Clinical trial results:
A multicenter, open-label, long-term extension safety and efficacy study of filgotinib treatment in subjects with moderately to severely active psoriatic arthritis

Summary

EudraCT number	2017-000545-52
Trial protocol	BE CZ BG ES
Global end of trial date	30 June 2021

Results information

Result version number	v1 (current)
This version publication date	13 July 2022
First version publication date	13 July 2022

Trial information

Trial identification

Sponsor protocol code	GLPG0634-CL-225

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03320876
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Galapagos NV
Sponsor organisation address	Generaal De Wittelaan L11 A3 , Mechelen, Belgium, 2800
Public contact	Galapagos Medical Information, Galapagos NV, medicalinfo@glpg.com
Scientific contact	Galapagos Medical Information, Galapagos NV, medicalinfo@glpg.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	30 June 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	30 June 2021
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To evaluate the long-term safety and tolerability of filgotinib in participants with psoriatic arthritis (PsA).

Protection of trial subjects:

This clinical study was conducted in accordance with the ethical principles that have their origin in the "Declaration of Helsinki" and its amendments in force at the time of the clinical study (2013 version). It was also carried out in conformity with the protocol, the International Council for Harmonisation for Good Clinical Practice (ICH-GCP) Guideline E6 (R2), and local ethical and legal requirements. The investigator informed the participants of the risks and benefits of the clinical study. The participants were informed that they could withdraw from the clinical study at any time for any reason.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	26 July 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Poland: 34
Country: Number of subjects enrolled	Spain: 10
Country: Number of subjects enrolled	Belgium: 1
Country: Number of subjects enrolled	Bulgaria: 12
Country: Number of subjects enrolled	Czechia: 6
Country: Number of subjects enrolled	Estonia: 15
Country: Number of subjects enrolled	Ukraine: 44
Worldwide total number of subjects	122
EEA total number of subjects	78

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	0

months)	
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	109
From 65 to 84 years	13
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants who completed 16 weeks of double-blind treatment in the core study (GLPG0634-CL-224) and who fulfilled the inclusion and exclusion criteria were followed-up for safety and tolerability in this long-term extension (LTE) study. Study was conducted at 25 sites in Belgium, Bulgaria, Czech Republic, Estonia, Poland, Spain, and Ukraine.

Pre-assignment

Screening details:

122 participants were rolled over from core study to LTE study and received long-term treatment with filgotinib.

Patient’s Global Assessment of Disease Activity (PGADA);Health Assessment Questionnaire-Disability Index (HAQ-DI);Spondyloarthritis Research Consortium of Canada (SPARCC);Physician’s Global Assessment of Disease Activity (PhGADA).

Period 1

Period 1 title	Overall period (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Filgotinib (Core Study) and Filgotinib (LTE Study)

Arm description:

Participants received filgotinib 200 milligrams (mg) tablet, orally, once daily up to Week 16 in GLPG0634-CL-224 core study (2016-003637-14) followed by filgotinib 200 mg tablet, orally, once daily up to 212 weeks in this GLPG0634-CL-225 long-term extension (LTE) study (2017-000545-52).

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

Dosage and administration details:

One filgotinib 200 mg tablet orally once daily for 212 weeks.

Arm title	Placebo (Core Study) and Filgotinib (LTE Study)

Arm description:

Participants received placebo (matched to filgotinib) tablet, orally, once daily up to Week 16 in GLPG0634-CL-224 core study (2016-003637-14) followed by filgotinib 200 mg tablet, orally, once daily up to 212 weeks in this GLPG0634-CL-225 LTE study (2017-000545-52).

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

Dosage and administration details:

One filgotinib 200 mg tablet orally once daily for 212 weeks.

Number of subjects in period 1	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)
Started	59	63
Completed	0	0
Not completed	59	63
Withdrew Consent	20	9
Study Terminated By Sponsor	36	47
Adverse event, non-fatal	3	5
Investigator's Discretion	-	2

Baseline characteristics

Reporting groups	
Reporting group title	Filgotinib (Core Study) and Filgotinib (LTE Study)
Reporting group description:	
Participants received filgotinib 200 milligrams (mg) tablet, orally, once daily up to Week 16 in GLPG0634-CL-224 core study (2016-003637-14) followed by filgotinib 200 mg tablet, orally, once daily up to 212 weeks in this GLPG0634-CL-225 long-term extension (LTE) study (2017-000545-52).	
Reporting group title	Placebo (Core Study) and Filgotinib (LTE Study)
Reporting group description:	
Participants received placebo (matched to filgotinib) tablet, orally, once daily up to Week 16 in GLPG0634-CL-224 core study (2016-003637-14) followed by filgotinib 200 mg tablet, orally, once daily up to 212 weeks in this GLPG0634-CL-225 LTE study (2017-000545-52).	

Reporting group values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)	Total
Number of subjects	59	63	122
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	52	57	109
From 65-84 years	7	6	13
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	32	28	60
Male	27	35	62
Race Units: Subjects			
White	59	63	122

End points

End points reporting groups

Reporting group title	Filgotinib (Core Study) and Filgotinib (LTE Study)

Reporting group description:

Participants received filgotinib 200 milligrams (mg) tablet, orally, once daily up to Week 16 in GLPG0634-CL-224 core study (2016-003637-14) followed by filgotinib 200 mg tablet, orally, once daily up to 212 weeks in this GLPG0634-CL-225 long-term extension (LTE) study (2017-000545-52).

Reporting group title	Placebo (Core Study) and Filgotinib (LTE Study)

Reporting group description:

Participants received placebo (matched to filgotinib) tablet, orally, once daily up to Week 16 in GLPG0634-CL-224 core study (2016-003637-14) followed by filgotinib 200 mg tablet, orally, once daily up to 212 weeks in this GLPG0634-CL-225 LTE study (2017-000545-52).

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

Subject analysis set description:

Participants received filgotinib 200 mg tablet, orally, once daily up to 212 weeks in this GLPG0634-CL-225 LTE study (2017-000545-52).

Subject analysis set title	LTE Full Analysis Set (FAS)
Subject analysis set type	Full analysis

Subject analysis set description:

LTE FAS included all participants who rolled over and received at least one dose of study drug in LTE study.

Primary: Percentage of Participants who Experienced Treatment Emergent Adverse Events (TEAEs), Serious Adverse Events (SAEs), and Discontinued the Study Due to TEAEs

End point title	Percentage of Participants who Experienced Treatment Emergent Adverse Events (TEAEs), Serious Adverse Events (SAEs), and Discontinued the Study Due to TEAEs[1]

End point description:

An adverse event (AE) was any untoward medical occurrence in a participant administered study drug and which did not necessarily have a causal relationship with study drug. An SAE was defined as an event that resulted in death, life-threatening event, in-patient existing or prolongation of hospitalization, significant disability/incapacity, a congenital anomaly/birth defect or a medically important event. A TEAE was any AE with an onset date on or after the first dose of filgotinib in LTE study and no later than 30 days after permanent discontinuation of filgotinib or any AEs leading to premature discontinuation of filgotinib in LTE study regardless of onset date. TEAEs that occurred in LTE study was included. LTE Safety Analysis Set included all participants who received at least one dose of study drug in LTE study.

End point type	Primary

End point timeframe:

From first dose (LTE Study) up to 30 days after last dose of filgotinib in LTE study (maximum up to 212 weeks)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The endpoint is descriptive in nature.

End point values	Filgotinib 200 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	122			
Units: percentage of participants				
number (not applicable)				
TEAEs	79.5			
SAEs	15.6			

Discontinuations due to AEs	6.6			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Severity Grade 3 or Above Treatment-Emergent Laboratory Abnormalities

End point title	Percentage of Participants With Severity Grade 3 or Above Treatment-Emergent Laboratory Abnormalities[2]

End point description:

Treatment-emergent laboratory abnormalities were graded using Common Terminology Criteria for Adverse Events (CTCAE) Version 4.03 of Adverse Events and Laboratory abnormalities. Laboratory abnormalities were graded as Grade 1 (mild), Grade 2 (moderate), Grade 3 (severe), Grade 4 (Life-threatening), Grade 5 (Death). A treatment-emergent laboratory abnormality was defined as an increase of at least 1 toxicity grade from core baseline at any time post-baseline up to and including the last dose date of filgotinib plus 30 days. The most severe treatment-emergent abnormality that occurred in LTE study were included. LTE Safety Analysis Set.

End point type	Primary

End point timeframe:

From Baseline up to 30 days after last dose of filgotinib in LTE study (maximum up to 212 weeks)

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The endpoint is descriptive in nature.

End point values	Filgotinib 200 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	122			
Units: percentage of participants				
number (not applicable)	27			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved Minimal Disease Activity (MDA) Response

End point title	Percentage of Participants Who Achieved Minimal Disease Activity (MDA) Response

End point description:

MDA: measure of disease remission, based on composite score of 7 domains. One would achieve MDA if ≥ 5 of 7 criteria were met: Tender joint count (TJC) ≤1 (based on 68 joints);swollen joint count (SJC) ≤1 (based on 66 joints); Psoriatic Arthritis Disease Activity score (PASI) ≤1 with core baseline affected body surface area (BSA) <3% (total score= 0 [no disease] to 72 [maximal disease]);Patient's Global Assessment of Psoriatic Arthritis Pain Intensity (PGAP Pain) ≤15 (assessed on 0-100 mm visual analog scale (VAS); 0 [no pain] to 100 [serious pain]);PGADA ≤20 (assessed on 0-100 mm VAS; 0 [very well] to 100 [very poor]);HAQ-DI score ≤0.5 (assessment of ability to perform task; contains 20 questions, 8 components; score= 0 [without difficulty] to 3 [unable to do]); SPARCC Enthesitis Index ≤1 with

enthesitis at core baseline (total score= 0 to 16 with higher score indicates higher enthesitis burden). Data summarized using observed cases (OC) method. LTE FAS with available data.

End point type	Secondary

End point timeframe:

Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	63		
Units: percentage of participants				
number (not applicable)				
Week 4 (n= 59, 63)	22.0	17.5		
Week 16 (n= 57, 62)	35.1	24.2		
Week 28 (n= 54, 60)	37.0	33.3		
Week 40 (n= 55, 59)	45.5	28.8		
Week 52 (n= 54, 57)	35.2	31.6		
Week 64 (n= 50, 56)	34.0	35.7		
Week 76 (n= 51, 55)	45.1	36.4		
Week 88 (n= 49, 54)	49.0	40.7		
Week 100 (n= 45, 52)	44.4	40.4		
Week 112 (n= 44, 49)	45.5	36.7		
Week 124 (n= 37, 50)	48.6	44.0		
Week 136 (n= 39, 48)	59.0	39.6		
Week 148 (n= 38, 49)	55.3	36.7		
Week 172 (n= 33, 45)	48.5	42.2		
Week 196 (n= 10, 10)	30.0	40.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants achieving MDA Very Low Disease Activity (VLDA)

End point title	Percentage of Participants achieving MDA Very Low Disease Activity (VLDA)

End point description:

MDA: measure of disease remission, based on composite score of 7 domains. One would achieve VLDA MDA if all of the 7 criteria were met: TJC ≤1 (based on 68 joints); SJC ≤1 (based on 66 joints); PASI ≤1 with core baseline affected BSA <3% (total score= 0 [no disease] to 72 [maximal disease]); PGAP Pain ≤15 (assessed on 0-100 mm VAS; 0 [no pain] to 100 [serious pain]); PGADA ≤20 (assessed on 0-100 mm VAS; 0 [very well] to 100 [very poor]); HAQ-DI score ≤0.5 (assessment of ability to perform task; contains 20 questions, 8 components; score= 0 [without difficulty] to 3 [unable to do]); SPARCC Enthesitis Index ≤1 with enthesitis at core baseline (total score= 0 to 16 with higher score indicates higher enthesitis burden). Data summarized using OC method. LTE FAS with available data.

End point type	Secondary

End point timeframe:

Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	63		
Units: percentage of participants				
number (not applicable)				
Week 4 (n= 59, 63)	1.7	6.3		
Week 16 (n= 57, 62)	5.3	8.1		
Week 28 (n= 54, 60)	9.3	10.0		
Week 40 (n= 55, 59)	16.4	10.2		
Week 52 (n= 54, 56)	11.1	10.7		
Week 64 (n= 50, 56)	8.0	8.9		
Week 76 (n= 51, 55)	9.8	14.5		
Week 88 (n= 49, 54)	22.4	13.0		
Week 100 (n= 45, 52)	13.3	13.5		
Week 112 (n= 44, 49)	13.6	14.3		
Week 124 (n= 37, 50)	13.5	8.0		
Week 136 (n= 39, 48)	20.5	14.6		
Week 148 (n= 38, 49)	23.7	12.2		
Week 172 (n= 33, 45)	18.2	11.1		
Week 196 (n= 10, 10)	0.0	20.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Psoriatic Arthritis Disease Activity Score (PASDAS) Low Disease Activity (LDA) (PASDAS ≤ 3.2)

End point title	Percentage of Participants With Psoriatic Arthritis Disease Activity Score (PASDAS) Low Disease Activity (LDA) (PASDAS ≤ 3.2)

End point description:

PASDAS:composite disease activity measure for psoriatic arthritis and includes:PGADA (assessed on 0-100 mm VAS; 0 [very well] to 100 [very poor]);PhGADA (assessed on 0 to 100 mm VAS; 0 [no disease activity] to 100 [maximum disease activity]);Physical Component Score (PCS) (score range = 0-100, higher scores indicates better health status) of SF-36 (questionnaire which measures quality of life across 8 domains);TJC68; SJC66; Leeds Enthesitis Index (LEI) (assessed at 6 sites; score range= 0-6, higher scores indicates higher degree of enthesitis); Tender Dactylitis Count (TDC) (score range= 0-60, higher score indicates higher degree of dactylitis); C-reactive protein (CRP). PASDAS derivation: [0.18*√PhGADA+0.159*√PGADA−0.253*√PCS+0.101*Ln(SJC66+1)+0.048*Ln(TJC68+1)+0.23*Ln(LEI+1)+0.377*Ln(TDC+1)+0.102*Ln(CRP+1)+2]*1.5. Score ranges from 0-10, lower score indicates better function. PASDAS LDA is defined as PASDAS ≤ 3.2. Data was summarized using the OC method. LTE FAS with available data.

End point type	Secondary

End point timeframe:

Weeks 4, 52, 100, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	56	61		
Units: percentage of participants				
number (not applicable)				
Week 4 (n= 56, 61)	50.0	31.1		
Week 52 (n= 54, 56)	57.4	48.2		
Week 100 (n= 45, 52)	62.2	55.8		
Week 148 (n= 36, 49)	66.7	51.0		
Week 172 (n= 33, 45)	66.7	57.8		
Week 196 (n= 10, 10)	40.0	40.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With PASDAS Very Low Disease Activity (VLDA) (PASDAS ≤1.9)

End point title	Percentage of Participants With PASDAS Very Low Disease Activity (VLDA) (PASDAS ≤1.9)

End point description:

PASDAS: composite disease activity measure for psoriatic arthritis and includes: PGADA (assessed on 0-100 mm VAS; 0 [very well] to 100 [very poor]); PhGADA (assessed on 0 to 100 mm VAS; 0 [no disease activity] to 100 [maximum disease activity], respectively); PCS (score range = 0-100, higher scores indicates better health status) of SF-36 (questionnaire which measures quality of life across 8 domains); TJC68; SJC66; LEI (assessed at 6 sites; score range= 0-6, higher scores indicates higher degree of enthesitis); TDC (score range= 0-60, higher score indicates higher degree of dactylitis); and CRP. PASDAS derivation: [0.18*√PhGADA+0.159*√PGADA–0.253*√PCS+0.101*Ln(SJC66+1)+0.048*Ln(TJC68+1)+0.23*Ln(LEI+1)+0.377*Ln(TDC+1)+0.102*Ln(CRP+1)+2]*1.5. Score ranges from 0-10, lower score indicates better function. PASDAS VLDA is defined as PASDAS ≤1.9. Data was summarized using OC method. LTE

End point type	Secondary

End point timeframe:

Weeks 4, 52, 100, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	56	61		
Units: percentage of participants				
number (not applicable)				
Week 4 (n= 56, 61)	8.9	8.2		

Week 52 (n= 54, 56)	18.5	21.4		
Week 100 (n= 45, 52)	24.4	23.1		
Week 148 (n= 36, 49)	33.3	22.4		
Week 172 (n= 33, 45)	30.3	17.8		
Week 196 (n= 10, 10)	10.0	20.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved an American College of Rheumatology 20 (ACR20) Response

End point title	Percentage of Participants Who Achieved an American College of Rheumatology 20 (ACR20) Response

End point description:

ACR20 response was achieved when the participant had: ≥20% improvement from baseline in TJC68, SJC66, and in at least 3 of the following 5 items: PGADA using 0 to 100 mm VAS, on a scale of 0 (very well) to 100 (very poor); PhGADA using 0 to 100 mm VAS, on a scale of 0 (no disease activity) to 100 (maximum disease activity); HAQ-DI [assessment of ability to perform task; contains 20 questions,8 components: dressing/ grooming, arising, eating, walking, hygiene, reach, grip and activities and scores on a scale of 0 (without difficulty) to 3 (unable to do)]; and CRP. Data was summarized using OC method. LTE FAS with available data.

End point type	Secondary

End point timeframe:

Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	62		
Units: percentage of participants				
number (not applicable)				
Week 4 (n= 59, 62)	88.1	71.0		
Week 16 (n= 57, 62)	84.2	79.0		
Week 28 (n= 54, 60)	90.7	83.3		
Week 40 (n= 55, 59)	90.9	83.1		
Week 52 (n= 54, 56)	83.3	78.6		
Week 64 (n= 50, 55)	88.0	81.8		
Week 76 (n= 51, 54)	88.2	75.9		
Week 88 (n= 49, 53)	87.8	75.5		
Week 100 (n= 45, 52)	88.9	75.0		
Week 112 (n= 44, 49)	84.1	77.6		
Week 124 (n= 37, 50)	94.6	82.0		
Week 136 (n= 39, 48)	89.7	81.3		
Week 148 (n= 38, 49)	92.1	81.6		
Week 172 (n= 33, 44)	93.9	84.1		
Week 196 (n= 10, 10)	80.0	70.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved an American College of Rheumatology 50 (ACR50) Response

End point title	Percentage of Participants Who Achieved an American College of Rheumatology 50 (ACR50) Response

End point description:

ACR50 response was achieved when the participant had: ≥50% improvement from baseline in TJC68, SJC66, and in at least 3 of the following 5 items: PGADA using 0 to 100 mm VAS, on a scale of 0 (very well) to 100 (very poor); PhGADA using 0 to 100 mm VAS, on a scale of 0 (no disease activity) to 100 (maximum disease activity); HAQ-DI [assessment of ability to perform task; contains 20 questions,8 components: dressing/ grooming, arising, eating, walking, hygiene, reach, grip and activities and scores on a scale of 0 (without difficulty) to 3 (unable to do)]; and CRP. Data was summarized using OC method. LTE FAS with available data.

End point type	Secondary

End point timeframe:

Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	58	62		
Units: percentage of participants				
number (not applicable)				
Week 4 (n= 58, 62)	58.6	32.3		
Week 16 (n= 57, 61)	66.7	44.3		
Week 28 (n= 54, 60)	74.1	53.3		
Week 40 (n= 55, 59)	70.9	47.5		
Week 52 (n= 54, 57)	64.8	45.6		
Week 64 (n= 50, 55)	76.0	56.4		
Week 76 (n= 51, 54)	70.6	46.3		
Week 88 (n= 49, 54)	75.5	51.9		
Week 100 (n= 45, 52)	68.9	50.0		
Week 112 (n= 44, 49)	68.2	51.0		
Week 124 (n= 37, 50)	75.7	52.0		
Week 136 (n= 39, 47)	71.8	51.1		
Week 148 (n= 37, 49)	73.0	51.0		
Week 172 (n= 32, 44)	68.8	52.3		
Week 196 (n= 10, 10)	70.0	40.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved an American College of Rheumatology 70 (ACR70) Response

End point title	Percentage of Participants Who Achieved an American College of Rheumatology 70 (ACR70) Response

End point description:

ACR70 response was achieved when the participant had: ≥70% improvement from baseline in TJC68, SJC66, and in at least 3 of the following 5 items: PGADA using 0 to 100 mm VAS, on a scale of 0 (very well) to 100 (very poor); PhGADA using 0 to 100 mm VAS, on a scale of 0 (no disease activity) to 100 (maximum disease activity); HAQ-DI [assessment of ability to perform task; contains 20 questions,8 components: dressing/ grooming, arising, eating, walking, hygiene, reach, grip and activities and scores on a scale of 0 (without difficulty) to 3 (unable to do)]; and CRP. Data was summarized using OC method. LTE FAS with available data.

End point type	Secondary

End point timeframe:

Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	62		
Units: percentage of participants				
number (not applicable)				
Week 4 (n= 59, 62)	28.8	16.1		
Week 16 (n= 57, 62)	42.1	25.8		
Week 28 (n= 54, 60)	50.0	30.0		
Week 40 (n= 55, 59)	49.1	28.8		
Week 52 (n= 54, 57)	40.7	26.3		
Week 64 (n= 50, 55)	52.0	29.1		
Week 76 (n= 51, 54)	54.9	33.3		
Week 88 (n= 49, 54)	46.9	29.6		
Week 100 (n= 45, 52)	44.4	34.6		
Week 112 (n= 44, 49)	47.7	34.7		
Week 124 (n= 37, 50)	48.6	36.0		
Week 136 (n= 39, 48)	61.5	33.3		
Week 148 (n= 38, 49)	52.6	30.6		
Week 172 (n= 32, 44)	46.9	34.1		
Week 196 (n= 10, 10)	20.0	30.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved an American College of Rheumatology 90 (ACR90) Response

End point title	Percentage of Participants Who Achieved an American College of Rheumatology 90 (ACR90) Response

End point description:

ACR90 response was achieved when the participant had: ≥90% improvement from baseline in TJC68, SJC66, and in at least 3 of the following 5 items: PGADA using 0 to 100 mm VAS, on a scale of 0 (very well) to 100 (very poor); PhGADA using 0 to 100 mm VAS, on a scale of 0 (no disease activity) to 100 (maximum disease activity); HAQ-DI [assessment of ability to perform task; contains 20 questions,8 components: dressing/ grooming, arising, eating, walking, hygiene, reach, grip and activities and scores on a scale of 0 (without difficulty) to 3 (unable to do)]; and CRP. Data was summarized using OC method. LTE FAS with available data.

End point type	Secondary

End point timeframe:

Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	63		
Units: percentage of participants				
number (not applicable)				
Week 4 (n= 59, 63)	1.7	4.8		
Week 16 (n= 57, 62)	3.5	4.8		
Week 28 (n= 54, 60)	11.1	11.7		
Week 40 (n= 55, 59)	12.7	15.3		
Week 52 (n= 54, 57)	9.3	17.5		
Week 64 (n= 51, 56)	13.7	17.9		
Week 76 (n= 51, 54)	15.7	18.5		
Week 88 (n= 48, 54)	14.6	18.5		
Week 100 (n= 45, 52)	13.3	15.4		
Week 112 (n= 44, 49)	13.6	16.3		
Week 124 (n= 37, 50)	13.5	14.0		
Week 136 (n= 39, 48)	12.8	16.7		
Week 148 (n= 38, 49)	15.8	18.4		
Week 172 (n= 33, 44)	18.2	6.8		
Week 196 (n= 10, 10)	0.0	20.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Core Baseline in Disease Activity in Psoriatic Arthritis (DAPSA) Score at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

End point title	Change From Core Baseline in Disease Activity in Psoriatic Arthritis (DAPSA) Score at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

End point description:

DAPSA score was calculated by summing the following components: TJC68; SJC66; PGADA (assessed on 0 to 10 cm VAS; 0 [very well] to 10 [very poor]); PGAP Pain (assessed on 0 to 10 cm VAS; 0 [no pain] to 10 [serious pain]) and CRP. DAPSA scores 0-4 = remission, 5-14 = low disease activity, 15-28 = moderate disease activity, and >28 = high disease activity. A negative change from baseline indicates improvement. LTE FAS with available data.

End point type	Secondary

End point timeframe:

Baseline (Core Study), Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	57	62		
Units: score on a scale				
arithmetic mean (standard deviation)				
Change at Week 4 (n= 56, 62)	-30.9 (± 13.48)	-28.8 (± 15.51)		
Change at Week 16 (n= 57, 62)	-31.9 (± 14.37)	-34.0 (± 16.17)		
Change at Week 28 (n= 53, 60)	-33.8 (± 15.12)	-35.5 (± 17.99)		
Change at Week 40 (n= 55, 59)	-35.5 (± 14.98)	-36.5 (± 17.78)		
Change at Week 52 (n= 54, 56)	-33.7 (± 14.91)	-34.6 (± 19.56)		
Change at Week 64 (n= 50, 56)	-34.4 (± 15.44)	-36.4 (± 18.58)		
Change at Week 76 (n= 51, 55)	-34.7 (± 15.26)	-37.6 (± 17.89)		
Change at Week 88 (n= 47, 54)	-34.5 (± 15.40)	-37.0 (± 18.38)		
Change at Week 100 (n= 45, 52)	-33.7 (± 16.98)	-36.1 (± 18.54)		
Change at Week 112 (n= 44, 46)	-33.9 (± 15.88)	-38.1 (± 17.70)		

Change at Week 124 (n= 36, 50)	-34.8 (± 13.77)	-37.1 (± 17.64)		
Change at Week 136 (n= 39, 46)	-33.1 (± 14.66)	-38.1 (± 16.84)		
Change at Week 148 (n= 37, 49)	-35.0 (± 14.98)	-35.6 (± 17.87)		
Change at Week 172 (n= 33, 45)	-35.2 (± 12.68)	-37.9 (± 19.57)		
Change at Week 196 (n= 10, 10)	-43.3 (± 19.99)	-34.5 (± 17.81)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved DAPSA Remission/LDA (DAPSA ≤14)

End point title	Percentage of Participants Who Achieved DAPSA Remission/LDA (DAPSA ≤14)

End point description:

DAPSA score was calculated by summing the following components: TJC68; SJC66; PGADA (assessed on 0 to 10 cm VAS; 0 [very well] to 10 [very poor]); PGAP Pain (assessed on 0 to 10 cm VAS; 0 [no pain] to 10 [serious pain]) and CRP. DAPSA scores 0-4 = remission, 5-14 = low disease activity, 15-28 = moderate disease activity, and >28 = high disease activity. DAPSA remission/LDA was defined as DAPSA ≤14. Data was summarized using OC method. LTE FAS with available data.

End point type	Secondary

End point timeframe:

Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	57	62		
Units: percentage of participants				
number (not applicable)				
Week 4 (n= 56, 62)	60.7	43.5		
Week 16 (n= 57, 62)	63.2	51.6		
Week 28 (n= 53, 60)	73.6	58.3		
Week 40 (n= 55, 59)	80.0	57.6		
Week 52 (n= 54, 56)	66.7	66.1		
Week 64 (n= 50, 56)	72.0	64.3		
Week 76 (n= 51, 55)	70.6	60.0		
Week 88 (n= 47, 54)	76.6	61.1		
Week 100 (n= 45, 52)	82.2	63.5		
Week 112 (n= 44, 46)	72.7	65.2		
Week 124 (n= 36, 50)	83.3	70.0		
Week 136 (n= 39, 46)	82.1	67.4		
Week 148 (n= 37, 49)	81.1	65.3		

Week 172 (n= 33, 45)	78.8	66.7		
Week 196 (n= 10, 10)	50.0	40.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved DAPSA Remission (DAPSA ≤4)

End point title	Percentage of Participants Who Achieved DAPSA Remission (DAPSA ≤4)

End point description:

DAPSA score was calculated by summing the following components: TJC68; SJC66; PGADA (assessed on 0 to 10 cm VAS; 0 [very well] to 10 [very poor]); PGAP Pain (assessed on 0 to 10 cm VAS; 0 [no pain] to 10 [serious pain]) and CRP. DAPSA scores 0-4 = remission, 5-14 = low disease activity, 15-28 = moderate disease activity, and >28 = high disease activity. DAPSA remission was defined as DAPSA ≤4. Data was summarized using OC method. LTE FAS with available data.

End point type	Secondary

End point timeframe:

Week 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	57	62		
Units: percentage of participants				
number (not applicable)				
Week 4 (n= 56, 62)	12.5	11.3		
Week 16 (n= 57, 62)	17.5	19.4		
Week 28 (n= 53, 60)	24.5	21.7		
Week 40 (n= 55, 59)	23.6	23.7		
Week 52 (n= 54, 56)	27.8	21.4		
Week 64 (n= 50, 56)	26.0	23.2		
Week 76 (n= 51, 55)	35.3	29.1		
Week 88 (n= 47, 54)	29.8	29.6		
Week 100 (n= 45, 52)	22.2	28.8		
Week 112 (n= 44, 46)	29.5	28.3		
Week 124 (n= 36, 50)	27.8	22.0		
Week 136 (n= 39, 46)	43.6	28.3		
Week 148 (n= 37, 49)	32.4	26.5		
Week 172 (n= 33, 45)	36.4	24.4		
Week 196 (n= 10, 10)	10.0	40.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Core Baseline in Psoriasis Area and Severity Index (PASI) Score at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

End point title	Change From Core Baseline in Psoriasis Area and Severity Index (PASI) Score at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

End point description:

PASI: assessed in participants with psoriasis covering ≥ 3% of the BSA at Baseline and is used to measure the severity and extent of psoriasis. In the PASI system, the body is divided into 4 regions: head (h), upper limbs (u), trunk (t) and lower limbs (l). Each of these areas are assessed separately for percentage of the area involved and for erythema (E), induration (I), and desquamation (D), 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). PASI score calculation: PASI = 0.1 * (Eh + Ih + Dh) * Ah + 0.2 *(Eu + Iu + Du) * Au + 0.3 * (Et + It + Dt) * At + 0.4 * (El + Il + Dl) * Al. PASI produces a numeric score ranging from 0 (no disease) to 72 (maximal disease). Higher score = more severe disease. A negative change from baseline indicates improvement. LTE FAS with available data.

End point type	Secondary

End point timeframe:

Baseline (Core Study), Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38	38		
Units: score on a scale				
arithmetic mean (standard deviation)				
Change at Week 4 (n= 38, 38)	-6.6 (± 9.46)	-5.1 (± 5.91)		
Change at Week 16 (n= 38, 38)	-6.6 (± 9.61)	-5.9 (± 9.26)		
Change at Week 28 (n= 38, 36)	-6.9 (± 8.84)	-7.6 (± 7.82)		
Change at Week 40 (n= 38, 35)	-6.7 (± 9.77)	-7.6 (± 7.52)		
Change at Week 52 (n= 36, 32)	-6.7 (± 9.61)	-6.6 (± 8.53)		
Change at Week 64 (n= 35, 33)	-7.6 (± 9.68)	-7.4 (± 7.44)		
Change at Week 76 (n= 35, 33)	-6.9 (± 8.67)	-7.6 (± 8.49)		
Change at Week 88 (n= 33, 32)	-7.1 (± 9.91)	-7.7 (± 8.01)		
Change at Week 100 (n= 29, 31)	-6.4 (± 9.31)	-7.1 (± 7.93)		
Change at Week 112 (n= 30, 28)	-7.2 (± 9.60)	-7.8 (± 8.16)		
Change at Week 124 (n= 25, 29)	-7.5 (± 9.89)	-7.1 (± 7.66)		
Change at Week 136 (n= 26, 27)	-6.6 (± 10.18)	-7.3 (± 8.11)		
Change at Week 148 (n= 25, 28)	-6.0 (± 11.53)	-7.6 (± 7.48)		
Change at Week 172 (n= 22, 25)	-5.9 (± 10.78)	-8.0 (± 8.83)		
Change at Week 196 (n= 8, 6)	-6.9 (± 7.54)	-3.8 (± 4.39)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Psoriasis Area and Severity Index 50% (PASI50) Improvement

End point title	Percentage of Participants With Psoriasis Area and Severity Index 50% (PASI50) Improvement

End point description:

PASI: assessed in participants with psoriasis covering ≥ 3% of BSA at Baseline and is used to measure severity and extent of psoriasis. In PASI system, body is divided into 4 regions: head (h), upper limbs (u), trunk (t) and lower limbs (l). Each of these areas are assessed separately for percentage of area involved and for erythema (E), induration (I), and desquamation (D), which are each rated on a scale of 0 to 4, (0 = none, 1 = mild, 2 = moderate, 3 = severe and 4 = very severe), which translates to numeric score that ranges from 0 (indicates no involvement) to 6 (90 percent [%] to 100% involvement). PASI score calculation: PASI = 0.1 * (Eh + Ih + Dh) * Ah + 0.2 *(Eu + Iu + Du) * Au + 0.3 * (Et + It + Dt) * At + 0.4 * (El + Il + Dl) * Al. PASI produces numeric score ranging from 0 (no disease) to 72 (maximal disease). PASI50, improvement threshold from baseline score is 50%. Higher score = more severe disease. Data was summarized using OC method. LTE FAS with available data.

End point type	Secondary

End point timeframe:

Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38	38		
Units: percentage of participants				
number (not applicable)				
Week 4 (n= 38, 38)	76.3	52.6		
Week 16 (n= 38, 38)	65.8	65.8		
Week 28 (n= 38, 36)	78.9	77.8		
Week 40 (n= 38, 35)	71.1	80.0		
Week 52 (n= 36, 32)	72.2	71.9		
Week 64 (n= 35, 33)	80.0	72.7		
Week 76 (n= 35, 33)	82.9	75.8		
Week 88 (n= 33, 32)	81.8	78.1		
Week 100 (n= 29, 31)	79.3	67.7		
Week 112 (n= 30, 28)	73.3	67.9		
Week 124 (n= 25, 29)	76.0	79.3		
Week 136 (n= 26, 27)	73.1	70.4		
Week 148 (n= 25, 28)	68.0	78.6		
Week 172 (n= 22, 25)	72.7	76.0		
Week 196 (n= 8, 6)	87.5	66.7		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Psoriasis Area and Severity Index 75%

(PASI75) Improvement

End point title	Percentage of Participants With Psoriasis Area and Severity Index 75% (PASI75) Improvement

End point description:

PASI: assessed in participants with psoriasis covering ≥ 3% of BSA at Baseline and is used to measure severity and extent of psoriasis. In PASI system, body is divided into 4 regions: head (h), upper limbs (u), trunk (t) and lower limbs (l). Each of these areas are assessed separately for percentage of area involved and for erythema (E), induration (I), and desquamation (D), which are each rated on a scale of 0 to 4, (0 = none, 1 = mild, 2 = moderate, 3 = severe and 4 = very severe), which translates to numeric score that ranges from 0 (indicates no involvement) to 6 (90 percent [%] to 100% involvement). PASI score calculation: PASI = 0.1 * (Eh + Ih + Dh) * Ah + 0.2 *(Eu + Iu + Du) * Au + 0.3 * (Et + It + Dt) * At + 0.4 * (El + Il + Dl) * Al. PASI produces numeric score ranging from 0 (no disease) to 72 (maximal disease). PASI75, improvement threshold from baseline score is 75%. Higher score = more severe disease. Data was summarized using OC method. LTE FAS with available data.

End point type	Secondary

End point timeframe:

Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38	38		
Units: percentage of participants				
number (not applicable)				
Week 4 (n= 38, 38)	42.1	31.6		
Week 16 (n= 38, 38)	44.7	44.7		
Week 28 (n= 38, 36)	50.0	44.4		
Week 40 (n= 38, 35)	52.6	40.0		
Week 52 (n= 36, 32)	38.9	50.0		
Week 64 (n= 35, 33)	48.6	45.5		
Week 76 (n= 35, 33)	54.3	51.5		
Week 88 (n= 33, 32)	57.6	56.3		
Week 100 (n= 29, 31)	55.2	51.6		
Week 112 (n= 30, 28)	50.0	50.0		
Week 124 (n= 25, 29)	52.0	48.3		
Week 136 (n= 26, 27)	46.2	59.3		
Week 148 (n= 25, 28)	48.0	50.0		
Week 172 (n= 22, 25)	50.0	60.0		
Week 196 (n= 8, 6)	87.5	50.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Psoriasis Area and Severity Index 100% (PASI100) Improvement

End point title	Percentage of Participants With Psoriasis Area and Severity Index 100% (PASI100) Improvement

End point description:

PASI: assessed in participants with psoriasis covering ≥ 3% of BSA at Baseline and is used to measure severity and extent of psoriasis. In PASI system, body is divided into 4 regions: head (h), upper limbs (u), trunk (t) and lower limbs (l). Each of these areas are assessed separately for percentage of area involved and for erythema (E), induration (I), and desquamation (D), which are each rated on a scale of 0 to 4, (0 = none, 1 = mild, 2 = moderate, 3 = severe and 4 = very severe), which translates to numeric score that ranges from 0 (indicates no involvement) to 6 (90 percent [%] to 100% involvement). PASI score calculation: PASI = 0.1 * (Eh + Ih + Dh) * Ah + 0.2 *(Eu + Iu + Du) * Au + 0.3 * (Et + It + Dt) * At + 0.4 * (El + Il + Dl) * Al. PASI produces numeric score ranging from 0 (no disease) to 72 (maximal disease). PASI100, improvement threshold from baseline score is 100%. Higher score = more severe disease. Data was summarized using OC method. LTE FAS with available data.

End point type	Secondary

End point timeframe:

Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38	38		
Units: percentage of participants				
number (not applicable)				
Week 4 (n= 38, 38)	13.2	10.5		
Week 16 (n= 38, 38)	21.1	10.5		
Week 28 (n= 38, 36)	15.8	13.9		
Week 40 (n= 38, 35)	13.2	11.4		
Week 52 (n= 36, 32)	13.9	18.8		
Week 64 (n= 35, 33)	14.3	15.2		
Week 76 (n= 35, 33)	25.7	18.2		
Week 88 (n= 33, 32)	15.2	15.6		
Week 100 (n= 29, 31)	17.2	19.4		
Week 112 (n= 30, 28)	16.7	14.3		
Week 124 (n= 25, 29)	16.0	10.3		
Week 136 (n= 26, 27)	11.5	14.8		
Week 148 (n= 25, 28)	12.0	14.3		
Week 172 (n= 22, 25)	22.7	16.0		
Week 196 (n= 8, 6)	25.0	33.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Core Baseline in Physician's Global Assessment of Psoriasis (PhGAP) at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

End point title	Change From Core Baseline in Physician's Global Assessment of Psoriasis (PhGAP) at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

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 LTE FAS with psoriasis covering >=3% of the BSA at Baseline and with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Core Study), Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38	38		
Units: score on a scale				
arithmetic mean (standard deviation)				
Change at Week 4 (n= 38, 38)	-0.9 (± 1.04)	-1.1 (± 0.93)		
Change at Week 16 (n= 38, 38)	-1.1 (± 1.20)	-1.2 (± 0.97)		
Change at Week 28 (n= 38, 36)	-1.2 (± 0.93)	-1.3 (± 1.24)		
Change at Week 40 (n= 38, 35)	-1.3 (± 1.21)	-1.3 (± 1.15)		
Change at Week 52 (n= 36, 32)	-1.2 (± 1.13)	-1.2 (± 1.23)		
Change at Week 64 (n= 35, 33)	-1.1 (± 1.19)	-1.2 (± 1.24)		
Change at Week 76 (n= 35, 33)	-1.2 (± 1.19)	-1.4 (± 1.25)		
Change at Week 88 (n= 33, 32)	-1.1 (± 1.12)	-1.3 (± 1.20)		
Change at Week 100 (n= 29, 31)	-1.2 (± 1.18)	-1.2 (± 1.23)		
Change at Week 112 (n= 30, 28)	-0.9 (± 1.25)	-1.3 (± 1.27)		
Change at Week 124 (n= 25, 29)	-1.3 (± 1.31)	-1.3 (± 1.11)		
Change at Week 136 (n= 26, 27)	-1.1 (± 1.06)	-1.4 (± 1.25)		
Change at Week 148 (n= 25, 28)	-1.2 (± 1.37)	-1.2 (± 1.42)		
Change at Week 172 (n= 22, 25)	-1.2 (± 1.31)	-1.4 (± 1.26)		
Change at Week 196 (n= 8, 6)	-1.5 (± 0.76)	-1.2 (± 1.33)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Core Baseline in Patient's Global Assessment of Psoriasis (PGAP) at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

End point title	Change From Core Baseline in Patient's Global Assessment of Psoriasis (PGAP) at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

End point description:

The PGAP is a single-item, patient-completed assessment used to evaluate the overall extent of psoriasis-related cutaneous disease at a particular point in time using a 5-point Likert scale (0=clear, 1= almost clear, 2= mild, 3= moderate and 4=severe). Participants in the LTE FAS with psoriasis covering >=3% of the BSA at baseline and with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Core Study), Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38	38		
Units: score on a scale				
arithmetic mean (standard deviation)				
Change at Week 4 (n= 38, 38)	-0.9 (± 1.06)	-0.6 (± 1.05)		
Change at Week 16 (n= 38, 38)	-1.2 (± 1.08)	-0.8 (± 1.14)		
Change at Week 28 (n= 38, 36)	-1.0 (± 0.94)	-1.0 (± 1.31)		
Change at Week 40 (n= 38, 35)	-1.2 (± 1.11)	-0.9 (± 1.02)		
Change at Week 52 (n= 36, 33)	-1.1 (± 0.84)	-1.0 (± 1.24)		
Change at Week 64 (n= 35, 33)	-0.9 (± 0.98)	-1.0 (± 1.15)		
Change at Week 76 (n= 35, 33)	-1.1 (± 0.95)	-0.9 (± 1.31)		
Change at Week 88 (n= 33, 32)	-1.2 (± 0.92)	-1.3 (± 1.08)		
Change at Week 100 (n= 29, 31)	-0.9 (± 1.13)	-1.1 (± 1.29)		
Change at Week 112 (n= 30, 28)	-0.7 (± 1.08)	-1.0 (± 1.23)		
Change at Week 124 (n= 25, 29)	-1.0 (± 1.08)	-0.9 (± 1.18)		
Change at Week 136 (n= 26, 27)	-1.2 (± 1.08)	-1.0 (± 1.33)		
Change at Week 148 (n= 25, 28)	-0.9 (± 1.20)	-1.0 (± 1.29)		
Change at Week 172 (n= 22, 25)	-1.1 (± 1.19)	-1.0 (± 0.79)		
Change at Week 196 (n= 8, 6)	-1.8 (± 1.04)	-0.7 (± 2.07)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Core Baseline in Modified Nail Psoriasis Area and Severity Index (mNAPSI) at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

End point title	Change From Core Baseline in Modified Nail Psoriasis Area and Severity Index (mNAPSI) at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

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, red spots in the lunula, nail bed hyperkeratosis and splinter hemorrhages) 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 LTE FAS with Psoriatic Nails (mNAPSI > 0) at Core Baseline and with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Core Study), Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38	40		
Units: score on a scale				
arithmetic mean (standard deviation)				
Change at Week 4 (n= 38, 40)	-5.4 (± 17.20)	-5.1 (± 14.53)		
Change at Week 16 (n= 37, 40)	-9.0 (± 16.12)	-7.1 (± 16.72)		
Change at Week 28 (n= 35, 40)	-12.1 (± 24.67)	-10.5 (± 15.50)		
Change at Week 40 (n= 35, 40)	-8.5 (± 17.07)	-7.9 (± 16.98)		
Change at Week 52 (n= 35, 38)	-7.9 (± 14.51)	-8.8 (± 14.24)		
Change at Week 64 (n= 33, 38)	-9.2 (± 21.58)	-8.5 (± 17.19)		
Change at Week 76 (n= 34, 38)	-10.0 (± 17.77)	-10.5 (± 17.21)		
Change at Week 88 (n= 32, 37)	-8.3 (± 18.35)	-8.9 (± 20.01)		
Change at Week 100 (n= 28, 35)	-5.7 (± 17.86)	-6.3 (± 13.60)		
Change at Week 112 (n= 30, 32)	-6.9 (± 17.91)	-11.0 (± 12.86)		
Change at Week 124 (n= 22, 33)	-7.0 (± 20.97)	-11.7 (± 13.15)		
Change at Week 136 (n= 24, 31)	-8.8 (± 18.79)	-13.1 (± 12.32)		
Change at Week 148 (n= 24, 32)	-9.6 (± 20.59)	-11.3 (± 13.69)		
Change at Week 172 (n= 22, 31)	-8.5 (± 19.55)	-10.1 (± 13.61)		
Change at Week 196 (n= 7, 4)	-1.1 (± 11.07)	-4.8 (± 16.68)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Core Baseline in Pruritis Numeric Rating Scale (NRS) at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

End point title	Change From Core Baseline in Pruritis Numeric Rating Scale (NRS) at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

End point description:

The participants rated their pruritus on a numeric rating scale ranging from 0-10, with 0 indicating no itching to 10 indicating worst possible itching. Participants in the LTE FAS with psoriasis covering >=3% of the BSA at baseline and with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Core Study), Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196 (LTE

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38	38		
Units: score on a scale				
arithmetic mean (standard deviation)				
Change at Week 4 (n= 38, 38)	-2.8 (± 2.14)	-2.5 (± 2.17)		
Change at Week 16 (n= 38, 38)	-3.3 (± 2.48)	-2.6 (± 2.28)		
Change at Week 28 (n= 38, 36)	-3.3 (± 2.61)	-3.2 (± 2.52)		
Change at Week 40 (n= 38, 35)	-3.3 (± 2.57)	-2.7 (± 2.26)		
Change at Week 52 (n= 36, 33)	-3.0 (± 2.35)	-2.7 (± 2.38)		
Change at Week 64 (n= 35, 33)	-3.0 (± 2.45)	-3.0 (± 2.27)		
Change at Week 76 (n= 35, 33)	-3.5 (± 2.16)	-2.8 (± 2.39)		
Change at Week 88 (n= 33, 32)	-2.9 (± 2.63)	-2.9 (± 2.24)		
Change at Week 100 (n= 29, 31)	-2.8 (± 2.82)	-2.6 (± 2.53)		
Change at Week 112 (n= 30, 28)	-2.9 (± 2.56)	-2.9 (± 2.34)		
Change at Week 124 (n= 25, 29)	-2.5 (± 3.18)	-3.0 (± 2.83)		
Change at Week 136 (n= 26, 27)	-2.5 (± 2.98)	-2.7 (± 2.51)		
Change at Week 148 (n= 25, 28)	-3.2 (± 3.14)	-2.6 (± 2.34)		
Change at Week 172 (n= 22, 25)	-2.7 (± 2.46)	-2.8 (± 2.45)		
Change at Week 196 (n= 8, 6)	-4.9 (± 2.03)	-4.2 (± 1.60)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved Imrovement in Pruritus NRS Score of ≥3

End point title	Percentage of Participants who Achieved Imrovement in Pruritus NRS Score of ≥3

End point description:

The participants rated their pruritus on a numeric rating scale ranging from 0-10, with 0 indicating no itching to 10 indicating worst possible itching. Participants with improvement from core baseline in pruritis NRS score of ≥3 were reported. Data was summarized using OC method. Participants in the LTE 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, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	32	34		
Units: percentage of participants				
number (not applicable)				
Week 4 (n= 32, 34)	71.9	55.9		
Week 16 (n= 32, 34)	71.9	55.9		
Week 28 (n= 32, 32)	78.1	65.6		
Week 40 (n= 32, 31)	71.9	58.1		
Week 52 (n= 31, 30)	67.7	56.7		
Week 64 (n= 30, 30)	70.0	70.0		
Week 76 (n= 30, 30)	80.0	56.7		
Week 88 (n= 28, 29)	67.9	62.1		
Week 100 (n= 24, 28)	66.7	50.0		
Week 112 (n= 25, 26)	72.0	57.7		
Week 124 (n= 21, 26)	61.9	65.4		
Week 136 (n= 21, 24)	61.9	54.2		
Week 148 (n= 20, 25)	75.0	52.0		
Week 172 (n= 17, 23)	64.7	56.5		
Week 196 (n= 8, 5)	87.5	100.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Core Baseline in the Leeds Enthesitis Index (LEI) in those Participants with enthesitis (LEI > 0) at Core Baseline at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

End point title	Change from Core Baseline in the Leeds Enthesitis Index (LEI) in those Participants with enthesitis (LEI > 0) at Core Baseline at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

End point description:

The LEI was developed to assess enthesitis in participants with psoriatic arthritis. The LEI examined tenderness at six sites: lateral epicondyle (left and right), medial femoral condyle (left and right), and achilles tendon insertion (left and right). Each site was assessed as either tender (score=1) or not tender (score=0). The LEI was derived as the sum of the tenderness over the 6 sites mentioned above. The LEI score ranged from 0 (0 sites with tenderness) to 6 (worst possible score; 6 sites with tenderness), with higher scores indicating higher degree of enthesitis. LTE FAS with available data.

End point type	Secondary

End point timeframe:

Baseline (Core Study), Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	42		
Units: score on a scale				
arithmetic mean (standard deviation)				
Change at Week 4 (n= 30, 42)	-2.1 (± 1.53)	-1.7 (± 1.68)		
Change at Week 16 (n= 29, 41)	-2.2 (± 1.42)	-1.9 (± 1.46)		
Change at Week 28 (n= 27, 40)	-2.6 (± 1.28)	-1.8 (± 1.55)		
Change at Week 40 (n= 27, 40)	-2.6 (± 1.28)	-2.2 (± 1.32)		
Change at Week 52 (n= 27, 37)	-2.5 (± 1.34)	-2.1 (± 1.69)		
Change at Week 64 (n= 26, 37)	-2.5 (± 1.30)	-2.1 (± 1.64)		
Change at Week 76 (n= 27, 37)	-2.6 (± 1.39)	-2.1 (± 1.54)		
Change at Week 88 (n= 25, 36)	-2.6 (± 1.29)	-2.1 (± 1.71)		
Change at Week 100 (n= 24, 34)	-2.5 (± 1.44)	-2.1 (± 1.62)		
Change at Week 112 (n= 23, 33)	-2.4 (± 1.44)	-2.3 (± 1.57)		
Change at Week 124 (n= 21, 33)	-2.5 (± 1.44)	-2.3 (± 1.51)		
Change at Week 136 (n= 20, 32)	-2.4 (± 1.31)	-2.3 (± 1.49)		
Change at Week 148 (n= 21, 33)	-2.4 (± 1.20)	-2.0 (± 1.78)		
Change at Week 172 (n= 18, 30)	-2.2 (± 1.38)	-2.0 (± 1.71)		
Change at Week 196 (n= 7, 7)	-2.3 (± 1.50)	-1.9 (± 2.19)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Core Baseline in Spondyloarthritis Research Consortium of Canada (SPARCC) Enthesitis Index at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

End point title	Change From Core Baseline in Spondyloarthritis Research Consortium of Canada (SPARCC) Enthesitis Index at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

End point description:

The enthesitis examination is based on the 16 anatomical sites for tenderness by palpation: 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 (non-tender) and 1 (tender). SPARCC enthesitis index is derived as the sum of the tenderness over the 16 sites and has an overall total score ranging from 0 to 16. Higher score indicates higher enthesitis burden. A negative change from baseline indicates improvement. Participants in the LTE FAS with Enthesitis (SPARCC Enthesitis Index > 0) at baseline and with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Core Study), Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34	46		
Units: score on a scale				
arithmetic mean (standard deviation)				
Change at Week 4 (n= 34, 46)	-3.6 (± 2.82)	-3.9 (± 4.06)		
Change at Week 16 (n= 33, 45)	-3.8 (± 3.21)	-4.2 (± 3.45)		
Change at Week 28 (n= 32, 44)	-4.4 (± 3.08)	-4.1 (± 3.85)		
Change at Week 40 (n= 32, 44)	-4.5 (± 3.08)	-4.6 (± 3.45)		
Change at Week 52 (n= 31, 41)	-4.4 (± 2.85)	-4.5 (± 3.91)		
Change at Week 64 (n= 31, 41)	-4.0 (± 2.87)	-4.7 (± 3.71)		
Change at Week 76 (n= 31, 41)	-4.3 (± 3.06)	-4.7 (± 3.90)		
Change at Week 88 (n= 29, 40)	-4.5 (± 2.69)	-4.9 (± 4.00)		
Change at Week 100 (n= 28, 38)	-4.3 (± 3.03)	-4.7 (± 4.15)		
Change at Week 112 (n= 26, 37)	-4.5 (± 2.96)	-4.8 (± 3.81)		
Change at Week 124 (n= 23, 36)	-4.7 (± 2.97)	-5.3 (± 3.82)		
Change at Week 136 (n= 23, 35)	-4.7 (± 2.90)	-5.1 (± 3.80)		
Change at Week 148 (n= 24, 36)	-4.6 (± 2.69)	-4.3 (± 4.49)		
Change at Week 172 (n= 21, 33)	-4.3 (± 2.85)	-4.5 (± 4.12)		
Change at Week 196 (n= 7, 7)	-4.1 (± 3.13)	-4.3 (± 4.82)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Core Baseline in Leeds Dactylitis Index (LDI) at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

End point title	Change From Core Baseline in Leeds Dactylitis Index (LDI) at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

End point description:

LDI quantitatively measures dactylitis using circumference and tenderness of involved digits and control digits. Digits affected by dactylitis: are those with an ≥10% difference in ratio of circumference of affected digit to contralateral digit. Control digit is either the contralateral digit (digit on opposite hand or foot), or if contralateral digit is also affected, values from standard reference table. LDI measures the ratio of circumference of affected digit to circumference of digit on contralateral hand or foot using Leeds Dactylometer. LDI score: is based on circumference of dactylitic finger/toe (mm), circumference of contralateral digit (mm), tenderness score (0 = no tenderness, 1 = tender). Tenderness: score= 0 (no tenderness) to 3 (tender & withdrawn). Higher LDI= worse dactylitis. Negative change from baseline= improvement. Participants in the LTE FAS participants who had dactylitis (LDI >0) at core baseline and with available data were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Core Study), Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	26		
Units: score on a scale				
arithmetic mean (standard deviation)				
Change at Week 4 (n= 18, 26)	-38.9 (± 35.36)	-37.0 (± 26.65)		
Change at Week 16 (n= 18, 25)	-39.6 (± 37.74)	-40.4 (± 25.17)		
Change at Week 28 (n= 17, 26)	-40.3 (± 37.88)	-39.8 (± 24.92)		
Change at Week 40 (n= 17, 25)	-41.5 (± 38.14)	-38.3 (± 25.05)		
Change at Week 52 (n= 18, 23)	-40.4 (± 37.40)	-36.9 (± 24.08)		
Change at Week 64 (n= 16, 22)	-42.7 (± 39.06)	-34.5 (± 29.95)		
Change at Week 76 (n= 17, 22)	-42.0 (± 37.89)	-34.1 (± 30.31)		
Change at Week 88 (n= 15, 22)	-38.9 (± 34.76)	-37.1 (± 24.78)		
Change at Week 100 (n= 15, 20)	-38.9 (± 34.78)	-37.0 (± 25.36)		
Change at Week 112 (n= 15, 21)	-39.1 (± 34.66)	-37.4 (± 24.89)		
Change at Week 124 (n= 13, 20)	-40.5 (± 36.64)	-37.0 (± 25.35)		
Change at Week 136 (n= 14, 20)	-38.6 (± 36.45)	-37.0 (± 25.35)		
Change at Week 148 (n= 14, 20)	-38.6 (± 36.47)	-32.8 (± 31.80)		
Change at Week 172 (n= 13, 18)	-41.6 (± 36.11)	-34.7 (± 31.89)		
Change at Week 196 (n= 3, 5)	-56.3 (± 55.30)	-32.7 (± 32.76)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Core Baseline in Health Assessment Questionnaire-Disability Index (HAQ-DI) Total Score at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

End point title	Change From Core Baseline in Health Assessment Questionnaire-Disability Index (HAQ-DI) Total Score at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

End point description:

The HAQ-DI is used to monitor the participant's self-assessed physical function or disability. It is a 20-question instrument which assesses the degree of difficulty a person has in accomplishing tasks in 8 function areas (getting dressed, arising, eating, walking, sleeping, hygiene, reaching, gripping, errands and chores). Responses were scored on a 4-point Likert scale from 0= without difficulty, to 3= unable to do. The need for aids/devices or help from another person were also recorded. The HAQ-DI total score ranges from 0 to 3 with higher scores indicating greater dysfunction. LTE FAS with available data.

End point type	Secondary

End point timeframe:

Baseline (Core Study), Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	63		
Units: score on a scale				
arithmetic mean (standard deviation)				
Change at Week 4 (n= 59, 63)	-0.65 (± 0.504)	-0.46 (± 0.557)		
Change at Week 16 (n= 57, 62)	-0.73 (± 0.542)	-0.54 (± 0.604)		
Change at Week 28 (n= 54, 60)	-0.77 (± 0.591)	-0.60 (± 0.585)		
Change at Week 40 (n= 55, 59)	-0.85 (± 0.534)	-0.61 (± 0.646)		
Change at Week 52 (n= 54, 57)	-0.70 (± 0.571)	-0.50 (± 0.712)		
Change at Week 64 (n= 51, 56)	-0.85 (± 0.604)	-0.51 (± 0.684)		
Change at Week 76 (n= 51, 55)	-0.76 (± 0.591)	-0.51 (± 0.676)		
Change at Week 88 (n= 49, 54)	-0.82 (± 0.541)	-0.48 (± 0.682)		
Change at Week 100 (n= 45, 52)	-0.79 (± 0.628)	-0.49 (± 0.663)		
Change at Week 112 (n= 44, 49)	-0.74 (± 0.585)	-0.52 (± 0.653)		
Change at Week 124 (n= 37, 50)	-0.74 (± 0.558)	-0.53 (± 0.693)		
Change at Week 136 (n= 39, 48)	-0.80 (± 0.572)	-0.54 (± 0.738)		
Change at Week 148 (n= 38, 49)	-0.76 (± 0.602)	-0.51 (± 0.732)		
Change at Week 172 (n= 33, 45)	-0.83 (± 0.603)	-0.50 (± 0.733)		
Change at Week 196 (n= 10, 10)	-0.70 (± 0.461)	-0.38 (± 0.486)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Core Baseline in Functional Assessment of Chronic Illness Therapy Fatigue Scale (FACIT-Fatigue scale) Total Score at Weeks 4, 52, 100, 148, 172 and 196

End point title	Change From Core Baseline in Functional Assessment of Chronic Illness Therapy Fatigue Scale (FACIT-Fatigue scale) Total Score at Weeks 4, 52, 100, 148, 172 and 196

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 5-point Likert scale with 0 =not at all to 4=very much. The total score ranges from 0 to 52. The lower the score, the better the quality of life. LTE FAS with available data.

End point type	Secondary

End point timeframe:

Baseline (Core Study), Weeks 4, 52, 100, 148 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	63		
Units: score on a scale				
arithmetic mean (standard deviation)				
Change at Week 4 (n= 59, 63)	9.7 (± 9.33)	8.3 (± 8.98)		
Change at Week 52 (n= 54, 59)	10.1 (± 8.97)	8.5 (± 10.31)		
Change at Week 100 (n= 51, 53)	10.3 (± 9.64)	8.9 (± 10.87)		
Change at Week 148 (n= 39, 50)	11.9 (± 10.03)	9.9 (± 10.52)		
Change at Week 172 (n= 33, 45)	12.0 (± 8.72)	9.8 (± 10.53)		
Change at Week 196 (n= 10, 10)	14.1 (± 7.85)	5.3 (± 7.04)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Core Baseline in 36-item Short-Form Health Survey (SF-36) Mental Component Summary (MCS) Score at Weeks 4, 52, 100, 148, 172 and 196

End point title	Change From Core Baseline in 36-item Short-Form Health Survey (SF-36) Mental Component Summary (MCS) Score at Weeks 4, 52, 100, 148, 172 and 196

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, in 2 component summary (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 a better quality of life. LTE FAS with available data.

End point type	Secondary

End point timeframe:

Baseline (Core Study), Weeks 4, 52, 100, 148 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	63		
Units: score on a scale				
arithmetic mean (standard deviation)				
Change at Week 4 (n= 59, 63)	4.9 (± 9.34)	4.4 (± 8.22)		
Change at Week 52 (n= 54, 59)	5.2 (± 8.84)	5.4 (± 9.03)		
Change at Week 100 (n= 51, 53)	5.1 (± 10.51)	4.6 (± 9.68)		
Change at Week 148 (n= 39, 50)	8.0 (± 11.52)	4.5 (± 11.06)		
Change at Week 172 (n= 33, 45)	7.9 (± 10.06)	5.5 (± 9.90)		
Change at Week 196 (n= 10, 10)	5.6 (± 7.21)	4.1 (± 8.44)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Core Baseline in SF-36 Physical Component Summary (PCS) Score at Weeks 4, 52, 100, 148, 172 and 196

End point title	Change From Core Baseline in SF-36 Physical Component Summary (PCS) Score at Weeks 4, 52, 100, 148, 172 and 196

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 in 2 component summary (MCS and PCS). PCS consists of physical functioning, bodily pain, role-physical, and general health perception. 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. LTE FAS with available data.

End point type	Secondary

End point timeframe:

Baseline (Core Study), Weeks 4, 52, 100, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	63		
Units: score on a scale				
arithmetic mean (standard deviation)				
Change at Week 4 (n= 59, 63)	8.9 (± 7.08)	5.8 (± 8.01)		
Change at Week 52 (n= 54, 59)	9.0 (± 8.34)	6.0 (± 9.38)		
Change at Week 100 (n= 51, 53)	9.4 (± 7.54)	7.2 (± 9.56)		
Change at Week 148 (n= 39, 50)	9.4 (± 8.05)	7.1 (± 9.31)		
Change at Week 172 (n= 33, 45)	9.9 (± 7.79)	6.4 (± 7.62)		
Change at Week 196 (n= 10, 10)	8.6 (± 6.11)	3.7 (± 6.81)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Core Baseline in Psoriatic Arthritis Impact of Disease Questionnaire (PsAID) Total Score at Weeks 4, 52, 100, 148, 172 and 196

End point title	Change From Core Baseline in Psoriatic Arthritis Impact of Disease Questionnaire (PsAID) Total Score at Weeks 4, 52, 100, 148, 172 and 196

End point description:

The PsAID questionnaire assesses the impact of PsA on people's lives. The PsAID is calculated based on 9 NRS questions. The 9 NRS is focused on pain; fatigue; skin problems; work and/or leisure activities; functional capacity; discomfort; sleep disturbence; coping; anxiety, fear and uncertainity. Each NRS is assessed as a number between 0 and 10. Total score is calculated as the sum of the individual scores, (which were multiplied by a weighting factor) divided by 20 for a total possible score of 0 to 10, where higher score indicates worse status. LTE FAS with available data.

End point type	Secondary

End point timeframe:

Baseline (Core Study), Weeks 4, 52, 100, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	63		
Units: score on a scale				
arithmetic mean (standard deviation)				
Change at Week 4 (n= 59, 63)	-2.8 (± 1.80)	-2.1 (± 2.14)		
Change at Week 52 (n= 54, 59)	-3.0 (± 1.92)	-2.3 (± 2.41)		
Change at Week 100 (n= 51, 53)	-3.0 (± 1.90)	-2.4 (± 2.55)		
Change at Week 148 (n= 39, 50)	-3.2 (± 2.18)	-2.3 (± 2.52)		
Change at Week 172 (n= 33, 45)	-3.3 (± 1.84)	-2.3 (± 2.34)		
Change at Week 196 (n= 10, 10)	-3.6 (± 1.23)	-1.6 (± 2.43)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Core Baseline in Individual ACR Component: Physician's Global Assessment of Disease Activity (PhGADA) at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

End point title	Change From Core Baseline in Individual ACR Component:

	Physician's Global Assessment of Disease Activity (PhGADA) at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

End point description:

PhGADA is assessed by the physician using 0 to 100 mm VAS on a scale of 0 (no disease activity) to 100 (extreme disease activity). A negative change from baseline indicates improvement. LTE FAS with available data.

End point type	Secondary

End point timeframe:

Baseline (Core Study), Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	63		
Units: mm				
arithmetic mean (standard deviation)				
Change at Week 4 (n= 59, 63)	-46.1 (± 19.57)	-38.6 (± 21.41)		
Change at Week 16 (n= 57, 62)	-48.1 (± 20.74)	-42.6 (± 22.50)		
Change at Week 28 (n= 54, 60)	-48.9 (± 21.45)	-48.6 (± 22.02)		
Change at Week 40 (n= 55, 59)	-52.2 (± 20.68)	-49.0 (± 20.24)		
Change at Week 52 (n= 54, 56)	-50.6 (± 18.37)	-46.9 (± 23.69)		
Change at Week 64 (n= 50, 56)	-51.5 (± 22.53)	-48.6 (± 21.93)		
Change at Week 76 (n= 51, 55)	-52.8 (± 20.08)	-49.6 (± 21.97)		
Change at Week 88 (n= 49, 54)	-53.4 (± 20.20)	-49.4 (± 22.21)		
Change at Week 100 (n= 45, 52)	-50.4 (± 23.23)	-50.0 (± 22.23)		
Change at Week 112 (n= 44, 49)	-52.9 (± 18.90)	-50.4 (± 19.67)		
Change at Week 124 (n= 37, 50)	-52.1 (± 19.38)	-49.8 (± 20.32)		
Change at Week 136 (n= 39, 48)	-51.9 (± 19.81)	-49.4 (± 21.98)		
Change at Week 148 (n= 38, 49)	-53.1 (± 20.70)	-45.3 (± 25.52)		
Change at Week 172 (n= 33, 45)	-55.6 (± 19.48)	-50.8 (± 21.13)		
Change at Week 196 (n= 10, 10)	-53.3 (± 16.42)	-40.0 (± 18.67)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Core Baseline in Individual ACR Component: Patient's Global Assessment of Disease Activity (PGADA) at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

End point title	Change From Core Baseline in Individual ACR Component: Patient's Global Assessment of Disease Activity (PGADA) at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

End point description:

PGADA is assessed by the participants using a 0 to 100 mm VAS on a scale of 0 (very well) to 100 (very poor). A negative change from baseline indicates improvement. LTE FAS with available data.

End point type	Secondary

End point timeframe:

Baseline (Core Study), Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	63		
Units: mm				
arithmetic mean (standard deviation)				
Change at Week 4 (n= 59, 63)	-30.5 (± 23.76)	-23.8 (± 25.38)		
Change at Week 16 (n= 57, 62)	-29.8 (± 30.40)	-30.1 (± 24.50)		
Change at Week 28 (n= 54, 60)	-34.9 (± 24.65)	-31.3 (± 26.91)		
Change at Week 40 (n= 55, 59)	-36.0 (± 24.07)	-30.6 (± 27.79)		
Change at Week 52 (n= 54, 57)	-33.8 (± 25.25)	-31.2 (± 27.60)		
Change at Week 64 (n= 51, 56)	-33.7 (± 24.92)	-34.1 (± 25.81)		
Change at Week 76 (n= 51, 55)	-34.9 (± 25.69)	-32.1 (± 29.08)		
Change at Week 88 (n= 49, 54)	-36.6 (± 22.53)	-32.4 (± 27.72)		
Change at Week 100 (n= 45, 52)	-34.4 (± 26.34)	-32.2 (± 28.40)		
Change at Week 112 (n= 44, 49)	-29.9 (± 32.19)	-33.9 (± 25.34)		
Change at Week 124 (n= 37, 50)	-33.7 (± 27.87)	-34.9 (± 26.58)		
Change at Week 136 (n= 39, 48)	-37.1 (± 28.00)	-34.9 (± 25.91)		
Change at Week 148 (n= 38, 49)	-37.5 (± 28.21)	-33.0 (± 25.83)		
Change at Week 172 (n= 33, 45)	-35.0 (± 28.33)	-32.9 (± 24.19)		
Change at Week 196 (n= 10, 10)	-37.1 (± 20.80)	-26.1 (± 27.63)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Core Baseline in Individual ACR Component: Patient's Global Assessment of PsA Pain Intensity at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

End point title	Change From Core Baseline in Individual ACR Component: Patient's Global Assessment of PsA Pain Intensity at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

End point description:

Patient's Global Assessment of PsA Pain is assessed using a 0 to 100 mm VAS on a scale of 0 (no pain) to 100 (unbearable pain). A negative change from baseline indicates improvement. LTE FAS with available data.

End point type	Secondary

End point timeframe:

Baseline (Core Study), Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	63		
Units: mm				
arithmetic mean (standard deviation)				
Change at Week 4 (n= 59, 63)	-35.9 (± 22.96)	-23.3 (± 28.03)		
Change at Week 16 (n= 57, 62)	-37.7 (± 24.51)	-31.4 (± 25.81)		
Change at Week 28 (n= 54, 60)	-41.6 (± 22.90)	-32.8 (± 27.51)		
Change at Week 40 (n= 55, 59)	-42.2 (± 23.25)	-32.6 (± 27.41)		
Change at Week 52 (n= 54, 57)	-38.5 (± 23.90)	-30.4 (± 29.80)		
Change at Week 64 (n= 51, 56)	-41.2 (± 23.27)	-33.6 (± 28.10)		
Change at Week 76 (n= 51, 55)	-42.9 (± 22.01)	-31.0 (± 29.89)		
Change at Week 88 (n= 49, 54)	-43.1 (± 20.81)	-29.6 (± 29.71)		
Change at Week 100 (n= 45, 52)	-39.1 (± 26.53)	-30.5 (± 30.87)		
Change at Week 112 (n= 44, 49)	-40.0 (± 28.60)	-32.4 (± 26.84)		

Change at Week 124 (n= 37, 50)	-40.1 (± 22.40)	-33.0 (± 28.85)		
Change at Week 136 (n= 39, 48)	-42.5 (± 24.10)	-32.7 (± 27.50)		
Change at Week 148 (n= 38, 49)	-41.8 (± 24.22)	-31.0 (± 28.59)		
Change at Week 172 (n= 33, 45)	-38.3 (± 24.57)	-31.6 (± 26.66)		
Change at Week 196 (n= 10, 10)	-41.8 (± 14.28)	-31.7 (± 27.26)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Core Baseline in Individual ACR Component: TJC68 at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

End point title	Change From Core Baseline in Individual ACR Component: TJC68 at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

End point description:

TJC68 is an assessment of 68 joints. Each joint is evaluated as 'tender only', 'swollen only, 'tender and swollen', or 'asymptomatic'. 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. LTE FAS with available data.

End point type	Secondary

End point timeframe:

Baseline (Core Study), Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	63		
Units: joints				
arithmetic mean (standard deviation)				
Change at Week 4 (n= 59, 63)	-12.8 (± 8.49)	-14.7 (± 11.15)		
Change at Week 16 (n= 57, 62)	-14.0 (± 9.06)	-16.5 (± 11.07)		
Change at Week 28 (n= 54, 60)	-14.6 (± 9.75)	-17.4 (± 11.52)		
Change at Week 40 (n= 55, 59)	-15.8 (± 9.70)	-18.2 (± 11.93)		
Change at Week 52 (n= 54, 56)	-15.1 (± 8.85)	-17.0 (± 12.86)		
Change at Week 64 (n= 50, 56)	-15.2 (± 9.88)	-17.3 (± 12.05)		
Change at Week 76 (n= 51, 55)	-15.3 (± 9.62)	-18.7 (± 11.90)		

Change at Week 88 (n= 49, 54)	-14.9 (± 9.78)	-18.8 (± 11.78)		
Change at Week 100 (n= 45, 52)	-14.7 (± 10.12)	-17.7 (± 11.26)		
Change at Week 112 (n= 44, 49)	-15.5 (± 9.34)	-17.5 (± 11.56)		
Change at Week 124 (n= 37, 50)	-15.3 (± 8.84)	-17.6 (± 12.08)		
Change at Week 136 (n= 39, 48)	-14.0 (± 8.43)	-18.5 (± 11.36)		
Change at Week 148 (n= 38, 49)	-15.0 (± 9.15)	-16.7 (± 11.24)		
Change at Week 172 (n= 33, 45)	-15.8 (± 8.90)	-18.3 (± 12.90)		
Change at Week 196 (n= 10, 10)	-21.0 (± 11.83)	-16.8 (± 14.34)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Core Baseline in Individual ACR Component: SJC66 at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

End point title	Change From Core Baseline in Individual ACR Component: SJC66 at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

End point description:

SJC66 is an assessment of 66 joints. Each joint is evaluated as 'tender only', 'swollen only, 'tender and swollen', or 'asymptomatic'. It is derived as the sum of all swollen joints. The overall swollen joint count ranged from 0 to 66, with a higher score indicating a greater degree of swelling. A negative change from baseline indicates improvement. LTE FAS with available data.

End point type	Secondary

End point timeframe:

Baseline (Core Study), Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	63		
Units: joints				
arithmetic mean (standard deviation)				
Change at Week 4 (n= 59, 63)	-9.9 (± 4.78)	-9.2 (± 4.90)		
Change at Week 16 (n= 57, 62)	-10.1 (± 5.27)	-10.6 (± 5.61)		
Change at Week 28 (n= 54, 60)	-10.3 (± 5.28)	-11.1 (± 5.72)		
Change at Week 40 (n= 55, 59)	-10.8 (± 5.41)	-11.2 (± 6.02)		
Change at Week 52 (n= 54, 56)	-10.7 (± 5.22)	-10.9 (± 6.59)		
Change at Week 64 (n= 50, 56)	-10.8 (± 5.29)	-11.6 (± 6.36)		
Change at Week 76 (n= 51, 55)	-10.7 (± 5.58)	-11.8 (± 6.19)		
Change at Week 88 (n= 49, 54)	-10.5 (± 5.79)	-11.4 (± 6.44)		

Change at Week 100 (n= 45, 52)	-10.5 (± 6.10)	-11.7 (± 6.18)		
Change at Week 112 (n= 44, 49)	-10.2 (± 5.50)	-12.2 (± 6.53)		
Change at Week 124 (n= 37, 50)	-11.0 (± 5.38)	-11.7 (± 6.16)		
Change at Week 136 (n= 39, 48)	-10.0 (± 6.22)	-11.9 (± 6.20)		
Change at Week 148 (n= 38, 49)	-10.8 (± 5.63)	-11.7 (± 6.34)		
Change at Week 172 (n= 33, 45)	-11.0 (± 5.29)	-12.4 (± 6.65)		
Change at Week 196 (n= 10, 10)	-12.7 (± 8.37)	-11.3 (± 6.85)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Core Baseline in Individual ACR Component: CRP at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

End point title	Change From Core Baseline in Individual ACR Component: CRP at Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196

End point description:

Serum CRP was measured using a high sensitivity CRP (hsCRP) at the central laboratory to help assess the effect of filgotinib on the participant's psoriatic arthritis. A negative change from baseline indicates improvement. LTE FAS with available data.

End point type	Secondary

End point timeframe:

Baseline (Core Study), Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	57	62		
Units: mg/L				
arithmetic mean (standard deviation)				
Change at Week 4 (n= 56, 62)	-11.5 (± 19.22)	-7.3 (± 14.47)		
Change at Week 16 (n= 57, 62)	-10.9 (± 18.74)	-7.1 (± 16.37)		
Change at Week 28 (n= 54, 60)	-10.9 (± 16.81)	-6.2 (± 20.97)		
Change at Week 40 (n= 56, 60)	-11.3 (± 19.63)	-8.7 (± 16.70)		
Change at Week 52 (n= 54, 57)	-7.3 (± 25.08)	-6.6 (± 20.62)		
Change at Week 64 (n= 51, 56)	-9.5 (± 25.77)	-6.9 (± 18.80)		
Change at Week 76 (n= 51, 55)	-9.9 (± 21.30)	-7.0 (± 16.59)		
Change at Week 88 (n= 48, 54)	-12.8 (± 21.44)	-6.8 (± 15.99)		
Change at Week 100 (n= 45, 52)	-11.4 (± 20.85)	-4.7 (± 23.79)		
Change at Week 112 (n= 44, 46)	-12.3 (± 20.15)	-5.9 (± 22.39)		

Change at Week 124 (n= 36, 50)	-10.9 (± 18.13)	-9.2 (± 18.72)		
Change at Week 136 (n= 39, 46)	-10.8 (± 18.58)	-8.4 (± 17.55)		
Change at Week 148 (n= 38, 49)	-12.8 (± 21.59)	-8.0 (± 17.13)		
Change at Week 172 (n= 37, 49)	-13.1 (± 22.61)	-7.6 (± 19.65)		
Change at Week 196 (n= 18, 21)	-8.2 (± 23.47)	-2.3 (± 9.56)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Psoriasis Area and Severity Index 90% (PASI90) Improvement

End point title	Percentage of Participants With Psoriasis Area and Severity Index 90% (PASI90) Improvement

End point description:

PASI: assessed in participants with psoriasis covering ≥ 3% of BSA at Baseline and is used to measure severity and extent of psoriasis. In PASI system, body is divided into 4 regions: head (h), upper limbs (u), trunk (t) and lower limbs (l). Each of these areas are assessed separately for percentage of area involved and for erythema (E), induration (I), and desquamation (D), which are each rated on a scale of 0 to 4, (0 = none, 1 = mild, 2 = moderate, 3 = severe and 4 = very severe), which translates to numeric score that ranges from 0 (indicates no involvement) to 6 (90 percent [%] to 100% involvement). PASI score calculation: PASI = 0.1 * (Eh + Ih + Dh) * Ah + 0.2 *(Eu + Iu + Du) * Au + 0.3 * (Et + It + Dt) * At + 0.4 * (El + Il + Dl) * Al. PASI produces numeric score ranging from 0 (no disease) to 72 (maximal disease). PASI90, improvement threshold from baseline score is 90%. Higher score = more severe disease. Data was summarized using OC method. LTE FAS with available data.

End point type	Secondary

End point timeframe:

Weeks 4, 16, 28, 40, 52, 64, 76, 88, 100, 112, 124, 136, 148, 172 and 196 (LTE Study)

End point values	Filgotinib (Core Study) and Filgotinib (LTE Study)	Placebo (Core Study) and Filgotinib (LTE Study)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38	38		
Units: percentage of participants				
number (not applicable)				
Week 4 (n= 38, 38)	21.1	18.4		
Week 16 (n= 38, 38)	23.7	26.3		
Week 28 (n= 38, 36)	28.9	30.6		
Week 40 (n= 38, 35)	31.6	28.6		
Week 52 (n= 36, 32)	25.0	40.6		
Week 64 (n= 35, 33)	28.6	36.4		
Week 76 (n= 35, 33)	28.6	42.4		
Week 88 (n= 33, 32)	33.3	40.6		
Week 100 (n= 29, 31)	34.5	32.3		
Week 112 (n= 30, 28)	30.0	32.1		

Week 124 (n= 25, 29)	36.0	41.4		
Week 136 (n= 26, 27)	26.9	40.7		
Week 148 (n= 25, 28)	32.0	35.7		
Week 172 (n= 22, 25)	45.5	36.0		
Week 196 (n= 8, 6)	37.5	50.0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
From first dose (LTE study) up to 30 days after last dose of filgotinib in LTE study (maximum up to 212 weeks)	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	24.0

Reporting groups	
Reporting group title	Filgotinib 200 mg
Reporting group description:	
Participants received filgotinib 200 mg tablet, orally, once daily up to 212 weeks in this GLPG0634-CL-225 LTE study (2017-000545-52).	

Serious adverse events	Filgotinib 200 mg		
Total subjects affected by serious adverse events			
subjects affected / exposed	19 / 122 (15.57%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer			
subjects affected / exposed	1 / 122 (0.82%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Limb injury			
subjects affected / exposed	1 / 122 (0.82%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tendon rupture			
subjects affected / exposed	1 / 122 (0.82%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute myocardial infarction			

subjects affected / exposed	1 / 122 (0.82%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Angina unstable			
subjects affected / exposed	1 / 122 (0.82%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Neuropathy peripheral			
subjects affected / exposed	1 / 122 (0.82%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Iridocyclitis			
subjects affected / exposed	1 / 122 (0.82%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	1 / 122 (0.82%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal pain			
subjects affected / exposed	1 / 122 (0.82%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Gastric perforation			
subjects affected / exposed	1 / 122 (0.82%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Uterovaginal prolapse			

subjects affected / exposed	1 / 122 (0.82%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Nasal septum deviation			
subjects affected / exposed	1 / 122 (0.82%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	1 / 122 (0.82%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	1 / 122 (0.82%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spinal osteoarthritis			
subjects affected / exposed	1 / 122 (0.82%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
COVID-19			
subjects affected / exposed	1 / 122 (0.82%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
COVID-19 pneumonia			
subjects affected / exposed	2 / 122 (1.64%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			

subjects affected / exposed	1 / 122 (0.82%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peritonitis			
subjects affected / exposed	1 / 122 (0.82%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tick-borne viral encephalitis			
subjects affected / exposed	1 / 122 (0.82%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Filgotinib 200 mg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	65 / 122 (53.28%)		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	8 / 122 (6.56%)		
occurrences (all)	8		
Aspartate aminotransferase increased			
subjects affected / exposed	8 / 122 (6.56%)		
occurrences (all)	8		
Injury, poisoning and procedural complications			
Limb injury			
subjects affected / exposed	7 / 122 (5.74%)		
occurrences (all)	9		
Vascular disorders			
Hypertension			
subjects affected / exposed	14 / 122 (11.48%)		
occurrences (all)	17		
Skin and subcutaneous tissue disorders			
Psoriasis			

subjects affected / exposed occurrences (all)	13 / 122 (10.66%) 16		
Musculoskeletal and connective tissue disorders Psoriatic arthropathy subjects affected / exposed occurrences (all)	 15 / 122 (12.30%) 22		
Infections and infestations COVID-19 subjects affected / exposed occurrences (all) Latent tuberculosis subjects affected / exposed occurrences (all) Nasopharyngitis subjects affected / exposed occurrences (all) Upper respiratory tract infection subjects affected / exposed occurrences (all)	 10 / 122 (8.20%) 11 15 / 122 (12.30%) 15 26 / 122 (21.31%) 40 9 / 122 (7.38%) 12		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 July 2017	The protocol was updated with clinical information around serious infections, lymphoma and other malignancies in the benefit/risk assessment in accordance with the Investigator's Brochure.
20 August 2018	The protocol was updated to enhance safety for subjects participating in this LTE study and to align procedures with other LTE studies in the filgotinib development program. Hereto, annual TB testing was introduced in the protocol for subjects that tested negative for TB at screening for the core study GLPG0634-CL-224 (from which subjects rolled over) and a discontinuation criterion on active TB was included.
28 January 2020	- The duration of the study was extended until filgotinib was registered for PsA or until Week 304, whichever occurred first. Considering the favorable efficacy data, prolonging the study allowed extended availability of filgotinib for subjects benefitting from the IP. -In addition, in agreement with the IDMC chair, it was decided to not continue the IDMC reviews during the extension as a large database of long-term safety and efficacy data was available with filgotinib in RA and other indications. The current study was open-label; safety and efficacy data were continuously monitored by the sponsor. -The class of JAK inhibitors has been associated with an increased risk of thromboembolic events; therefore, the FDA requested sponsors to consider additional risk mitigation measures for inflammatory bowel disease studies. The sponsor decided to implement the measures agreed with the FDA for all ongoing studies with filgotinib, regardless of indication. These measures included a specific stopping rule for subjects experiencing a thromboembolic events meeting the SAE criteria; recording of specific information relevant to thromboembolic events to facilitate the assessment of the event; adjudication of thromboembolic events should these occur; and an instruction for the investigator to refer any subject experiencing a thromboembolic event to a specialist for evaluation of the risk of recurrence.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
29 March 2021	The sponsor decided to discontinue development of the filgotinib program in PsA and prematurely terminated the study.	-

Notes:

Limitations and caveats

None reported