

Filgotinib 100 mg tablet orally once daily + PTM filgotinib 200 mg tablet orally once daily for up to 34 weeks. Participants received adalimumab 40 mg in the Main Study.

Arm type	Experimental

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

Dosage and administration details:

100 mg administered once daily with or without food

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

Dosage and administration details:

PTM filgotinib 200 mg administered orally 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 34 weeks. Participants received placebo in the Main Study.

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

Dosage and administration details:

200 mg administered once daily with or without food

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

Dosage and administration details:

PTM filgotinib 100 mg administered orally 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 34 weeks. Participants received placebo in the Main Study.

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

Dosage and administration details:

100 mg administered once daily with or without food

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

Dosage and administration details:

PTM filgotinib 200 mg administered orally 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 Adalimumab 40 mg (LTE)
Started	4	3	1
Completed	0	0	0
Not completed	4	3	1
Adverse event, non-fatal	-	-	-
Study terminated by sponsor	4	3	1

Number of subjects in period 2	Filgotinib 100 mg From Adalimumab 40 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)	Filgotinib 100 mg From Placebo (LTE)
Started	1	2	2
Completed	0	0	0
Not completed	1	2	2
Adverse event, non-fatal	-	1	-
Study terminated by sponsor	1	1	2

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 + PTM adalimumab subcutaneous (SC) injection every two weeks 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 + PTM Adalimumab SC injection every two weeks for 16 weeks.	
Reporting group title	Adalimumab 40 mg (Main Study)
Reporting group description:	
PTM filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily + Adalimumab 40 mg SC injection every two weeks 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 + PTM adalimumab SC injection every two weeks for 16 weeks.	

Reporting group values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Adalimumab 40 mg (Main Study)
Number of subjects	19	19	9
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	49	46	50
standard deviation	± 13.4	± 10.4	± 10.4
Gender categorical Units: Subjects			
Female	9	7	4
Male	10	12	5
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	1	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	18	18	8
More than one race	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	1	0	0
Not Hispanic or Latino	18	19	9
Unknown or Not Reported	0	0	0

Reporting group values	Placebo (Main Study)	Total	

Number of subjects	20	67	
Age categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	47		
standard deviation	± 15.8	-	
Gender categorical Units: Subjects			
Female	10	30	
Male	10	37	
Race Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	0	3	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	0	0	
White	20	64	
More than one race	0	0	
Ethnicity Units: Subjects			
Hispanic or Latino	1	2	
Not Hispanic or Latino	19	65	
Unknown or Not Reported	0	0	

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 + PTM adalimumab subcutaneous (SC) injection every two weeks 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 + PTM Adalimumab SC injection every two weeks for 16 weeks.	
Reporting group title	Adalimumab 40 mg (Main Study)
Reporting group description:	
PTM filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily + Adalimumab 40 mg SC injection every two weeks 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 + PTM adalimumab SC injection every two weeks 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 34 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 34 weeks. Participants received filgotinib 100 mg in the Main Study.	
Reporting group title	Filgotinib 200 mg From Adalimumab 40 mg (LTE)
Reporting group description:	
Filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily for up to 34 weeks. Participants received adalimumab 40 mg in the Main Study.	
Reporting group title	Filgotinib 100 mg From Adalimumab 40 mg (LTE)
Reporting group description:	
Filgotinib 100 mg tablet orally once daily + PTM filgotinib 200 mg tablet orally once daily for up to 34 weeks. Participants received adalimumab 40 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 34 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 34 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.

End point type	Primary

End point timeframe:

Week 12

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	19	9	20
Units: percentage of participants				
number (confidence interval 95%)	76.8 (57.2 to 96.5)	63.2 (38.8 to 87.5)	67.2 (38.8 to 98.3)	44.8 (22.8 to 66.7)

Statistical analyses

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.048 [1]
Method	Multiple imputation method
Parameter estimate	Difference in response rates
Point estimate	32.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	61.6

Notes:

[1] - The stratification factors (Geographic Region, Concurrent Use of conventional synthetic (cs) DMARD(s) and/or Apremilast at Randomization, Prior Use of biologic (bio) DMARD(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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.23 [2]
Method	Multiple imputation method
Parameter estimate	Difference in response rates
Point estimate	18.4

Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.4
upper limit	49.2

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 measure for psoriatic arthritis with components of PGADA [using VAS scale of 0=very well to 100=very poor]; PhGADA [using VAS 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 with a physical component summary(PCS)with a score range of 0-100, higher scores indicates better health]; TJC68; SJC66; leeds enthesitis index(LEI) [assessed at 6 sites with a score range of 0 to 6,higher scores with 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). Total score is calculated as the sum of the individual scores(each score adjusted by weighting factors).The score of PASDAS ranges from 0 to 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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	19	8	20
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	5.9 (± 1.32)	5.3 (± 0.99)	5.5 (± 1.05)	5.5 (± 1.05)
Change From Baseline at Wk 4 N=19,18,8,20	-1.5 (± 0.62)	-1.0 (± 0.99)	-1.3 (± 0.66)	-0.3 (± 0.80)
Change From Baseline at Wk 16 N=18,19,8,20	-2.5 (± 1.26)	-2.0 (± 1.48)	-2.6 (± 1.37)	-1.0 (± 1.04)

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)]; patient's global assessment of PsA pain intensity (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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	19	9	20
Units: percentage of participants				
number (confidence interval 95%)				
Wk 4 N=19,18,9,20	21.1 (0.1 to 42.0)	16.7 (0.0 to 36.7)	22.2 (0.0 to 54.9)	5.0 (0.0 to 17.1)
Wk 8 N=19,19,9,19	26.3 (3.9 to 48.7)	31.6 (8.0 to 55.1)	22.2 (0.0 to 54.9)	15.8 (0.0 to 34.8)
Wk 12 N=18,19,8,19	44.4 (18.7 to 70.2)	47.4 (22.3 to 72.5)	37.5 (0.0 to 77.3)	15.8 (0.0 to 34.8)
Wk 16 N=18,19,8,20	27.8 (4.3 to 51.2)	36.8 (12.5 to 61.2)	37.5 (0.0 to 77.3)	20.0 (0.0 to 40.0)

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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.17 [3]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	16.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.7
upper limit	41.9

Notes:

[3] - P-value was calculated by logistic regression with treatment group and stratification factors (geographic region and concurrent use of csDMARDs and/or apremilast at randomization) 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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.27 [4]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	11.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.3
upper limit	36.6

Notes:

[4] - P-value was calculated by logistic regression with treatment group and stratification factors (geographic region and concurrent use of csDMARDs and/or apremilast at randomization) 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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.42 [5]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	10.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.4
upper limit	41.5

Notes:

[5] - P-value was calculated by logistic regression with treatment group and stratification factors (geographic region and concurrent use of csDMARDs and/or apremilast at randomization) in the model.

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 12	
Comparison groups	Placebo (Main Study) v Filgotinib 200 mg (Main Study)
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.062 [6]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	28.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	-5
upper limit	62.3

Notes:

[6] - P-value was calculated by logistic regression with treatment group and stratification factors (geographic region and concurrent use of csDMARDs and/or apremilast at randomization) in the model.

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

Statistical analysis description:

Week 8

Comparison groups	Placebo (Main Study) v Filgotinib 100 mg (Main Study)
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.26 [7]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	15.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16
upper limit	47.6

Notes:

[7] - P-value was calculated by logistic regression with treatment group and stratification factors (geographic region and concurrent use of csDMARDs and/or apremilast at randomization) in the model.

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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.58 [8]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	7.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.6
upper limit	40.2

Notes:

[8] - P-value was calculated by logistic regression with treatment group and stratification factors (geographic region and concurrent use of csDMARDs and/or apremilast at randomization) in the model.

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

Statistical analysis description:

Week 12

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

Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.047 [9]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	31.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.5
upper limit	64.6

Notes:

[9] - P-value was calculated by logistic regression with treatment group and stratification factors (geographic region and concurrent use of csDMARDs and/or apremilast at randomization) 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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.27 [10]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	16.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.2
upper limit	49.9

Notes:

[10] - P-value was calculated by logistic regression with treatment group and stratification factors (geographic region and concurrent use of csDMARDs and/or apremilast at randomization) in the model.

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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	19	9	20
Units: percentage of participants				
number (confidence interval 95%)				
Wk 4 N=19,18,9,20	5.3 (0.0 to 17.9)	0 (0.0 to 2.8)	0 (0.0 to 5.6)	0 (0.0 to 2.5)
Wk 8 N=19,19,9,19	5.3 (0.0 to 17.9)	0 (0.0 to 2.6)	0 (0.0 to 5.6)	10.5 (0.0 to 27.0)
Wk 12 N=18,19,8,19	11.1 (0.0 to 28.4)	5.3 (0.0 to 17.9)	12.5 (0.0 to 41.7)	5.3 (0.0 to 17.9)
Wk 16 N=18,19,9,20	5.6 (0.0 to 18.9)	10.5 (0.0 to 27.0)	11.1 (0.0 to 37.2)	0 (0.0 to 2.5)

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	39
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	-9.9
upper limit	20.4

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	39
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	-5.3
upper limit	5.3

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	39
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	-27.6
upper limit	17.1

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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	-10.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-29.6
upper limit	8.5

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

Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	5.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.2
upper limit	28.9

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	39
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	-19.5
upper limit	19.5

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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	5.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.3
upper limit	21.4

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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	10.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.4
upper limit	29.5

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. The DAPSA score has a lower bound of 0 and has no upper bound. A higher DAPSA score indicated more active 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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	19	8	20
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	48.0 (± 25.55)	30.3 (± 10.43)	38.8 (± 20.82)	33.8 (± 17.55)
Change From Baseline at Wk 2 N=19,18,8,19	-12.5 (± 11.96)	-5.3 (± 9.12)	-10.9 (± 8.39)	-7.5 (± 11.72)
Change From Baseline at Wk 4 N=19,18,8,20	-19.3 (± 14.30)	-9.4 (± 12.13)	-14.2 (± 10.45)	-6.5 (± 8.41)
Change From Baseline at Wk 8 N=19,19,8,19	-28.4 (± 15.67)	-12.4 (± 11.06)	-17.8 (± 12.96)	-10.6 (± 8.87)
Change From Baseline at Wk 12 N=18,19,7,19	-27.4 (± 17.09)	-18.0 (± 11.00)	-25.2 (± 16.60)	-9.3 (± 9.81)
Change From Baseline at Wk 16 N=18,19,8,20	-28.1 (± 13.42)	-17.4 (± 12.16)	-25.1 (± 14.55)	-11.3 (± 12.18)

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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	5	4	4
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	3 (± 1.2)	2 (± 0.8)	2 (± 0.5)	2 (± 0.5)
Change From Baseline at Wk 2 N=8,5,4,3	-1 (± 0.5)	0 (± 0.0)	0 (± 0.5)	0 (± 0.0)
Change From Baseline at Wk 4	-1 (± 1.0)	0 (± 0.5)	-1 (± 1.0)	0 (± 0.5)
Change From Baseline at Wk 8	-1 (± 1.0)	-1 (± 0.7)	-1 (± 0.8)	-1 (± 1.0)
Change From Baseline at Wk 12 N=7,5,3,4	-1 (± 1.3)	-1 (± 1.1)	-2 (± 0.6)	0 (± 1.3)
Change From Baseline at Wk 16	-1 (± 0.7)	-1 (± 0.8)	-2 (± 0.6)	-1 (± 1.4)

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 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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	11	6	13
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	19 (± 15.1)	15 (± 12.9)	24 (± 32.3)	14 (± 12.9)
Change From Baseline at Wk 4 N=9,10,6,13	-3 (± 3.5)	1 (± 4.5)	-3 (± 10.0)	0 (± 8.2)
Change From Baseline at Wk 8 N=9,11,6,12	-3 (± 5.1)	-1 (± 5.9)	-6 (± 19.4)	-2 (± 5.0)
Change From Baseline at Wk 12 N=9,11,5,12	-4 (± 6.0)	0 (± 5.4)	-9 (± 23.2)	-3 (± 10.6)
Change From Baseline at Wk 16 N=8,11,6,13	0 (± 10.8)	-3 (± 9.6)	-14 (± 23.7)	-2 (± 9.2)

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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	9	6	11
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	2 (± 1.6)	2 (± 1.4)	2 (± 1.4)	2 (± 1.7)
Change From Baseline at Wk 4	-1 (± 0.8)	0 (± 0.7)	-1 (± 1.1)	0 (± 1.5)
Change From Baseline at Wk 8 N=10,9,6,10	-1 (± 0.8)	-1 (± 1.2)	-2 (± 1.5)	0 (± 1.3)
Change From Baseline at Wk 12 N=10,9,5,10	-1 (± 1.4)	-1 (± 1.6)	-2 (± 1.8)	0 (± 1.2)
Change From Baseline at Wk 16	-1 (± 1.2)	-1 (± 1.5)	-2 (± 1.6)	0 (± 1.5)

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. 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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	19	8	20
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	4.82 (± 1.857)	4.46 (± 2.115)	5.28 (± 1.765)	4.44 (± 2.071)
Change From Baseline at Wk 4 N=19,18,8,20	-1.71 (± 1.282)	-1.39 (± 1.214)	-1.73 (± 1.645)	-0.10 (± 1.520)
Change From Baseline at Wk 16	-2.06 (± 1.314)	-2.04 (± 1.740)	-2.56 (± 2.062)	-0.52 (± 2.176)

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 measure for psoriatic arthritis with components of PGADA [using VAS scale of 0=very well to 100=very poor]; PhGADA [using VAS 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 with a physical component summary (PCS) with a score range of 0-100, higher scores indicates better health]; TJC68; SJC66; leeds enthesitis index (LEI) [assessed at 6 sites with a score range of 0 to 6, higher scores with 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). Total score is calculated as the sum of the individual scores (each score adjusted by weighting factors). The score of PASDAS ranges from 0 to 10, lower scores 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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	19	9	20
Units: percentage of participants				
number (confidence interval 95%)				
Wk 4 N=19,18,8,20	21.1 (0.1 to 42.0)	11.1 (0.0 to 28.4)	0 (0.0 to 6.3)	5.0 (0.0 to 17.1)
Wk 16 N=18,19,8,20	38.9 (13.6 to 64.2)	42.1 (17.3 to 66.9)	50.0 (9.1 to 90.9)	15.0 (0.0 to 33.1)

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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	16.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.7
upper limit	41.9

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 16	
Comparison groups	Placebo (Main Study) v Filgotinib 200 mg (Main Study)
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	23.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.8
upper limit	56.6

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main St
Statistical analysis description: Week 4	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	39
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	-16.5
upper limit	28.8

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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	27.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.2
upper limit	59.4

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 measure for psoriatic arthritis with components of PGADA [using VAS scale of 0=very well to 100=very poor]; PhGADA [using VAS 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 with a physical component summary (PCS) with a score range of 0-100, higher scores indicates better health]; TJC68; SJC66; leeds enthesitis index (LEI) [assessed at 6 sites with a score range of 0 to 6, higher scores with 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). Total score is calculated as the sum of the individual scores (each score adjusted by weighting factors). The score of PASDAS ranges from 0 to 10, lower scores 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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	19	9	20
Units: percentage of participants				
number (confidence interval 95%)				
Wk 4 N=19,18,8,20	0 (0.0 to 2.6)	0 (0.0 to 2.8)	0 (0.0 to 6.3)	0 (0.0 to 2.5)
Wk 16 N=18,19,8,20	16.7 (0.0 to 36.7)	10.5 (0.0 to 27.0)	12.5 (0.0 to 41.7)	5.0 (0.0 to 17.1)

Statistical analyses

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

Statistical analysis description:

Week 4

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

Number of subjects included in analysis	39
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	-5.3
upper limit	5.3

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	39
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	-5.1
upper limit	5.1

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 16	
Comparison groups	Placebo (Main Study) v Filgotinib 100 mg (Main Study)
Number of subjects included in analysis	39
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	-16.4
upper limit	27.4

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

Comparison groups	Placebo (Main Study) v Filgotinib 200 mg (Main Study)
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	11.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.3
upper limit	36.6

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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	19	9	20
Units: percentage of participants				
number (confidence interval 95%)				
Wk 2 N=19,18,9,19	26.3 (3.9 to 48.7)	5.6 (0.0 to 18.9)	11.1 (0.0 to 37.2)	10.5 (0.0 to 27.0)
Wk 4 N=19,18,9,20	52.6 (27.5 to 77.7)	27.8 (4.3 to 51.2)	33.3 (0.0 to 69.7)	10.0 (0.0 to 25.6)
Wk 8 N=19,19,9,19	73.7 (51.3 to 96.1)	36.8 (12.5 to 61.2)	55.6 (17.5 to 93.6)	31.6 (8.0 to 55.1)
Wk 12 N=18,19,8,19	77.8 (55.8 to 99.8)	63.2 (38.8 to 87.5)	75.0 (38.7 to 100.0)	42.1 (17.3 to 66.9)
Wk 16 N=18,19,9,20	88.9 (71.6 to 100.0)	52.6 (27.5 to 77.7)	77.8 (45.1 to 100.0)	45.0 (20.7 to 69.3)

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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2 [11]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	15.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.6
upper limit	45.2

Notes:

[11] - P-value was calculated by logistic regression with treatment group and stratification factors (geographic region and concurrent use of csDMARDs and/or apremilast at randomization) in the model.

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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6 [12]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	-5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.8
upper limit	17.8

Notes:

[12] - P-value was calculated by logistic regression with treatment group and stratification factors (geographic region and concurrent use of csDMARDs and/or apremilast at randomization) 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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.008 [13]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	42.6

Confidence interval	
level	95 %
sides	2-sided
lower limit	11.5
upper limit	73.8

Notes:

[13] - P-value was calculated by logistic regression with treatment group and stratification factors (geographic region and concurrent use of csDMARDs and/or apremilast at randomization) 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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.17 [14]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	17.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12
upper limit	47.6

Notes:

[14] - P-value was calculated by logistic regression with treatment group and stratification factors (geographic region and concurrent use of csDMARDs and/or apremilast at randomization) 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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.011 [15]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	42.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.1
upper limit	76.2

Notes:

[15] - P-value was calculated by logistic regression with treatment group and stratification factors (geographic region and concurrent use of csDMARDs and/or apremilast at randomization) 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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.69 [16]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	5.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-30.1
upper limit	40.6

Notes:

[16] - P-value was calculated by logistic regression with treatment group and stratification factors (geographic region and concurrent use of csDMARDs and/or apremilast at randomization) in the model.

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

Statistical analysis description:

Week 12

Comparison groups	Placebo (Main Study) v Filgotinib 100 mg (Main Study)
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.19 [17]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	21.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.2
upper limit	57.4

Notes:

[17] - P-value was calculated by logistic regression with treatment group and stratification factors (geographic region and concurrent use of csDMARDs and/or apremilast at randomization) in the model.

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

Statistical analysis description:

Week 12

Comparison groups	Placebo (Main Study) v Filgotinib 200 mg (Main Study)
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.033 [18]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	35.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	70.4

Notes:

[18] - P-value was calculated by logistic regression with treatment group and stratification factors (geographic region and concurrent use of csDMARDs and/or apremilast at randomization) in the model.

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Comparison groups	Filgotinib 200 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007 [19]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	43.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.4
upper limit	75.4

Notes:

[19] - P-value was calculated by logistic regression with treatment group and stratification factors (geographic region and concurrent use of csDMARDs and/or apremilast at randomization) in the model.

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.63 [20]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	7.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-28.8
upper limit	44.1

Notes:

[20] - P-value was calculated by logistic regression with treatment group and stratification factors (geographic region and concurrent use of csDMARDs and/or apremilast at randomization) in the model.

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

End point title	Percentage of Participants Who Achieved 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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	19	9	20
Units: percentage of participants				
number (confidence interval 95%)				
Wk 2 N=19,18,9,19	5.3 (0.0 to 17.9)	0 (0.0 to 2.8)	0 (0.0 to 5.6)	5.3 (0.0 to 17.9)
Wk 4 N=19,18,9,20	10.5 (0.0 to 27.0)	5.6 (0.0 to 18.9)	0 (0.0 to 5.6)	5.0 (0.0 to 17.1)
Wk 8 N=19,19,9,19	31.6 (8.0 to 55.1)	26.3 (3.9 to 48.7)	11.1 (0.0 to 37.2)	10.5 (0.0 to 27.0)
Wk 12 N=18,19,8,19	55.6 (29.8 to 81.3)	42.1 (17.3 to 66.9)	37.5 (0.0 to 77.3)	10.5 (0.0 to 27.0)
Wk 16 N=18,19,9,20	27.8 (4.3 to 51.2)	47.4 (22.3 to 72.5)	33.3 (0.0 to 69.7)	15.0 (0.0 to 33.1)

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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.98 [21]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.5
upper limit	19.5

Notes:
[21] - P-value was calculated by logistic regression with treatment group and stratification factors (geographic region and concurrent use of csDMARDs and/or apremilast at randomization) in the model.

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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5 [22]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	-5.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.7
upper limit	10.2

Notes:

[22] - P-value was calculated by logistic regression with treatment group and stratification factors (geographic region and concurrent use of csDMARDs and/or apremilast at randomization) 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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.54 [23]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	5.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.4
upper limit	27.4

Notes:

[23] - P-value was calculated by logistic regression with treatment group and stratification factors (geographic region and concurrent use of csDMARDs and/or apremilast at randomization) 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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.92 [24]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19
upper limit	20.1

Notes:

[24] - P-value was calculated by logistic regression with treatment group and stratification factors (geographic region and concurrent use of csDMARDs and/or apremilast at randomization) 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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.13 [25]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	21.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.3
upper limit	51.4

Notes:

[25] - P-value was calculated by logistic regression with treatment group and stratification factors (geographic region and concurrent use of csDMARDs and/or apremilast at randomization) 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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.22 [26]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	15.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.6
upper limit	45.2

Notes:

[26] - P-value was calculated by logistic regression with treatment group and stratification factors (geographic region and concurrent use of csDMARDs and/or apremilast at randomization) 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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007 [27]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	45
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.8
upper limit	77.2

Notes:

[27] - P-value was calculated by logistic regression with treatment group and stratification factors (geographic region and concurrent use of csDMARDs and/or apremilast at randomization) 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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.039 [28]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	31.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.2
upper limit	63

Notes:

[28] - P-value was calculated by logistic regression with treatment group and stratification factors (geographic region and concurrent use of csDMARDs and/or apremilast at randomization) 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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.34 [29]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	12.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.4
upper limit	44

Notes:

[29] - P-value was calculated by logistic regression with treatment group and stratification factors (geographic region and concurrent use of csDMARDs and/or apremilast at randomization) 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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.04 [30]
Method	Regression, Logistic
Parameter estimate	Difference in response rates
Point estimate	32.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	64.9

Notes:

[30] - P-value was calculated by logistic regression with treatment group and stratification factors (geographic region and concurrent use of csDMARDs and/or apremilast at randomization) in the model.

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

End point title	Percentage of Participants Who Achieved 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 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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	19	9	20
Units: percentage of participants				
number (confidence interval 95%)				
Wk 2 N=19,18,9,19	5.3 (0.0 to 17.9)	0 (0.0 to 2.8)	0 (0.0 to 5.6)	0 (0.0 to 2.6)
Wk 4 N=19,18,9,20	5.3 (0.0 to 17.9)	0 (0.0 to 2.8)	0 (0.0 to 5.6)	0 (0.0 to 2.5)

Wk 8 N=19,19,9,19	15.8 (0.0 to 34.8)	10.5 (0.0 to 27.0)	0 (0.0 to 5.6)	5.3 (0.0 to 17.9)
Wk 12 N=18,19,8,19	27.8 (4.3 to 51.2)	26.3 (3.9 to 48.7)	12.5 (0.0 to 41.7)	0 (0.0 to 2.6)
Wk 16 N=18,19,9,20	22.2 (0.2 to 44.2)	31.6 (8.0 to 55.1)	22.2 (0.0 to 54.9)	10.0 (0.0 to 25.6)

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	39
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	-10
upper limit	20.6

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	39
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	-5.4
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	39
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	-9.9
upper limit	20.4

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 8	
Comparison groups	Placebo (Main Study) v Filgotinib 200 mg (Main Study)
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	10.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14
upper limit	35

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 4	
Comparison groups	Placebo (Main Study) v Filgotinib 100 mg (Main Study)
Number of subjects included in analysis	39
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	-5.3
upper limit	5.3

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

Comparison groups	Placebo (Main Study) v Filgotinib 200 mg (Main Study)
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	27.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.7
upper limit	53.9

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 8	
Comparison groups	Placebo (Main Study) v Filgotinib 100 mg (Main Study)
Number of subjects included in analysis	39
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	-17.1
upper limit	27.6

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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	26.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.3
upper limit	51.4

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	39
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	-16.3
upper limit	40.8

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	39
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	-8.2
upper limit	51.4

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 is 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. 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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	19	9	20
Units: tender joint count				
arithmetic mean (standard deviation)				
Baseline	22 (± 14.9)	13 (± 8.5)	17 (± 11.0)	14 (± 11.6)
Change From Baseline at Wk 2 N=19,18,9,19	-6 (± 8.7)	-1 (± 5.2)	-5 (± 3.9)	-3 (± 6.6)
Change From Baseline at Wk 4 N=19,18,9,20	-9 (± 10.3)	-3 (± 7.9)	-7 (± 5.3)	-3 (± 4.6)
Change From Baseline at Wk 8 N=19,19,9,19	-13 (± 9.9)	-5 (± 6.3)	-7 (± 7.4)	-4 (± 4.8)
Change From Baseline at Wk 12 N=18,19,8,19	-13 (± 7.4)	-7 (± 7.4)	-10 (± 8.5)	-4 (± 4.5)
Change From Baseline at Wk 16 N=18,19,9,20	-14 (± 7.7)	-7 (± 7.9)	-10 (± 6.1)	-5 (± 8.3)

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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	19	9	20
Units: swollen joint count				
arithmetic mean (standard deviation)				
Baseline	14 (± 10.3)	7 (± 3.3)	11 (± 7.3)	8 (± 5.9)
Change From Baseline at Wk 2 N=19,18,9,19	-3 (± 3.8)	-1 (± 3.5)	-5 (± 5.2)	-2 (± 4.7)
Change From Baseline at Wk 4 N=19,18,9,20	-5 (± 6.2)	-2 (± 2.9)	-4 (± 7.0)	-2 (± 3.1)
Change From Baseline at Wk 8 N=19,19,9,19	-9 (± 7.0)	-3 (± 4.0)	-6 (± 6.1)	-3 (± 2.9)
Change From Baseline at Wk 12 N=18,19,8,19	-8 (± 8.9)	-4 (± 3.1)	-8 (± 7.3)	-4 (± 2.9)

Change From Baseline at Wk 16 N=18,19,9,20	-8 (± 7.9)	-4 (± 3.8)	-8 (± 6.7)	-4 (± 3.9)

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 is 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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	19	8	20
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	54 (± 26.0)	58 (± 22.8)	47 (± 24.2)	52 (± 24.0)
Change From Baseline at Wk 2 N=19,18,8,19	-15 (± 17.8)	-17 (± 26.6)	3 (± 8.6)	-10 (± 12.6)
Change From Baseline at Wk 4 N=19,18,8,20	-23 (± 20.3)	-23 (± 32.2)	-3 (± 11.4)	-4 (± 16.6)
Change From Baseline at Wk 8 N=19,19,8,19	-24 (± 22.6)	-28 (± 33.8)	-4 (± 17.1)	-16 (± 23.4)
Change From Baseline at Wk 12 N=18,19,7,19	-27 (± 25.9)	-38 (± 29.9)	-29 (± 19.7)	-9 (± 24.7)
Change From Baseline at Wk 16 N=18,19,8,20	-31 (± 26.4)	-34 (± 28.5)	-25 (± 25.3)	-12 (± 23.5)

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

	4, 8, 12, and 16

End point description:

PhGADA is 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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	19	8	20
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	68 (± 16.4)	56 (± 14.3)	65 (± 13.1)	62 (± 13.4)
Change From Baseline at Wk 2 N=19,18,8,19	-17 (± 12.3)	-4 (± 11.0)	-12 (± 9.2)	-8 (± 9.8)
Change From Baseline at Wk 4 N=19,18,8,20	-23 (± 14.5)	-12 (± 18.6)	-29 (± 14.8)	-8 (± 11.5)
Change From Baseline at Wk 8 N=19,19,8,19	-35 (± 15.1)	-17 (± 17.4)	-35 (± 13.6)	-21 (± 13.7)
Change From Baseline at Wk 12 N=18,19,7,19	-36 (± 18.8)	-26 (± 22.4)	-42 (± 20.8)	-21 (± 21.8)
Change From Baseline at Wk 16 N=18,19,8,20	-37 (± 16.4)	-27 (± 21.6)	-44 (± 21.0)	-19 (± 20.2)

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 is 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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	19	8	20
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	60 (± 24.7)	45 (± 22.3)	48 (± 24.3)	56 (± 24.2)
Change From Baseline at Wk 2 N=19,18,8,19	-16 (± 15.2)	-4 (± 16.7)	-5 (± 9.5)	-8 (± 11.5)
Change From Baseline at Wk 4 N=19,18,8,20	-24 (± 20.9)	-13 (± 18.6)	-10 (± 9.8)	-1 (± 14.3)
Change From Baseline at Wk 8 N=19,19,8,19	-33 (± 20.9)	-13 (± 23.4)	-3 (± 17.3)	-11 (± 25.3)
Change From Baseline at Wk 12 N=18,19,7,19	-33 (± 23.7)	-19 (± 21.0)	-28 (± 20.7)	-8 (± 23.3)
Change From Baseline at Wk 16 N=18,19,8,20	-29 (± 24.5)	-17 (± 26.5)	-27 (± 15.2)	-12 (± 21.7)

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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	19	9	20
Units: mg/L				
arithmetic mean (standard deviation)				
Baseline	8.08 (± 9.335)	3.14 (± 2.673)	10.56 (± 16.354)	7.11 (± 9.727)
Change From Baseline at Wk 2 N=19,18,9,19	-6.37 (± 8.518)	-0.10 (± 5.313)	-7.70 (± 11.874)	0.50 (± 4.063)
Change From Baseline at Wk 4 N=19,18,9,20	-6.68 (± 8.998)	-0.95 (± 2.564)	-5.99 (± 8.981)	3.96 (± 13.594)
Change From Baseline at Wk 8 N=19,19,9,19	-5.13 (± 11.271)	-0.69 (± 4.474)	-6.40 (± 9.740)	-1.15 (± 4.979)

Change From Baseline at Wk 12 N=18,19,8,19	-6.04 (± 8.518)	-1.11 (± 3.161)	-3.80 (± 7.334)	2.25 (± 7.788)
Change From Baseline at Wk 16 N=18,19,9,20	-5.88 (± 9.195)	-0.47 (± 5.496)	-6.80 (± 10.918)	1.05 (± 5.623)

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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	19	8	20
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	4.9 (± 1.27)	4.2 (± 0.78)	4.5 (± 0.97)	4.4 (± 0.92)
Change From Baseline at Wk 2 N=19,18,8,19	-0.9 (± 0.62)	-0.5 (± 0.74)	-0.9 (± 0.70)	-0.6 (± 0.83)
Change From Baseline at Wk 4 N=19,18,8,20	-1.2 (± 0.63)	-0.9 (± 1.04)	-1.2 (± 0.60)	-0.5 (± 0.65)
Change From Baseline at Wk 8 N=19,19,8,19	-1.8 (± 0.87)	-1.2 (± 0.71)	-1.2 (± 0.83)	-1.0 (± 0.66)
Change From Baseline at Wk 12 N=18,19,7,19	-1.9 (± 0.96)	-1.5 (± 0.89)	-1.9 (± 0.88)	-0.8 (± 0.78)
Change From Baseline at Wk 16 N=18,19,8,20	-1.8 (± 0.62)	-1.8 (± 0.97)	-2.0 (± 0.71)	-0.8 (± 0.92)

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 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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	19	9	20
Units: percentage of participants				
number (confidence interval 95%)				
Wk 2 N=19,18,9,19	31.6 (8.0 to 55.1)	33.3 (8.8 to 57.9)	33.3 (0.0 to 69.7)	42.1 (17.3 to 66.9)
Wk 4 N=19,18,9,20	36.8 (12.5 to 61.2)	44.4 (18.7 to 70.2)	55.6 (17.5 to 93.6)	25.0 (3.5 to 46.5)
Wk 8 N=19,19,9,19	63.2 (38.8 to 87.5)	63.2 (38.8 to 87.5)	33.3 (0.0 to 69.7)	52.6 (27.5 to 77.7)
Wk 12 N=18,19,8,19	66.7 (42.1 to 91.2)	68.4 (44.9 to 92.0)	62.5 (22.7 to 100.0)	36.8 (12.5 to 61.2)
Wk 16 N=18,19,9,20	50.0 (24.1 to 75.9)	84.2 (65.2 to 100.0)	66.7 (30.3 to 100.0)	45.0 (20.7 to 69.3)

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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	-10.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-46.3
upper limit	25.2

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	39
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	-45.3
upper limit	27.7

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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	11.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.1
upper limit	45.8

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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	19.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.6
upper limit	54.5

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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	10.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26
upper limit	47

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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	31.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.8
upper limit	67

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 8	
Comparison groups	Placebo (Main Study) v Filgotinib 100 mg (Main Study)
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	10.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26
upper limit	47

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 12	
Comparison groups	Placebo (Main Study) v Filgotinib 200 mg (Main Study)
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	29.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.3
upper limit	66

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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	39.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.8
upper limit	71.6

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 16	
Comparison groups	Placebo (Main Study) v Filgotinib 200 mg (Main Study)
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	5

Confidence interval	
level	95 %
sides	2-sided
lower limit	-32
upper limit	42

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. 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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	19	9	20
Units: percentage of participants				
number (confidence interval 95%)				
Wk 2 N=19,18,9,19	10.5 (0.0 to 27.0)	11.1 (0.0 to 28.4)	22.2 (0.0 to 54.9)	10.5 (0.0 to 27.0)
Wk 4 N=19,18,9,20	10.5 (0.0 to 27.0)	27.8 (4.3 to 51.2)	22.2 (0.0 to 54.9)	15.0 (0.0 to 33.1)
Wk 8 N=19,19,9,19	47.4 (22.3 to 72.5)	26.3 (3.9 to 48.7)	22.2 (0.0 to 54.9)	26.3 (3.9 to 48.7)
Wk 12 N=18,19,8,19	55.6 (29.8 to 81.3)	42.1 (17.3 to 66.9)	50.0 (9.1 to 90.9)	21.1 (0.1 to 42.0)
Wk 16 N=18,19,9,20	44.4 (18.7 to 70.2)	52.6 (27.5 to 77.7)	44.4 (6.4 to 82.5)	20.0 (0.0 to 40.0)

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	39
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	-24.8
upper limit	24.8

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	39
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	-24.9
upper limit	26

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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	-4.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-30.5
upper limit	21.5

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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	12.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.4
upper limit	44

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 8	
Comparison groups	Placebo (Main Study) v Filgotinib 100 mg (Main Study)
Number of subjects included in analysis	39
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	-33.3
upper limit	33.3

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 8	
Comparison groups	Placebo (Main Study) v Filgotinib 200 mg (Main Study)
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	21.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.1
upper limit	56.3

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

Statistical analysis description: Week 12	
Comparison groups	Placebo (Main Study) v Filgotinib 100 mg (Main Study)
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	21.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13
upper limit	55.1

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 12	
Comparison groups	Placebo (Main Study) v Filgotinib 200 mg (Main Study)
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	34.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3
upper limit	69.3

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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	24.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.7
upper limit	58.6

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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	32.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	66.2

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.	
End point type	Secondary
End point timeframe:	
Approximately 16 weeks	

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	19	9	20
Units: days				
median (full range (min-max))	57 (13 to 116)	58 (14 to 116)	29 (14 to 127)	59 (14 to 133)

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. The DAPSA score has a lower bound of 0 and has no upper bound. A higher DAPSA score indicated more active 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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	19	9	20
Units: percentage of participants				
number (confidence interval 95%)				
Wk 2 N=19,18,9,19	15.8 (0.0 to 34.8)	11.1 (0.0 to 28.4)	22.2 (0.0 to 54.9)	31.6 (8.0 to 55.1)
Wk 4 N=19,18,9,20	31.6 (8.0 to 55.1)	38.9 (13.6 to 64.2)	44.4 (6.4 to 82.5)	25.0 (3.5 to 46.5)
Wk 8 N=19,19,9,19	52.6 (27.5 to 77.7)	42.1 (17.3 to 66.9)	33.3 (0.0 to 69.7)	36.8 (12.5 to 61.2)
Wk 12 N=18,19,8,19	61.1 (35.8 to 86.4)	57.9 (33.1 to 82.7)	62.5 (22.7 to 100.0)	36.8 (12.5 to 61.2)
Wk 16 N=18,19,9,20	44.4 (18.7 to 70.2)	63.2 (38.8 to 87.5)	55.6 (17.5 to 93.6)	40.0 (16.0 to 64.0)

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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	-15.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-47.6
upper limit	16

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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	-20.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-51.3
upper limit	10.4

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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	6.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26.8
upper limit	39.9

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 8	
Comparison groups	Placebo (Main Study) v Filgotinib 200 mg (Main Study)
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	15.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.7
upper limit	52.3

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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	13.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.8
upper limit	48.6

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 12	
Comparison groups	Placebo (Main Study) v Filgotinib 200 mg (Main Study)
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	24.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.4
upper limit	60.9

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 8	
Comparison groups	Placebo (Main Study) v Filgotinib 100 mg (Main Study)
Number of subjects included in analysis	39
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	-31
upper limit	41.6

Statistical analysis title	Fil 200 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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	21.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.2
upper limit	57.4

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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	4.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-32.3
upper limit	41.2

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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	23.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.5
upper limit	58.8

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. The DAPSA score has a lower bound of 0 and has no upper bound. A higher DAPSA score indicated more active 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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	19	9	20
Units: percentage of participants				
number (confidence interval 95%)				
Wk 2 N=19,18,9,19	5.3 (0.0 to 17.9)	0 (0.0 to 2.8)	0 (0.0 to 5.6)	5.3 (0.0 to 17.9)
Wk 4 N=19,18,9,20	5.3 (0.0 to 17.9)	5.6 (0.0 to 18.9)	0 (0.0 to 5.6)	5.0 (0.0 to 17.1)
Wk 8 N=19,19,9,19	10.5 (0.0 to 27.0)	5.3 (0.0 to 17.9)	0 (0.0 to 5.6)	10.5 (0.0 to 27.0)
Wk 12 N=18,19,8,19	22.2 (0.2 to 44.2)	31.6 (8.0 to 55.1)	12.5 (0.0 to 41.7)	5.3 (0.0 to 17.9)
Wk 16 N=18,19,9,20	16.7 (0.0 to 36.7)	21.1 (0.1 to 42.0)	22.2 (0.0 to 54.9)	10.0 (0.0 to 25.6)

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	39
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	-19.5
upper limit	19.5

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	39
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	-20.7
upper limit	10.2

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	39
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	-18.7
upper limit	19.3

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	39
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	-19
upper limit	20.1

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	39
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	-24.8
upper limit	24.8

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	39
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	-27.6
upper limit	17.1

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 12	

Comparison groups	Placebo (Main Study) v Filgotinib 100 mg (Main Study)
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	26.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.1
upper limit	54.8

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 12	
Comparison groups	Placebo (Main Study) v Filgotinib 200 mg (Main Study)
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.1
upper limit	44

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	39
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	-20.3
upper limit	33.6

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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	11.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.6
upper limit	38.7

Secondary: Time to Achieve DAPSA LDA

End point title	Time to Achieve DAPSA LDA

End point description:

DAPSA is sum of 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. The DAPSA score has a lower bound of 0 and has no upper bound. A higher DAPSA score indicated more active disease activity. Time to achieve DAPSA LDA is the number of days from the first dose date of study drug administration to the first time when a participant achieves DAPSA LDA. If DAPSA LDA is not achieved during main study phase, the time will be censored at the last non-missing DAPSA LDA assessment date during main study phase. If the component scores are at different dates for a visit, the latest date will be used to derive time to achieve DAPSA LDA. Participants in the FAS with available data were analyzed. 99.999= Median was not calculated as there was than 50% of participants.

End point type	Secondary

End point timeframe:

Approximately 16 weeks

End point values	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	18	7	18
Units: days				
median (full range (min-max))	73 (15 to 116)	82 (15 to 128)	83 (15 to 127)	99.999 (14 to 133)

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 is 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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	19	9	20
Units: percentage of participants				
number (confidence interval 95%)				
Wk 2 N=19,18,9,19	31.6 (8.0 to 55.1)	16.7 (0.0 to 36.7)	11.1 (0.0 to 37.2)	31.6 (8.0 to 55.1)
Wk 4 N=19,18,9,20	57.9 (33.1 to 82.7)	38.9 (13.6 to 64.2)	44.4 (6.4 to 82.5)	30.0 (7.4 to 52.6)
Wk 8 N=19,19,9,19	78.9 (58.0 to 99.9)	47.4 (22.3 to 72.5)	44.4 (6.4 to 82.5)	57.9 (33.1 to 82.7)
Wk 12 N=18,19,8,19	72.2 (48.8 to 95.7)	68.4 (44.9 to 92.0)	75.0 (38.7 to 100.0)	47.4 (22.3 to 72.5)
Wk 16 N=18,19,9,20	88.9 (71.6 to 100.0)	57.9 (33.1 to 82.7)	77.8 (45.1 to 100.0)	45.0 (20.7 to 69.3)

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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	-14.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-47.4
upper limit	17.6

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	39
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	-34.8
upper limit	34.8

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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	8.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26.6
upper limit	44.3

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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	27.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.2
upper limit	63

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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	21.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13
upper limit	55.1

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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	-10.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-47.4
upper limit	26.3

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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	24.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.1
upper limit	60.8

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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	21.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.9
upper limit	57

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	39
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	43.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.4
upper limit	75.4

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	39
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	-23.4
upper limit	49.1

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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	5	4	4
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	9.5 (± 6.70)	13.8 (± 14.12)	6.5 (± 5.90)	9.6 (± 10.60)
Change From Baseline at Wk 4	-2.2 (± 5.19)	-5.0 (± 5.14)	-1.8 (± 1.54)	-1.1 (± 5.41)
Change From Baseline at Wk 8	-3.4 (± 4.91)	-5.5 (± 4.93)	-3.0 (± 1.98)	-5.6 (± 7.03)
Change From Baseline at Wk 12 N=7,5,3,4	-3.7 (± 5.65)	-5.6 (± 6.13)	-3.0 (± 2.10)	-4.9 (± 7.12)
Change From Baseline at Wk 16	-5.5 (± 7.80)	-7.0 (± 7.69)	-5.2 (± 4.56)	-6.4 (± 9.85)

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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	5	4	4
Units: percentage of participants				
number (confidence interval 95%)				
Wk 4	37.5 (0.0 to 77.3)	40.0 (0.0 to 92.9)	50.0 (0.0 to 100.0)	0 (0.0 to 12.5)
Wk 8	25.0 (0.0 to 61.3)	40.0 (0.0 to 92.9)	50.0 (0.0 to 100.0)	50.0 (0.0 to 100.0)
Wk 12 N=7,5,3,4	57.1 (13.3 to 100.0)	40.0 (0.0 to 92.9)	100.0 (83.3 to 100.0)	50.0 (0.0 to 100.0)
Wk 16	62.5 (22.7 to 100.0)	40.0 (0.0 to 92.9)	100.0 (87.5 to 100.0)	25.0 (0.0 to 79.9)

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	12
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	37.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.8
upper limit	89.8

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	9
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	40
Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.4
upper limit	100

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	12
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	-100
upper limit	51.2

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	9
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	-10
Confidence interval	
level	95 %
sides	2-sided
lower limit	-97.7
upper limit	77.7

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	12
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	-73.7
upper limit	88

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description: Week 16	
Comparison groups	Placebo (Main Study) v Filgotinib 200 mg (Main Study)
Number of subjects included in analysis	12
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	37.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-35.3
upper limit	100

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

Statistical analysis description:	
Week 12	
Comparison groups	Placebo (Main Study) v Filgotinib 100 mg (Main Study)
Number of subjects included in analysis	9
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	-10
Confidence interval	
level	95 %
sides	2-sided
lower limit	-97.7
upper limit	77.7

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	9
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-67.9
upper limit	97.9

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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	5	4	4
Units: percentage of participants				
number (confidence interval 95%)				
Wk 4	12.5 (0.0 to 41.7)	20.0 (0.0 to 65.1)	0 (0.0 to 12.5)	0 (0.0 to 12.5)
Wk 8	25.0 (0.0 to 61.3)	40.0 (0.0 to 92.9)	25.0 (0.0 to 79.9)	0 (0.0 to 12.5)
Wk 12 N=7,5,3,4	42.9 (0.0 to 86.7)	40.0 (0.0 to 92.9)	66.7 (0.0 to 100.0)	0 (0.0 to 12.5)
Wk 16	62.5 (22.7 to 100.0)	20.0 (0.0 to 65.1)	75.0 (20.1 to 100.0)	25.0 (0.0 to 79.9)

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	12
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	-29.2
upper limit	54.2

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	9
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	-37.6
upper limit	77.6

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	12
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	-23.8
upper limit	73.8

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	9
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	40
Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.4
upper limit	100

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 12	
Comparison groups	Placebo (Main Study) v Filgotinib 100 mg (Main Study)

Number of subjects included in analysis	9
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	40
Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.4
upper limit	100

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 12	
Comparison groups	Placebo (Main Study) v Filgotinib 200 mg (Main Study)
Number of subjects included in analysis	12
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	42.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.4
upper limit	99.2

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 16	
Comparison groups	Placebo (Main Study) v Filgotinib 100 mg (Main Study)
Number of subjects included in analysis	9
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	-5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-82.5
upper limit	72.5

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

Comparison groups	Placebo (Main Study) v Filgotinib 200 mg (Main Study)
Number of subjects included in analysis	12
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	37.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-35.3
upper limit	100

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 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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	5	4	4
Units: percentage of participants				
number (confidence interval 95%)				
Wk 4	0 (0.0 to 6.3)	0 (0.0 to 10.0)	0 (0.0 to 12.5)	0 (0.0 to 12.5)
Wk 8	12.5 (0.0 to 41.7)	0 (0.0 to 10.0)	25.0 (0.0 to 79.9)	0 (0.0 to 12.5)
Wk 12 N=7,5,3,4	14.3 (0.0 to 47.4)	20.0 (0.0 to 65.1)	66.7 (0.0 to 100.0)	0 (0.0 to 12.5)
Wk 16	25.0 (0.0 to 61.3)	20.0 (0.0 to 65.1)	50.0 (0.0 to 100.0)	0 (0.0 to 12.5)

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	12
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	-18.8
upper limit	18.8

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	9
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	-22.5
upper limit	22.5

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	12
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	-29.2
upper limit	54.2

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	9
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	-22.5
upper limit	22.5

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	12
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	14.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-31.3
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	9
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	-37.6
upper limit	77.6

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	12
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	-23.8
upper limit	73.8

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	9
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	-37.6
upper limit	77.6

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 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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	5	4	4
Units: percentage of participants				
number (confidence interval 95%)				
Wk 4	0 (0.0 to 6.3)	0 (0.0 to 10.0)	0 (0.0 to 12.5)	0 (0.0 to 12.5)
Wk 8	0 (0.0 to 6.3)	0 (0.0 to 10.0)	25.0 (0.0 to 79.9)	0 (0.0 to 12.5)
Wk 12 N=7,5,3,4	14.3 (0.0 to 47.4)	0 (0.0 to 10.0)	66.7 (0.0 to 100.0)	0 (0.0 to 12.5)
Wk 16	12.5 (0.0 to 41.7)	20.0 (0.0 to 65.1)	25.0 (0.0 to 79.9)	0 (0.0 to 12.5)

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	12
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	-18.8
upper limit	18.8

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	9
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	-22.5
upper limit	22.5

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	12
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	-18.8
upper limit	18.8

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	9
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	-22.5
upper limit	22.5

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	12
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in response rates
Point estimate	14.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-31.3
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	9
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	-22.5
upper limit	22.5

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	12
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	-29.2
upper limit	54.2

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	9
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	-37.6
upper limit	77.6

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. 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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	9	6	11
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	4 (± 3.4)	4 (± 2.4)	4 (± 1.7)	5 (± 4.5)
Change From Baseline at Wk 4	-2 (± 2.6)	0 (± 2.0)	-2 (± 1.2)	0 (± 3.1)
Change From Baseline at Wk 8 N=10,9,6,10	-2 (± 2.4)	-1 (± 1.6)	-3 (± 1.9)	-2 (± 3.3)
Change From Baseline at Wk 12 N=10,9,5,10	-3 (± 3.5)	-2 (± 1.8)	-2 (± 1.5)	-1 (± 1.7)
Change From Baseline at Wk 16	-3 (± 3.3)	-2 (± 2.6)	-3 (± 1.5)	-1 (± 3.2)

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 quantitatively measures dactylitis using the circumference of involved digits and control digits and tenderness of involved digits. Digits affected by dactylitis are those with an at least 10% difference in the ratio of circumference of the affected digit to the contralateral digit (digit on opposite hand or foot), or if contralateral digit is also affected, values from a standard reference table. Total score= {{[Circumference involved digit/ Circumference contralateral Digit (or Tables)] - 1}x 100} x Tenderness score. Tenderness score (0 = no tenderness, and 1 = tender). The difference between circumference of affected finger and contralateral not affected digit cannot be defined for maximum value. No theoretical range exists for the Leeds Dactylitis Index. Lower Leeds Dactylitis Index score represent better outcome. A negative change from baseline indicates improvement. Participants in the FAS with dactylitis were analyzed. 9999=SD cannot be calculated for 1 participant.

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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	3	1	5
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	69.5 (± 56.62)	28.9 (± 17.35)	159.1 (± 9999)	15.2 (± 19.45)
Change From Baseline at Wk 4	-13.4 (± 16.81)	13.0 (± 19.44)	-159.1 (± 9999)	13.3 (± 30.64)
Change From Baseline at Wk 8	-40.8 (± 45.15)	-2.5 (± 18.34)	-159.1 (± 9999)	3.6 (± 40.81)
Change From Baseline at Wk 12	-49.3 (± 40.86)	-14.0 (± 9.80)	-159.1 (± 9999)	2.1 (± 44.13)
Change From Baseline at Wk 16	-40.2 (± 51.12)	8.4 (± 41.91)	-159.1 (± 9999)	2.0 (± 31.30)

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 is 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 is 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 were analyzed. 9999=SD cannot be calculated for one participant.

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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	3	1	5
Units: tender dactylitis count				
arithmetic mean (standard deviation)				
Baseline	4 (± 4.1)	2 (± 1.0)	6 (± 9999)	1 (± 1.3)
Change From Baseline at Wk 4	-1 (± 0.9)	1 (± 1.0)	-6 (± 9999)	0 (± 1.5)
Change From Baseline at Wk 8	-3 (± 3.3)	0 (± 1.5)	-6 (± 9999)	0 (± 2.1)
Change From Baseline at Wk 12	-3 (± 3.0)	-1 (± 1.5)	-6 (± 9999)	0 (± 2.2)
Change From Baseline at Wk 16	-3 (± 3.3)	0 (± 2.1)	-6 (± 9999)	0 (± 1.5)

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. A 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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	19	8	20
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	1.05 (± 0.601)	0.80 (± 0.547)	0.95 (± 0.630)	0.92 (± 0.602)
Change From Baseline at Wk 2 N=19,18,8,19	-0.13 (± 0.293)	-0.09 (± 0.345)	0.03 (± 0.332)	-0.08 (± 0.321)
Change From Baseline at Wk 4 N=19,18,8,20	-0.20 (± 0.264)	-0.24 (± 0.474)	-0.16 (± 0.297)	-0.01 (± 0.337)
Change From Baseline at Wk 8 N=19,19,8,19	-0.37 (± 0.387)	-0.24 (± 0.516)	-0.16 (± 0.281)	-0.12 (± 0.407)
Change From Baseline at Wk 12 N=18,19,7,19	-0.33 (± 0.374)	-0.20 (± 0.477)	-0.39 (± 0.274)	-0.07 (± 0.438)
Change From Baseline at Wk 16 N=18,19,8,20	-0.33 (± 0.407)	-0.33 (± 0.575)	-0.34 (± 0.297)	-0.19 (± 0.487)

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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.94 [31]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	-0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.22
upper limit	0.2

Notes:

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

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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.81 [32]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.18
upper limit	0.24

Notes:

[32] - P-value was calculated from MMRM including treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, and 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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.13 [33]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	-0.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.39
upper limit	0.05

Notes:

[33] - P-value was calculated from MMRM including treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, and 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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.073 [34]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	-0.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.43
upper limit	0.02

Notes:

[34] - P-value was calculated from MMRM including treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, and 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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.083 [35]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	-0.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.46
upper limit	0.03

Notes:

[35] - P-value was calculated from MMRM including treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, and 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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.28 [36]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	-0.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.38
upper limit	0.11

Notes:

[36] - P-value was calculated from MMRM including treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, and 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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.038 [37]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	-0.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.54
upper limit	-0.02

Notes:

[37] - P-value was calculated from MMRM including treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, and 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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.25 [38]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	-0.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.41
upper limit	0.11

Notes:

[38] - P-value was calculated from MMRM including treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, and 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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.41 [39]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	-0.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.39
upper limit	0.16

Notes:

[39] - P-value was calculated from MMRM including treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, and 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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.26 [40]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	-0.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.43
upper limit	0.12

Notes:

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

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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	19	8	20
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	32.5 (± 9.83)	33.9 (± 13.06)	33.4 (± 10.66)	31.4 (± 10.37)
Change From Baseline at Wk 4 N=19,18,8,20	4.6 (± 9.75)	4.1 (± 8.53)	0.5 (± 7.23)	1.6 (± 6.53)
Change From Baseline at Wk 16	5.6 (± 9.45)	6.4 (± 10.42)	4.6 (± 9.18)	2.4 (± 9.27)

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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.14 [41]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	3.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	7.9

Notes:

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

Statistical analysis title	Fil 100 mg (Main Study) vs Placebo (Main Stu
Statistical analysis description:	
Week 4	
Comparison groups	Filgotinib 100 mg (Main Study) v Placebo (Main Study)
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.18 [42]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	3.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.5
upper limit	7.7

Notes:

[42] - P-value was calculated from MMRM including treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, and 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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.15 [43]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	3.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	8.7

Notes:

[43] - P-value was calculated from MMRM including treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, and 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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.062 [44]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	4.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3
upper limit	9.9

Notes:

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

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 is 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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	19	8	20
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	49.9 (± 12.48)	50.5 (± 11.43)	44.8 (± 7.67)	48.9 (± 9.27)
Change From Baseline at Wk 4 N=19,18,8,20	3.3 (± 9.66)	0.4 (± 9.40)	0.6 (± 6.80)	-0.4 (± 5.58)
Change From Baseline at Wk 16	2.8 (± 10.34)	0.2 (± 9.42)	-0.4 (± 5.58)	0.3 (± 5.95)

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 is 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)	Adalimumab 40 mg (Main Study)	Placebo (Main Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	19	8	20
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	37.1 (± 8.11)	39.2 (± 9.60)	39.2 (± 7.58)	37.2 (± 7.83)
Change From Baseline at Wk 4 N=19,18,8,20	6.4 (± 5.87)	5.6 (± 7.00)	2.9 (± 7.12)	1.1 (± 5.24)
Change From Baseline at Wk 16	8.4 (± 6.86)	7.4 (± 9.80)	8.1 (± 7.73)	4.6 (± 7.85)

Statistical analyses

Statistical analysis title	Fil 200 mg (Main Study) vs Placebo (Main Study)
Statistical analysis description:	
Week 4	
Comparison groups	Placebo (Main Study) v Filgotinib 100 mg (Main Study)
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.006 [45]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	4.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.5
upper limit	8.3

Notes:

[45] - P-value was calculated from MMRM including treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, and 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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003 [46]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	5.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.9
upper limit	8.6

Notes:

[46] - P-value was calculated from MMRM including treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, and 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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.076 [47]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	3.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.4
upper limit	8

Notes:

[47] - P-value was calculated from MMRM including treatment, visit (categorical), treatment by visit, stratification factors, baseline value as fixed effects, and 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	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1 [48]
Method	MMRM
Parameter estimate	LS Mean Treatment Difference
Point estimate	3.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	7.7

Notes:

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

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse Events: First dose date up to 50 weeks plus 30 days; All-Cause Mortality: Randomization up to 50 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 + PTM adalimumab SC injection every two weeks 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 + PTM Adalimumab SC injection every two weeks for 16 weeks.

Reporting group title	Adalimumab 40 mg (Main Study)

Reporting group description:

PTM filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily + Adalimumab 40 mg SC injection every two weeks 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 + PTM adalimumab SC injection every two weeks for 16 weeks.

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 34 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 34 weeks. Participants received filgotinib 100 mg in the Main Study.

Reporting group title	Filgotinib 200 mg From Adalimumab 40 mg (LTE)

Reporting group description:

Filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily for up to 34 weeks. Participants received adalimumab 40 mg in the Main Study.

Reporting group title	Filgotinib 100 mg From Adalimumab 40 mg (LTE)

Reporting group description:

Filgotinib 100 mg tablet orally once daily + PTM filgotinib 200 mg tablet orally once daily for up to 34 weeks. Participants received adalimumab 40 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 34 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 34

Serious adverse events	Filgotinib 200 mg (Main Study)	Filgotinib 100 mg (Main Study)	Adalimumab 40 mg (Main Study)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 19 (0.00%)	1 / 19 (5.26%)	0 / 9 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 19 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Helicobacter infection			
subjects affected / exposed	0 / 19 (0.00%)	1 / 19 (5.26%)	0 / 9 (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

Serious adverse events	Placebo (Main Study)	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 20 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Helicobacter infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Filgotinib 200 mg From Adalimumab 40 mg (LTE)	Filgotinib 100 mg From Adalimumab 40 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 2 (50.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Helicobacter infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
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)		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Helicobacter infection			
subjects affected / exposed	0 / 2 (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)	Adalimumab 40 mg (Main Study)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 19 (21.05%)	7 / 19 (36.84%)	2 / 9 (22.22%)
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 19 (5.26%)	1 / 19 (5.26%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 19 (0.00%)	1 / 19 (5.26%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 19 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Initial insomnia			
subjects affected / exposed	0 / 19 (0.00%)	1 / 19 (5.26%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 19 (5.26%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	1 / 19 (5.26%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0

Rib fracture			
subjects affected / exposed	0 / 19 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Tension headache			
subjects affected / exposed	0 / 19 (0.00%)	1 / 19 (5.26%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	0 / 19 (0.00%)	1 / 19 (5.26%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	0 / 19 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 19 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 19 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 19 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Hepatobiliary disorders			
Hepatic steatosis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 19 (5.26%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 19 (5.26%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 19 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	0 / 19 (0.00%)	1 / 19 (5.26%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Tendon pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 19 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Covid-19			
subjects affected / exposed	0 / 19 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 19 (5.26%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Laryngitis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 19 (5.26%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 19 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Suspected COVID-19			
subjects affected / exposed	0 / 19 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 19 (0.00%)	1 / 19 (5.26%)	0 / 9 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Placebo (Main Study)	Filgotinib 200 mg From Filgotinib 200 mg (LTE)	Filgotinib 100 mg From Filgotinib 100 mg (LTE)
Total subjects affected by non-serious adverse events			

subjects affected / exposed	9 / 20 (45.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 20 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 20 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 20 (5.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Initial insomnia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 20 (5.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 20 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rib fracture			

subjects affected / exposed	0 / 20 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Tension headache			
subjects affected / exposed	1 / 20 (5.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	0 / 20 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	3 / 20 (15.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Abdominal pain			
subjects affected / exposed	1 / 20 (5.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	0 / 20 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 20 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatic steatosis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	1 / 20 (5.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	1 / 20 (5.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue			

disorders			
Arthralgia			
subjects affected / exposed	1 / 20 (5.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	0 / 20 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tendon pain			
subjects affected / exposed	1 / 20 (5.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	2 / 20 (10.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Covid-19			
subjects affected / exposed	2 / 20 (10.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Folliculitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Suspected COVID-19			
subjects affected / exposed	1 / 20 (5.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Filgotinib 200 mg From Adalimumab 40 mg (LTE)	Filgotinib 100 mg From Adalimumab 40 mg (LTE)	Filgotinib 200 mg From Placebo (LTE)
Total subjects affected by non-serious adverse events			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 2 (50.00%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Initial insomnia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rib fracture			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Tension headache			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatic steatosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue			

disorders			
Arthralgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tendon pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Covid-19			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Suspected COVID-19			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Filgotinib 100 mg From Placebo (LTE)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 2 (50.00%)		

Vascular disorders Hypertension subjects affected / exposed occurrences (all)	 0 / 2 (0.00%) 0		
General disorders and administration site conditions Asthenia subjects affected / exposed occurrences (all) Fatigue subjects affected / exposed occurrences (all) Pyrexia subjects affected / exposed occurrences (all)	 0 / 2 (0.00%) 0 0 / 2 (0.00%) 0 0 / 2 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	 0 / 2 (0.00%) 0		
Psychiatric disorders Initial insomnia subjects affected / exposed occurrences (all) Insomnia subjects affected / exposed occurrences (all)	 0 / 2 (0.00%) 0 0 / 2 (0.00%) 0		
Investigations Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	 0 / 2 (0.00%) 0		
Injury, poisoning and procedural complications Fall subjects affected / exposed occurrences (all) Rib fracture subjects affected / exposed occurrences (all)	 1 / 2 (50.00%) 1 1 / 2 (50.00%) 1		

Nervous system disorders			
Tension headache			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Abdominal pain			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Diarrhoea			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Stomatitis			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Hepatobiliary disorders			
Hepatic steatosis			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Rash			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Pain in extremity			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Tendon pain			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Covid-19			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Folliculitis			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Laryngitis			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Nasopharyngitis			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Suspected COVID-19			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 2 (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	• Clarified initial DMC data review. • Clarified laboratory retesting criteria. • Clarified inadequate responder definition. • Clarified vaccination recommendations. • Optional skin biopsy time points were revised. • Inconsistencies to the MRI investigation were corrected. • Clarified the primary estimand. • Viral monitoring frequency was increased. • Urine drug screen panel was revised. • Aligned C-reactive protein (CRP) blinding to be consistent throughout protocol. • Secondary and exploratory endpoints were recategorized. • Clarified stratification at randomization • Added optional HLA-B27 sample collection. • CTCAE Version 4.03 was updated to Version 5.0. • Added follicle-stimulating hormone testing after screening. • Updated sample questionnaires for Clinical and Patient Reported Outcomes and corrected inconsistencies with nomenclature. • Eligibility criteria was clarified as needed. • Inconsistencies regarding timing of the first MRI (at screening) were corrected. • Inconsistencies regarding the window for imaging assessments were corrected.

17 April 2020	• Increased planned number of sites to support enrollment. • Removed secondary objective for modified Total Sharp Score (mTSS). • Removed restriction on use of Week 16 data. • Updated Study Design to end (Main Study) at Week 16, revised last in-clinic visit at • Week 120, reduced study duration to 2.25 years, and reduced sample size. • Corrected and clarified inclusion and exclusion criteria with respect to cyclosporine removal, • region-specific age requirements, and total bilirubin at screening; removed inclusion criteria for x-rays • Updated key secondary, other secondary, and exploratory endpoints including the removal of mTSS endpoint. • Added description for graphical approach test procedures and safety estimands; updated sample size assumptions and calculations. • Updated Preclinical Pharmacology and Toxicology section to align with current IB. • Added patient discontinuation requirement for thromboembolic events and for patients with active disease at Week 24. • Included biomarker collection visits in Study Procedures Table footnotes and peripheral blood mononuclear cell collection clarification for North America only. • Clarified patient could withdraw MRI consent, and updated objectives to match revised collection time point. • Removed CRP collection at screening and updated CRP at Day 1 to be unblinded to the sponsor. • Updated concomitant medications as a result of shortened Main Study and to include a note for medications that could cause dermatitis and exacerbate psoriasis. • Revised timing of rescue therapy with uncontrolled PsA disease activity. • Updated AE terminology, Special Situations reporting, SAE and death reporting. • Added toxicity management for thromboembolic events. • Added more detailed process language for DMC. • Updated MACE and thromboembolic events language to include/add more detailed description of adjudication process. • Clarified when early termination and safety follow-up visits were to occur.

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Due to early termination of the study and insufficient number of participants enrolled, all the hypothesis testing performed and the p values reported were nominal. Therefore, the results need to be interpreted with caution.

Notes: