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

## Summary

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

**Results information**

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

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | GS-US-417-0302 |

**Additional study identifiers**

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT02873936 |
| WHO universal trial number (UTN) | - |

Notes:

**Sponsors**

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

Notes:

**Paediatric regulatory details**

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

Notes:

## Results analysis stage

| | |
|---|---|
| Analysis stage | Final |
| Date of interim/final analysis | 26 June 2018 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 20 March 2018 |
| Global end of trial reached? | Yes |
| Global end of trial date | 26 June 2018 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

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

Protection of trial subjects:

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

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

Background therapy:

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

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 27 July 2016 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

## Population of trial subjects

### Subjects enrolled per country

| | |
|---|---|
| Country: Number of subjects enrolled | Poland: 19 |
| Country: Number of subjects enrolled | Spain: 16 |
| Country: Number of subjects enrolled | United Kingdom: 10 |
| Country: Number of subjects enrolled | Belgium: 13 |
| Country: Number of subjects enrolled | France: 9 |
| Country: Number of subjects enrolled | Germany: 15 |
| Country: Number of subjects enrolled | Hungary: 16 |
| Country: Number of subjects enrolled | United States: 255 |

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

Notes:

| **Subjects enrolled per age group** | |
|---|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 336 |
| From 65 to 84 years | 113 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details:

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

### Pre-assignment

Screening details:

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

### Period 1

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

### Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | Filgotinib 200 mg |

Arm description:

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

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

Dosage and administration details:

200 mg tablet administered once daily

| | |
|---|---|
| Investigational medicinal product name | Placebo to match (PTM ) filgotinib 100 mg |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |

Dosage and administration details:

PTM filgotinib 100 mg administered once daily

| | |
|---|---|
| **Arm title** | Filgotinib 100 mg |

Arm description:

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

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

| | |
|---|---|
| Dosage and administration details:<br>100 mg tablet administered once daily | |
| Investigational medicinal product name | PTM filgotinib 200 mg |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |
| Dosage and administration details:<br>PTM filgotinib 200 mg administered once daily | |
| **Arm title** | Placebo |
| Arm description:<br>Participants were administered PTM filgotinib 200 mg tablet orally, once daily + PTM filgotinib 100 mg tablet orally, once daily + stable dose of permitted csDMARDs for median exposure of 24 weeks. | |
| Arm type | Placebo |
| Investigational medicinal product name | PTM filgotinib 100 mg |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |
| Dosage and administration details:<br>PTM filgotinib 100 mg administered once daily | |
| Investigational medicinal product name | PTM filgotinib 200 mg |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |
| Dosage and administration details:<br>PTM filgotinib 200 mg administered once daily | |

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

Notes:

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

## Baseline characteristics

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

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

| Reporting group values | Total | | |
|---|---|---|---|
| Number of subjects | 448 | | |

| | | | |
|---|---|---|---|
| Age categorical<br>Units: Subjects | | | |

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

## End points

### End points reporting groups

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

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

| End point title | Percentage of Participants who Achieved an American College of Rheumatology (ACR) 20% Improvement (ACR20) Response at Week 12 |
|---|---|
| End point description: | |
| ACR20 response is achieved when the participant has: ≥20% improvement (reduction) from baseline in tender joint count based on 68 joints (TJC68), swollen joint count based on 66 joints (SJC66) and in at least 3 of the following 5 items: physician's global assessment of disease activity (PGA), subject's global assessment of disease activity (SGA) using visual analog scale (VAS) on a scale of 0 (no disease activity) to 100 (maximum disease activity),participant`s pain assessment using VAS on a scale of 0 (no pain) to 100 (unbearable pain),health assessment questionnaire disability index (HAQ-DI) score contains 20 questions,8 components: dressing/grooming,arising, eating, walking, hygiene, reach, grip and activities scored on a scale of 0 (without difficulty) to 3 (unable to do);high-sensitivity C-reactive protein (hsCRP). Full Analysis Set included participants who were randomized and received at least 1 dose of study drug. Participants with<br>missing outcomes were set as non-responders. | |
| End point type | Primary |
| End point timeframe: | |
| Week 12 | |

| End point values | Filgotinib 200 mg | Filgotinib 100 mg | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 147 | 153 | 148 | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 66.0 (58.0 to 74.0) | 57.5 (49.4 to 65.7) | 31.1 (23.3 to 38.9) | |

### Statistical analyses

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

Notes:

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

| Statistical analysis title | Filgotinib 100 mg vs Placebo |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [2] |
| Method | Regression, Logistic |
| Parameter estimate | Difference in Response Rates |
| Point estimate | 26.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 15 |
| upper limit | 37.9 |

Notes:

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

## Secondary: Percentage of Participants who Achieved Disease Activity Score 28 C-Reactive Protein (DAS28(CRP)) ≤ 3.2 at Week 12

| End point title | Percentage of Participants who Achieved Disease Activity Score 28 C-Reactive Protein (DAS28(CRP)) ≤ 3.2 at Week 12 |
|---|---|

End point description:

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

| End point type | Secondary |
|---|---|

End point timeframe:

Week 12

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

**Statistical analyses**

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

Notes:

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

| Statistical analysis title | Filgotinib 100 mg vs Placebo |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [4] |
| Method | Regression, Logistic |
| Parameter estimate | Difference in Response Rates |
| Point estimate | 21.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 11.4 |
| upper limit | 32 |

Notes:

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

**Secondary: Change from Baseline in the Health Assessment Questionnaire -**

## Disability Index (HAQ-DI) Score at Week 12

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

End point description:

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

| | |
|---|---|
| End point type | Secondary |

End point timeframe:

Baseline; Week 12

| End point values | Filgotinib 200 mg | Filgotinib 100 mg | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 147 | 153 | 148 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline | 1.70 (± 0.656) | 1.64 (± 0.683) | 1.65 (± 0.633) | |
| Change from Baseline at Week 12 (N=137,140,129) | -0.55 (± 0.590) | -0.48 (± 0.602) | -0.23 (± 0.547) | |

### Statistical analyses

| Statistical analysis title | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

Least squares (LS)-Mean, 95% confidence interval (CI), and P-value were provided from mixed effects model for repeated measure (MMRM). Missing change scores were not imputed using the MMRM approach assuming an unstructured variance-covariance matrix for the repeated measures.

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

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [6] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -0.27 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.4 |
| upper limit | -0.14 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.065 |

Notes:

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

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

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

End point description:

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

| End point type | Secondary |
|---|---|

End point timeframe:

Weeks 4, 12, and 24

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

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

**Statistical analyses**

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|
| Statistical analysis description: | |
| Week 4 | |
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [7] |
| Method | Regression, Logistic |
| Parameter estimate | Difference in Response Rates |
| Point estimate | 15 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 6.4 |
| upper limit | 23.7 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|
| Statistical analysis description: | |
| Week 4 | |
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [8] |
| Method | Regression, Logistic |
| Parameter estimate | Difference in Response Rates |
| Point estimate | 14.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 5.7 |
| upper limit | 22.6 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|
| Statistical analysis description: | |
| Week 12 | |
| Comparison groups | Filgotinib 200 mg v Placebo |

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

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

Week 12

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

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

Week 24

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [11] |
| Method | Regression, Logistic |
| Parameter estimate | Difference in Response Rates |
| Point estimate | 26.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 15.8 |
| upper limit | 37.6 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|
| Statistical analysis description: | |
| Week 24 | |
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.002 [12] |
| Method | Regression, Logistic |
| Parameter estimate | Difference in Response Rates |
| Point estimate | 16.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 5.9 |
| upper limit | 26.9 |

Notes:

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

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

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

End point description:

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

| End point type | Secondary |
|---|---|

End point timeframe:

Weeks 4, 12, and 24

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

## Statistical analyses

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|
| Statistical analysis description: | |
| Week 4 | |
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.16 [13] |
| Method | Regression, Logistic |
| Parameter estimate | Difference in Response Rates |
| Point estimate | 3.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.9 |
| upper limit | 8.8 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|
| Statistical analysis description: | |
| Week 4 | |
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.039 [14] |
| Method | Regression, Logistic |
| Parameter estimate | Difference in Response Rates |
| Point estimate | 5.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 11.6 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|
| Statistical analysis description: | |
| Week 12 | |
| Comparison groups | Filgotinib 200 mg v Placebo |

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

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

Week 12

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

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

Week 24

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [17] |
| Method | Regression, Logistic |
| Parameter estimate | Difference in Response Rates |
| Point estimate | 23.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 14.5 |
| upper limit | 33.3 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|
| Statistical analysis description: | |
| Week 24 | |
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.004 [18] |
| Method | Regression, Logistic |
| Parameter estimate | Difference in Response Rates |
| Point estimate | 12.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 3.7 |
| upper limit | 20.6 |

Notes:

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

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

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

End point description:

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

| End point type | Secondary |
|---|---|

End point timeframe:

Weeks 4, and 24

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

## Statistical analyses

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

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|
| Statistical analysis description: | |
| Week 4 | |
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [20] |
| Method | Regression, Logistic |
| Parameter estimate | Difference in Response Rates |
| Point estimate | 18.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 7.5 |
| upper limit | 30 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|
| Statistical analysis description: | |
| Week 24 | |
| Comparison groups | Filgotinib 200 mg v Placebo |

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

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

Week 24

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

Notes:

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

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

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

End point description:

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

| | |
|---|---|
| End point type | Secondary |

End point timeframe:

Baseline; Weeks 4, 12, and 24

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

## Statistical analyses

| Statistical analysis title | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 294 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.003 [23] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -7 |
| upper limit | -1 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.4 |

Notes:

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

| Statistical analysis title | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.027 [24] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -6 |
| upper limit | 0 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.4 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 294 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [25] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -8 |
| upper limit | -3 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.3 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [26] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -7 |
| upper limit | -2 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.3 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 294 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [27] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -10 |
| upper limit | -4 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.5 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.006 [28] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -7 |
| upper limit | -1 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.5 |

Notes:

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

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

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

End point description:

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

| | |
|---|---|
| End point type | Secondary |

End point timeframe:

Baseline; Weeks 4, 12, and 24

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

### Statistical analyses

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 294 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.008 [29] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -5 |
| upper limit | -1 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.65 [30] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2 |
| upper limit | 1 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 294 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [31] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -5 |
| upper limit | -2 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.9 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.008 [32] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -4 |
| upper limit | -1 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.9 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 294 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [33] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -5 |
| upper limit | -2 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.9 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.039 [34] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -4 |
| upper limit | 0 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.9 |

Notes:

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

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

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

End point description:

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

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline; Weeks 4, 12, and 24

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

## Statistical analyses

| Statistical analysis title | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [35] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -12 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -17 |
| upper limit | -7 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 2.7 |

Notes:

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

| Statistical analysis title | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [36] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -11 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -16 |
| upper limit | -5 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 2.7 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [37] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -18 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -24 |
| upper limit | -12 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 3 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [38] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -13 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -19 |
| upper limit | -7 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 3 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [39] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -18 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -25 |
| upper limit | -12 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 3.4 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [40] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -13 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -19 |
| upper limit | -6 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 3.4 |

Notes:

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

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

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

End point description:

PGA was assessed by the physician using a VAS on a scale of 0 (no disease activity) to 3 (maximum disease activity). A negative change from baseline indicates improvement. Participants in the Full Analysis Set with available data were analyzed.

| | |
|---|---|
| End point type | Secondary |

End point timeframe:

Baseline; Weeks 4, 12, and 24

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

### Statistical analyses

| Statistical analysis title | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

Week 4; LS-Mean, 95% CI, and P-value were provided from MMRM. Missing change scores were not

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [41] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -12 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -17 |
| upper limit | -7 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 2.6 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [42] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -10 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -15 |
| upper limit | -5 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 2.6 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [43] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -16 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -22 |
| upper limit | -11 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 2.8 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [44] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -13 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -18 |
| upper limit | -7 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 2.7 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [45] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -13 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -18 |
| upper limit | -8 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 2.7 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.052 [46] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -11 |
| upper limit | 0 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 2.7 |

Notes:

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

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

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

End point description:

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

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline; Weeks 4, 12, and 24

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

## Statistical analyses

| Statistical analysis title | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [47] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -16 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -21 |
| upper limit | -10 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 2.7 |

Notes:

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

| Statistical analysis title | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [48] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -14 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -19 |
| upper limit | -8 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 2.7 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [49] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -17 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -23 |
| upper limit | -11 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 3.1 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [50] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -13 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -19 |
| upper limit | -7 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 3.1 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [51] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -16 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -23 |
| upper limit | -10 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 3.4 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [52] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -12 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -19 |
| upper limit | -5 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 3.4 |

Notes:

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

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

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

End point description:

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

| | |
|---|---|
| End point type | Secondary |

End point timeframe:

Baseline; Weeks 4, and 24

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

## Statistical analyses

| | |
|---|---|
| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |

Statistical analysis description:

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

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

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.006 [54] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -0.15 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.26 |
| upper limit | -0.04 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.055 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [55] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -0.36 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.51 |
| upper limit | -0.21 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.075 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.003 [56] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -0.22 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.37 |
| upper limit | -0.08 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.075 |

Notes:

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

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

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

End point description:

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

| | |
|---|---|
| End point type | Secondary |

End point timeframe:

Baseline; Weeks 4, 12, and 24

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

## Statistical analyses

| Statistical analysis title | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [57] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -10.51 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -13.61 |
| upper limit | -7.41 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.578 |

Notes:

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

| Statistical analysis title | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [58] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -8.92 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -12.02 |
| upper limit | -5.82 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.577 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [59] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -10.94 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -14.19 |
| upper limit | -7.69 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.652 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [60] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -8.98 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -12.22 |
| upper limit | -5.73 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.651 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [61] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -9.87 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -13.73 |
| upper limit | -6 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.964 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [62] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -6.89 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -10.8 |
| upper limit | -2.98 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.987 |

Notes:

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

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

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

End point description:

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

| | |
|---|---|
| End point type | Secondary |

End point timeframe:

Weeks 4, 12, and 24

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

## Statistical analyses

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|
| Statistical analysis description: | |
| Week 4 | |
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [63] |
| Method | Regression, Logistic |
| Parameter estimate | Difference in Response Rates |
| Point estimate | 20.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 8.1 |
| upper limit | 32.1 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|
| Statistical analysis description: | |
| Week 4 | |
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.013 [64] |
| Method | Regression, Logistic |
| Parameter estimate | Difference in Response Rates |
| Point estimate | 14.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 2.4 |
| upper limit | 26.5 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|
| Statistical analysis description: | |
| Week 12 | |
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [65] |
| Method | Regression, Logistic |
| Parameter estimate | Difference in Response Rates |
| Point estimate | 22.2 |

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

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

Week 12

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [66] |
| Method | Regression, Logistic |
| Parameter estimate | Difference in Response Rates |
| Point estimate | 21.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 10 |
| upper limit | 33.6 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

Week 24

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [67] |
| Method | Regression, Logistic |
| Parameter estimate | Difference in Response Rates |
| Point estimate | 33.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 21.8 |
| upper limit | 44.9 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

Week 24

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |

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

Notes:

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

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

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

End point description:

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

| | |
|---|---|
| End point type | Secondary |

End point timeframe:

Baseline; Weeks 4, 12, and 24

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

### Statistical analyses

| Statistical analysis title | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |

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

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [70] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -0.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.9 |
| upper limit | -0.4 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.13 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [71] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -1.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.5 |
| upper limit | -0.9 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.15 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [72] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.3 |
| upper limit | -0.7 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.15 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [73] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -1.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.5 |
| upper limit | -0.8 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.17 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [74] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -0.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.1 |
| upper limit | -0.4 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.17 |

Notes:

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

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

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

End point description:

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

| End point type | Secondary |
|---|---|

End point timeframe:

Weeks 4, and 24

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

**Statistical analyses**

| Statistical analysis title | Filgotinib 200 mg vs Placebo |
|---|---|
| Statistical analysis description: | |
| Week 4 | |
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.004 [75] |
| Method | Regression, Logistic |
| Parameter estimate | Difference in Response Rates |
| Point estimate | 12.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 3.5 |
| upper limit | 21.2 |

Notes:

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

| Statistical analysis title | Filgotinib 100 mg vs Placebo |
|---|---|
| Statistical analysis description: | |
| Week 4 | |
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.003 [76] |
| Method | Regression, Logistic |
| Parameter estimate | Difference in Response Rates |
| Point estimate | 12.8 |

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

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

Week 24

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [77] |
| Method | Regression, Logistic |
| Parameter estimate | Difference in Response Rates |
| Point estimate | 27.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 16.3 |
| upper limit | 38.4 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

Week 24

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.001 [78] |
| Method | Regression, Logistic |
| Parameter estimate | Difference in Response Rates |
| Point estimate | 17 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 6.2 |
| upper limit | 27.7 |

Notes:

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

## Secondary: Percentage of Participants Who Achieved DAS28 (CRP) < 2.6 at Weeks 4, 12, and 24

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

End point description:

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

| End point type | Secondary |
|---|---|

End point timeframe:

Weeks 4, 12, and 24

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

**Statistical analyses**

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

Week 4

| Comparison groups | Filgotinib 200 mg v Placebo |
|---|---|
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.012 [79] |
| Method | Regression, Logistic |
| Parameter estimate | Difference in Response Rates |
| Point estimate | 7.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.3 |
| upper limit | 13.7 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

Week 4

| Comparison groups | Filgotinib 100 mg v Placebo |
|---|---|

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

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

Week 12

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [81] |
| Method | Regression, Logistic |
| Parameter estimate | Difference in Response Rates |
| Point estimate | 14.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 5.6 |
| upper limit | 23.1 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

Week 12

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [82] |
| Method | Regression, Logistic |
| Parameter estimate | Difference in Response Rates |
| Point estimate | 17.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 8.5 |
| upper limit | 26.2 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|
| Statistical analysis description: | |
| Week 24 | |
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [83] |
| Method | Regression, Logistic |
| Parameter estimate | Difference in Response Rates |
| Point estimate | 18.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 8.6 |
| upper limit | 28.3 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|
| Statistical analysis description: | |
| Week 24 | |
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.003 [84] |
| Method | Regression, Logistic |
| Parameter estimate | Difference in Response Rates |
| Point estimate | 14 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 4.6 |
| upper limit | 23.4 |

Notes:

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

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

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

End point description:

ACR-N is defined as the smallest percentage improvement from baseline in swollen joints, tender joints and the median of the following 5 items (PGA, SGA, subject`s pain assessment, HAQ-DI and hsCRP). It has a range between 0 and 100%. PGA and SGA assessed using VAS on a scale of 0-100 [0 and 100 indicating no disease activity and maximum disease activity]; subject`s pain assessment using VAS on a scale of 0-100 [0 and 100 indicating no pain and unbearable pain]; HAQ-DI score contains 20 questions,8 components: dressing/grooming, arising, eating, walking, hygiene, reach, grip and activities

scored on a scale of 0-3 [0 and 3 indicating without difficulty and unable to do]. If this calculation results in a negative value, then the ACR-N is set to 0. The ACR-N value indicates an improvement of N%, with higher numbers indicating greater improvement. Participants in the Full Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|
| End point timeframe: | |
| Weeks 4, 12, and 24 | |

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

**Statistical analyses**

No statistical analyses for this end point

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

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

End point description:

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

| End point type | Secondary |
|---|---|
| End point timeframe: | |
| Weeks 4, 12, and 24 | |

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

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

**Statistical analyses**

No statistical analyses for this end point

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

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

End point description:

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

| | |
|---|---|
| End point type | Secondary |

End point timeframe:

Baseline; Weeks 4, 12, and 24

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

**Statistical analyses**

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [85] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -7.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -10 |
| upper limit | -4.2 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.47 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [86] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -7.9 |
| upper limit | -2.2 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.46 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [87] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -9.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -12.6 |
| upper limit | -6.5 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.56 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [88] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -7.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -10.6 |
| upper limit | -4.5 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.55 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [89] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -8.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -11.9 |
| upper limit | -5.5 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.64 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.003 [90] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -4.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -8.2 |
| upper limit | -1.6 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.66 |

Notes:

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

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

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

End point description:

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

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline; Weeks 4, 12, and 24

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

## Statistical analyses

| Statistical analysis title | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [91] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -8.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -11.1 |
| upper limit | -5.1 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.52 |

Notes:

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

| Statistical analysis title | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [92] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -5.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -8.9 |
| upper limit | -2.9 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.52 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [93] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -10.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -13.8 |
| upper limit | -7.5 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.6 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [94] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -8.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -11.8 |
| upper limit | -5.5 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.59 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 295 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [95] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -10.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -13.5 |
| upper limit | -6.8 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.7 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [96] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | -6.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -9.4 |
| upper limit | -2.7 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.71 |

Notes:

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

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

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

End point description:

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

| | |
|---|---|
| End point type | Secondary |

End point timeframe:

Weeks 4, 12, and 24

| End point values | Filgotinib 200 mg | Filgotinib 100 mg | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 147 | 153 | 148 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 4 (N=147,149,146) | 35.4 (± 8.72) | 36.4 (± 9.29) | 33.7 (± 8.67) | |
| Week 12 (N=142,144,133) | 38.3 (± 10.14) | 38.6 (± 9.39) | 35.1 (± 9.90) | |
| Week 24 (N=123,112,92) | 40.4 (± 9.64) | 40.3 (± 10.31) | 37.7 (± 9.09) | |

### Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline; Weeks 4, 12, and 24

| **End point values** | Filgotinib 200 mg | Filgotinib 100 mg | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 146 | 153 | 148 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline | 30.4 (± 7.75) | 31.7 (± 7.76) | 31.1 (± 8.17) | |
| Change from Baseline at Week 4 (N=146,149,146) | 5.1 (± 6.34) | 4.5 (± 6.53) | 2.5 (± 5.91) | |
| Change from Baseline at Week 12 (N=141,144,133) | 7.6 (± 7.68) | 6.8 (± 8.22) | 3.6 (± 8.16) | |
| Change from Baseline at Week 24 (N=122,112,92) | 9.4 (± 8.23) | 9.0 (± 8.44) | 6.6 (± 7.95) | |

## Statistical analyses

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

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

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.005 [98] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | 2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.6 |
| upper limit | 3.4 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.7 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 294 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [99] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | 4.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 2.5 |
| upper limit | 6.1 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.92 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [100] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | 3.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.6 |
| upper limit | 5.2 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.92 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 294 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [101] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | 3.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.9 |
| upper limit | 5.9 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.02 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.002 [102] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | 3.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.1 |
| upper limit | 5.2 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.03 |

Notes:

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

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

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

End point description:

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

| | |
|---|---|
| End point type | Secondary |

End point timeframe:

Weeks 4, 12, and 24

| End point values | Filgotinib 200 mg | Filgotinib 100 mg | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 147 | 153 | 148 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 4 (N=147,149,146) | 48.0 (± 11.48) | 47.3 (± 11.51) | 45.5 (± 11.11) | |
| Week 12 (N=142,144,133) | 50.2 (± 10.58) | 48.8 (± 11.02) | 47.9 (± 11.01) | |
| Week 24 (N=123,112,92) | 50.6 (± 10.35) | 49.5 (± 10.72) | 49.1 (± 10.56) | |

### Statistical analyses

No statistical analyses for this end point

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

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

| | |
|---|---|
| | 24 |

End point description:

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

| | |
|---|---|
| End point type | Secondary |

End point timeframe:

Baseline; Weeks 4, 12, and 24

| **End point values** | Filgotinib 200 mg | Filgotinib 100 mg | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 146 | 153 | 148 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline | 44.5 (± 11.97) | 44.2 (± 11.59) | 44.3 (± 11.32) | |
| Change from Baseline at Week 4 (N=146,149,146) | 3.5 (± 9.17) | 3.0 (± 9.03) | 1.2 (± 9.34) | |
| Change from Baseline at Week 12 (N=141,144,133) | 5.3 (± 10.60) | 4.6 (± 9.76) | 3.7 (± 9.17) | |
| Change from Baseline at Week 24 (N=122,112,92) | 6.5 (± 12.50) | 4.6 (± 9.22) | 4.3 (± 9.44) | |

## Statistical analyses

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 294 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.019 [103] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | 2.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.4 |
| upper limit | 4.2 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.97 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.073 [104] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | 1.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.2 |
| upper limit | 3.6 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.97 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 294 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.045 [105] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | 2.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 4.1 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.03 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.32 [106] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | 1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1 |
| upper limit | 3 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.02 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 294 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.12 [107] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | 1.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.5 |
| upper limit | 4.2 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.19 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 301 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.96 [108] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | 0.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2.3 |
| upper limit | 2.4 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.2 |

Notes:

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

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

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

End point description:

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

| | |
|---|---|
| End point type | Secondary |

End point timeframe:

Weeks 4, 12, and 24

| End point values | Filgotinib 200 mg | Filgotinib 100 mg | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 147 | 153 | 148 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 4 (N=145,144,144) | 30.4 (± 12.48) | 30.3 (± 12.30) | 27.9 (± 11.29) | |
| Week 12 (N=141,143,132) | 34.0 (± 12.08) | 32.1 (± 13.66) | 30.4 (± 11.79) | |
| Week 24 (N=123,110,90) | 36.3 (± 11.58) | 34.4 (± 12.51) | 33.3 (± 11.26) | |

### Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline; Weeks 4, 12, and 24

| **End point values** | Filgotinib 200 mg | Filgotinib 100 mg | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 146 | 152 | 147 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline | 24.2 (± 11.47) | 23.7 (± 12.30) | 25.4 (± 10.89) | |
| Change from Baseline at Week 4 (N=144,144,144) | 6.2 (± 10.20) | 6.4 (± 9.87) | 2.2 (± 8.92) | |
| Change from Baseline at Week 12 (N=140,143,132) | 9.6 (± 11.24) | 8.3 (± 10.80) | 4.5 (± 10.37) | |
| Change from Baseline at Week 24 (N=122,110,90) | 11.6 (± 11.67) | 9.8 (± 10.39) | 7.0 (± 10.23) | |

## Statistical analyses

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| Comparison groups | Filgotinib 200 mg v Placebo |
|---|---|
| Number of subjects included in analysis | 293 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [109] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | 3.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.6 |
| upper limit | 5.7 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.05 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 299 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.002 [110] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | 3.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.2 |
| upper limit | 5.4 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.05 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 293 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [111] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | 5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 2.6 |
| upper limit | 7.3 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.19 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 299 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.007 [112] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | 3.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.9 |
| upper limit | 5.5 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.18 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 293 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 [113] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | 4.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 2.1 |
| upper limit | 7.1 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.28 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 299 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.11 [114] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | 2.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.5 |
| upper limit | 4.7 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.3 |

Notes:

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

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

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

End point description:

The EQ-5D-5 levels (EQ-5D-5L) is a standardized measure of health status of the participant at the visit (same day) that provides a simple, generic measure of health for clinical and economic appraisal. EQ-5D-5L consists of 2 components: a descriptive system of the participant`s health and a rating of his or her current health state on a 0-100 VAS. The descriptive system comprises the following 5 dimensions: mobility, self-care, usual activities (Usu Act), pain/discomfort (Pai/Disc), and anxiety/depression (Anx/Dep). Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems, and extreme problems. Rating gets recorded on a vertical VAS in which the endpoints are labelled best imaginable health state is 100 (on the top) and worst imaginable health state is 0 (on the bottom). Higher scores of EQ VAS indicate better health. Participants in the Full Analysis Set with available data were analyzed.

| | |
|---|---|
| End point type | Secondary |

End point timeframe:

Weeks (Wk) 4, 12, and 24

| **End point values** | Filgotinib 200 mg | Filgotinib 100 mg | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 147 | 153 | 148 | |
| Units: participants | | | | |
| Mobility: Wk 4: No Problems (N=145,144,144) | 34 | 45 | 32 | |
| Mobility: Wk 4: Slight Problems (N=145,144,144) | 58 | 49 | 49 | |
| Mobility: Wk 4: Moderate Problems (N=145,144,144) | 38 | 33 | 36 | |
| Mobility: Wk 4: Severe Problems (N=145,144,144) | 15 | 16 | 25 | |
| Mobility: Wk 4: Extreme Problems (N=145,144,144) | 0 | 1 | 2 | |
| Mobility: Wk 12: No Problems (N=141,143,132) | 47 | 57 | 38 | |

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

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

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

### Statistical analyses

No statistical analyses for this end point

## Secondary: EQ-5D Current Health VAS at Weeks 4, 12, and 24

| End point title | EQ-5D Current Health VAS at Weeks 4, 12, and 24 |
|---|---|

End point description:

EQ-5D-5L is a standardized measure of health status of the participant at the visit (same day) that provides a simple, generic measure of health for clinical and economic appraisal. Participant rates their current health state on a 0-100 VAS. It gets recorded on a vertical VAS in which the endpoints are labelled best imaginable health state is 100 (on the top) and worst imaginable health state is 0 (on the bottom). Higher scores of EQ VAS indicate better health. Participants in the Full Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Weeks 4, 12, and 24

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

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in EQ-5D Current Health VAS at Weeks 4, 12, and 24

| End point title | Change From Baseline in EQ-5D Current Health VAS at Weeks 4, 12, and 24 |
|---|---|

End point description:

The EQ-5D-5L is a standardized measure of health status of the participant at the visit (same day) that provides a simple, generic measure of health for clinical and economic appraisal. Participant rates their current health state on a 0-100 VAS. It gets recorded on a vertical VAS in which the endpoints are labeled best imaginable health state is 100 (on the top) and worst imaginable health state is 0 (on the bottom). Higher scores of EQ VAS indicate better health. Positive change indicates improvement (better health). Participants in the Full Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline; Weeks 4, 12, and 24

| **End point values** | Filgotinib 200 mg | Filgotinib 100 mg | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 146 | 152 | 147 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline | 49.0 (± 24.7) | 46.0 (± 24.0) | 46.0 (± 22.4) | |
| Change from Baseline at Week 4 (N=144,144,144) | 10.0 (± 27.6) | 14.0 (± 26.8) | 6.0 (± 26.0) | |
| Change from Baseline at Week 12 (N=140,143,132) | 17.0 (± 30.9) | 19.0 (± 26.4) | 12.0 (± 26.5) | |
| Change from Baseline at Week 24 (N=122,110,90) | 22.0 (± 30.8) | 25.0 (± 26.7) | 17.0 (± 25.4) | |

## Statistical analyses

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| Comparison groups | Filgotinib 200 mg v Placebo |
|---|---|
| Number of subjects included in analysis | 293 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.009 [115] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | 6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 2 |
| upper limit | 11 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 2.5 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 299 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.003 [116] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | 7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 3 |
| upper limit | 12 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 2.5 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 293 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.003 [117] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | 8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 3 |
| upper limit | 13 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 2.6 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |
| Number of subjects included in analysis | 299 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.006 [118] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | 7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 2 |
| upper limit | 12 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 2.6 |

Notes:

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

| **Statistical analysis title** | Filgotinib 200 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 200 mg v Placebo |
| Number of subjects included in analysis | 293 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.002 [119] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | 9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 3 |
| upper limit | 15 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 2.9 |

Notes:

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

| **Statistical analysis title** | Filgotinib 100 mg vs Placebo |
|---|---|

Statistical analysis description:

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

| | |
|---|---|
| Comparison groups | Filgotinib 100 mg v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 299 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.007 [120] |
| Method | MMRM |
| Parameter estimate | Least Squares Mean Difference |
| Point estimate | 8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 2 |
| upper limit | 14 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 2.9 |

Notes:

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

## Secondary: Work Productivity and Activity Impairment-Rheumatoid Arthritis (WPAI-RA): Mean Percentage of Work Time Missed (Absenteeism) at Weeks 4, 12, and 24

| | |
|---|---|
| End point title | Work Productivity and Activity Impairment-Rheumatoid Arthritis (WPAI-RA): Mean Percentage of Work Time Missed (Absenteeism) at Weeks 4, 12, and 24 |

End point description:

The WPAI is a questionnaire that measures impairments in work activities in participants with RA which consists of 6 questions: Q1-currently employed; Q2-work time missed due to RA; Q3-work time missed due to other reasons; Q4-hours actually worked; Q5-degree RA affected productivity while working (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant from working); Q6-degree RA affected productivity in regular unpaid activities (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant`s daily activities). Outcomes are expressed as impairment percentages: Absenteeism (work time missed) due to RA: 100×{Q2/(Q2+Q4)}. Higher numbers indicate greater impairment and less productivity. Participants in the Full Analysis Set with available data were analyzed.

| | |
|---|---|
| End point type | Secondary |

End point timeframe:

Weeks 4, 12, and 24

| End point values | Filgotinib 200 mg | Filgotinib 100 mg | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 147 | 153 | 148 | |
| Units: percentage of work time missed | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 4 (N=39,53,46) | 8.8 (± 21.01) | 18.2 (± 30.93) | 14.3 (± 27.52) | |
| Week 12 (N=38,48,45) | 5.6 (± 13.79) | 14.6 (± 27.13) | 12.1 (± 24.39) | |
| Week 24 (N=40,38,30) | 7.6 (± 16.37) | 13.8 (± 26.23) | 8.5 (± 18.08) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: WPAI-RA: Mean Percentage of Impairment While Working Due to RA (Presenteeism) at Weeks 4, 12, and 24

| End point title | WPAI-RA: Mean Percentage of Impairment While Working Due to RA (Presenteeism) at Weeks 4, 12, and 24 |
|---|---|

End point description:

The WPAI is a questionnaire that measures impairments in work activities in participants with RA which consists of 6 questions: Q1-currently employed; Q2-work time missed due to RA; Q3-work time missed due to other reasons; Q4-hours actually worked; Q5-degree RA affected productivity while working (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant from working); Q6-degree RA affected productivity in regular unpaid activities (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant`s daily activities). Outcomes are expressed as impairment percentages: Presenteeism (impairment while working) due to RA: 100×{Q5/10}. Higher numbers indicate greater impairment and less productivity. Participants in the Full Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Weeks 4, 12, and 24

| End point values | Filgotinib 200 mg | Filgotinib 100 mg | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 147 | 153 | 148 | |
| Units: percentage of impairment while working | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 4 (N=38,49,43) | 27.4 (± 22.50) | 37.8 (± 25.43) | 48.6 (± 29.81) | |
| Week 12 (N=38,46,43) | 23.9 (± 20.99) | 34.8 (± 27.22) | 44.2 (± 29.21) | |
| Week 24 (N=40,36,30) | 28.0 (± 27.57) | 25.6 (± 22.10) | 36.7 (± 26.95) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: WPAI-RA: Mean Percentage of Overall Work Productivity Impairment Due to RA at Weeks 4, 12, and 24

| End point title | WPAI-RA: Mean Percentage of Overall Work Productivity Impairment Due to RA at Weeks 4, 12, and 24 |
|---|---|

End point description:

The WPAI is a questionnaire that measures impairments in work activities in participants with RA which consists of 6 questions: Q1-currently employed; Q2-work time missed due to RA; Q3-work time missed due to other reasons; Q4-hours actually worked; Q5-degree RA affected productivity while working (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant from working); Q6-degree RA affected productivity in regular unpaid activities (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant`s daily activities). Outcomes are expressed as impairment percentages: Work productivity loss (overall work impairment) due to RA: 100×{Q2/(Q2+Q4) + [(1-Q2/(Q2+Q4) × (Q5/10)]}. Higher numbers indicate greater impairment and less productivity. Participants in the Full Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Weeks 4, 12, and 24

| End point values | Filgotinib 200 mg | Filgotinib 100 mg | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 147 | 153 | 148 | |
| Units: percentage of overall work productivity | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 4 (N=38,49,43) | 30.8 (± 24.36) | 43.1 (± 27.82) | 51.3 (± 30.85) | |
| Week 12 (N=38,46,43) | 26.9 (± 24.20) | 39.5 (± 29.37) | 46.9 (± 30.63) | |
| Week 24 (N=40,36,30) | 31.7 (± 29.94) | 31.4 (± 25.65) | 39.8 (± 29.49) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: WPAI-RA: Mean Percentage of Activity Impairment Due to RA at Weeks 4, 12, and 24

| End point title | WPAI-RA: Mean Percentage of Activity Impairment Due to RA at Weeks 4, 12, and 24 |
|---|---|

End point description:

The WPAI is a questionnaire that measures impairments in work activities in participants with RA which consists of 6 questions: Q1-currently employed; Q2-work time missed due to RA; Q3-work time missed due to other reasons; Q4-hours actually worked; Q5-degree RA affected productivity while working (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant from working); Q6-degree RA affected productivity in regular unpaid activities (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant`s daily activities). Outcomes are expressed as impairment percentages: Activity impairment due to RA: 100×{Q6/10}. If Question 1 (Are you currently employed?) is 'NO', then only the activity impairment score can be determined. Higher numbers indicate greater impairment and less productivity. Participants in the Full Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Weeks 4, 12, and 24

| End point values | Filgotinib 200 mg | Filgotinib 100 mg | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 147 | 153 | 148 | |
| Units: percentage of activity impairment | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 4 (N=145,144,144) | 49.6 (± 26.56) | 49.9 (± 27.43) | 60.3 (± 25.49) | |
| Week 12 (N=141,143,132) | 40.3 (± 26.75) | 45.5 (± 28.23) | 53.0 (± 27.26) | |
| Week 24 (N=123,110,90) | 33.3 (± 24.61) | 37.5 (± 27.00) | 45.7 (± 25.57) | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in WPAI-RA: Mean Percentage of Work Time Missed (Absenteeism) at Weeks 4, 12, and 24

| End point title | Change From Baseline in WPAI-RA: Mean Percentage of Work Time Missed (Absenteeism) at Weeks 4, 12, and 24 |
|---|---|

End point description:

The WPAI is a questionnaire that measures impairments in work activities in participants with RA which consists of 6 questions: Q1-currently employed; Q2-work time missed due to RA; Q3-work time missed due to other reasons; Q4-hours actually worked; Q5-degree RA affected productivity while working (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant from working); Q6-degree RA affected productivity in regular unpaid activities (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant`s daily activities). Outcomes are expressed as impairment percentages: Absenteeism (work time missed) due to RA: 100×{Q2/(Q2+Q4)}. Higher numbers indicate greater impairment and less productivity. A negative change from baseline indicates improvement. Participants in the Full Analysis Set with available data

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline; Weeks 4, 12, and 24

| End point values | Filgotinib 200 mg | Filgotinib 100 mg | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 35 | 54 | 48 | |
| Units: percentage of work time missed | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline | 11.3 (± 16.31) | 19.2 (± 28.57) | 10.8 (± 25.65) | |
| Change from Baseline at Week 4 (N=34,48,43) | -4.3 (± 20.98) | -3.4 (± 24.57) | 4.0 (± 20.75) | |
| Change from Baseline at Week 12 (N=31,46,40) | -3.6 (± 17.60) | -7.0 (± 30.93) | 3.8 (± 18.40) | |
| Change from Baseline at Week 24 (N=29,34,25) | -4.6 (± 22.50) | -3.1 (± 34.28) | 3.7 (± 25.13) | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in WPAI-RA: Mean Percentage of Impairment While Working Due to RA (Presenteeism) at Weeks 4, 12, and 24

| End point title | Change From Baseline in WPAI-RA: Mean Percentage of Impairment While Working Due to RA (Presenteeism) at Weeks 4, 12, and 24 |
|---|---|

End point description:

The WPAI is a questionnaire that measures impairments in work activities in participants with RA which consists of 6 questions: Q1-currently employed; Q2-work time missed due to RA; Q3-work time missed due to other reasons; Q4-hours actually worked; Q5-degree RA affected productivity while working (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant from working); Q6-degree RA affected productivity in regular unpaid activities (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant`s daily activities). Outcomes are expressed as impairment percentages: Presenteeism (impairment while working) due to RA: 100×

{Q5/10}. Higher numbers indicate greater impairment and less productivity. A negative change from baseline indicates improvement. Participants in the Full Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline; Weeks 4, 12, and 24

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

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in WPAI-RA: Mean Percentage of Overall Work Productivity Impairment Due to RA at Weeks 4, 12, and 24

| End point title | Change From Baseline in WPAI-RA: Mean Percentage of Overall Work Productivity Impairment Due to RA at Weeks 4, 12, and 24 |
|---|---|

End point description:

The WPAI is a questionnaire that measures impairments in work activities in participants with RA which consists of 6 questions: Q1-currently employed; Q2-work time missed due to RA; Q3-work time missed due to other reasons; Q4-hours actually worked; Q5-degree RA affected productivity while working (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant from working); Q6-degree RA affected productivity in regular unpaid activities (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant`s daily activities). Outcomes are expressed as impairment percentages: Work productivity loss (overall work impairment) due to RA: 100×{Q2/(Q2+Q4) + [(1-Q2/(Q2+Q4) × (Q5/10)]}. Higher numbers indicate greater impairment and less productivity. A negative change from baseline indicates improvement. Participants in the Full Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline; Weeks 4, 12, and 24

| End point values | Filgotinib 200 mg | Filgotinib 100 mg | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 35 | 51 | 46 | |
| Units: percentage of overall work productivity | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline | 52.0 (± 24.02) | 55.8 (± 30.53) | 56.7 (± 27.60) | |
| Change from Baseline at Week 4 (N=34,45,40) | -20.9 (± 28.94) | -12.3 (± 28.05) | -3.4 (± 25.48) | |
| Change from Baseline at Week 12 (N=31,42,38) | -22.8 (± 29.20) | -19.5 (± 31.49) | -8.3 (± 20.16) | |
| Change from Baseline at Week 24 (N=29,31,25) | -20.5 (± 26.20) | -26.4 (± 29.87) | -16.7 (± 33.28) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in WPAI-RA: Mean Percentage of Activity Impairment Due to RA at Weeks 4, 12, and 24

| End point title | Change From Baseline in WPAI-RA: Mean Percentage of Activity Impairment Due to RA at Weeks 4, 12, and 24 |
|---|---|

End point description:

The WPAI is a questionnaire that measures impairments in work activities in participants with RA which consists of 6 questions: Q1-currently employed; Q2-work time missed due to RA; Q3-work time missed due to other reasons; Q4-hours actually worked; Q5-degree RA affected productivity while working (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant from working); Q6-degree RA affected productivity in regular unpaid activities (0-10 VAS, with 0 indicating no effect and 10 indicating RA completely prevented the participant`s daily activities). Outcomes are expressed as impairment percentages: Activity impairment due to RA: 100×{Q6/10}. If Question 1 (Are you currently employed?) is 'NO', then only the activity impairment score can be determined. Higher numbers indicate greater impairment and less productivity. A negative change from baseline indicates improvement. Participants in the Full Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline; Weeks 4, 12, and 24

| End point values | Filgotinib 200 mg | Filgotinib 100 mg | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 146 | 152 | 147 | |
| Units: percentage of activity impairment | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline | 65.6 (± 22.16) | 64.6 (± 23.07) | 65.4 (± 23.33) | |
| Change from Baseline at Week 4 (N=144,144,144) | -16.0 (± 24.64) | -14.3 (± 22.89) | -4.7 (± 25.06) | |
| Change from Baseline at Week 12 (N=140,143,132) | -25.0 (± 26.81) | -19.2 (± 28.32) | -11.3 (± 25.75) | |
| Change from Baseline at Week 24 (N=122,110,90) | -32.5 (± 27.37) | -27.1 (± 27.97) | -18.4 (± 31.23) | |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

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

Adverse event reporting additional description:

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

| | |
|---|---|
| Assessment type | Systematic |

### Dictionary used

| | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 21.0 |

### Reporting groups

| | |
|---|---|
| Reporting group title | Filgotinib 200 mg |

Reporting group description:

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

| | |
|---|---|
| Reporting group title | Filgotinib 100 mg |

Reporting group description:

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

| | |
|---|---|
| Reporting group title | Placebo |

Reporting group description:

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

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

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

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

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

| | | | |
|---|---|---|---|
| Cellulitis | | | |
| subjects affected / exposed | 1 / 147 (0.68%) | 0 / 153 (0.00%) | 0 / 148 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gallbladder empyema | | | |
| subjects affected / exposed | 0 / 147 (0.00%) | 1 / 153 (0.65%) | 0 / 148 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vulval abscess | | | |
| subjects affected / exposed | 0 / 147 (0.00%) | 1 / 153 (0.65%) | 0 / 148 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 1 / 147 (0.68%) | 0 / 153 (0.00%) | 1 / 148 (0.68%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 147 (0.00%) | 0 / 153 (0.00%) | 1 / 148 (0.68%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lactic acidosis | | | |
| subjects affected / exposed | 1 / 147 (0.68%) | 0 / 153 (0.00%) | 0 / 148 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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

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

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

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

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

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported