



## Clinical trial results:

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

#### Summary

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

#### Results information

|                                |                  |
|--------------------------------|------------------|
| Result version number          | v1               |
| This version publication date  | 03 February 2022 |
| First version publication date | 03 February 2022 |

#### Trial information

##### Trial identification

|                       |                |
|-----------------------|----------------|
| Sponsor protocol code | GS-US-431-4566 |
|-----------------------|----------------|

##### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT04115748 |
| WHO universal trial number (UTN)   | -           |

Notes:

#### Sponsors

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

Notes:

#### Paediatric regulatory details

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

Notes:

## Results analysis stage

|  |                 |
|--|-----------------|
| Analysis stage                                       | Final           |
| Date of interim/final analysis                       | 11 May 2021     |
| Is this the analysis of the primary completion data? | Yes             |
| Primary completion date                              | 19 January 2021 |
| Global end of trial reached?                         | Yes             |
| Global end of trial date                             | 11 May 2021     |
| Was the trial ended prematurely?                     | Yes             |

Notes:

## General information about the trial

Main objective of the trial:

The primary objective of this study was to evaluate the effect of filgotinib compared to placebo as assessed by the American College of Rheumatology 20% improvement (ACR20) response in participants with active psoriatic arthritis who are naive to biologic disease-modifying anti-rheumatic drug (DMARD) therapy. The study consists of two parts, the Main Study and the Long Term Extension (LTE).

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

|   |                  |
|---|------------------|
| Actual start date of recruitment                          | 03 December 2019 |
| Long term follow-up planned                               | No               |
| Independent data monitoring committee (IDMC) involvement? | Yes              |

Notes:

## Population of trial subjects

### Subjects enrolled per country

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

Notes:

| <b>Subjects enrolled per age group</b>    |    |
|---|----|
| In utero                                  | 0  |
| Preterm newborn - gestational age < 37 wk | 0  |
| Newborns (0-27 days)                      | 0  |
| Infants and toddlers (28 days-23 months)  | 0  |
| Children (2-11 years)                     | 0  |
| Adolescents (12-17 years)                 | 0  |
| Adults (18-64 years)                      | 57 |
| From 65 to 84 years                       | 10 |
| 85 years and over                         | 0  |

## Subject disposition

### Recruitment

Recruitment details:

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

### Pre-assignment

Screening details:

161 participants were screened.

### Period 1

|                              |                             |
|------------------------------|-----------------------------|
| Period 1 title               | Main Study (Up to 16 Weeks) |
| Is this the baseline period? | Yes                         |
| Allocation method            | Randomised - controlled     |
| Blinding used                | Double blind                |
| Roles blinded                | Subject, Investigator       |

### Arms

|                              |                                |
|------------------------------|--------------------------------|
| Are arms mutually exclusive? | Yes                            |
| <b>Arm title</b>             | Filgotinib 200 mg (Main Study) |

Arm description:

Filgotinib 200 milligrams (mg) tablet orally once daily + placebo to match (PTM) filgotinib 100 mg tablet orally once daily + PTM adalimumab subcutaneous (SC) injection every two weeks for 16 weeks.

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

Dosage and administration details:

200 mg administered once daily with or without food

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

Dosage and administration details:

PTM filgotinib 100 mg administered once daily with or without food

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

Dosage and administration details:

PTM adalimumab administered once every 2 weeks

|                  |                                |
|------------------|--------------------------------|
| <b>Arm title</b> | Filgotinib 100 mg (Main Study) |
|------------------|--------------------------------|

Arm description:

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

|          |              |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

|   |                               |
|---|-------------------------------|
| Investigational medicinal product name  | Filgotinib                    |
| Investigational medicinal product code  |                               |
| Other name  | GS-6034                       |
| Pharmaceutical forms  | Film-coated tablet            |
| Routes of administration  | Oral use                      |
| Dosage and administration details:  |                               |
| 100 mg administered orally once daily with or without food  |                               |
| Investigational medicinal product name  | PTM filgotinib                |
| Investigational medicinal product code  |                               |
| Other name  |                               |
| Pharmaceutical forms  | Film-coated tablet            |
| Routes of administration  | Oral use                      |
| Dosage and administration details:  |                               |
| PTM filgotinib 200 mg administered orally once daily with or without food   |                               |
| Investigational medicinal product name  | PTM adalimumab                |
| Investigational medicinal product code  |                               |
| Other name  |                               |
| Pharmaceutical forms  | Injection                     |
| Routes of administration  | Subcutaneous use              |
| Dosage and administration details:  |                               |
| PTM adalimumab administered once every 2 weeks  |                               |
| <b>Arm title</b>  | Adalimumab 40 mg (Main Study) |
| Arm description:  |                               |
| PTM filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily + Adalimumab 40 mg SC injection every two weeks for 16 weeks. |                               |
| Arm type  | Experimental                  |
| Investigational medicinal product name  | PTM Filgotinib                |
| Investigational medicinal product code  |                               |
| Other name  | GS-6034                       |
| Pharmaceutical forms  | Film-coated tablet            |
| Routes of administration  | Oral use                      |
| Dosage and administration details:  |                               |
| Administered once daily with or without food  |                               |
| Investigational medicinal product name  | Adalimumab                    |
| Investigational medicinal product code  |                               |
| Other name  |                               |
| Pharmaceutical forms  | Injection                     |
| Routes of administration  | Subcutaneous use              |
| Dosage and administration details:  |                               |
| Adalimumab 40 mg administered once every 2 weeks  |                               |
| <b>Arm title</b>  | Placebo (Main Study)          |
| Arm description:  |                               |
| PTM filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily + PTM adalimumab SC injection every two weeks for 16 weeks.   |                               |
| Arm type  | Placebo                       |
| Investigational medicinal product name  | PTM filgotinib                |
| Investigational medicinal product code  |                               |
| Other name  |                               |
| Pharmaceutical forms  | Film-coated tablet            |
| Routes of administration  | Oral use                      |
| Dosage and administration details:  |                               |
| Administered orally once daily with or without food   |                               |

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

Dosage and administration details:

Injection administered subcutaneously once every 2 weeks

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

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

## Period 2

|                              |                                 |
|------------------------------|---------------------------------|
| Period 2 title               | LTE (After 16 Weeks to Week 50) |
| Is this the baseline period? | No                              |
| Allocation method            | Randomised - controlled         |
| Blinding used                | Double blind                    |
| Roles blinded                | Subject, Investigator           |

## Arms

|                              |  |
|------------------------------|--|
| Are arms mutually exclusive? | Yes  |
| Arm title                    | Filgotinib 200 mg From Filgotinib 200 mg (LTE) |

Arm description:

Long term extension (LTE):

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

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

|  |  |
|--|--|
| Dosage and administration details:   |  |
| 200 mg administered once daily with or without food  |  |
| Investigational medicinal product name   | PTM filgotinib                                 |
| Investigational medicinal product code   |  |
| Other name   |  |
| Pharmaceutical forms   | Film-coated tablet                             |
| Routes of administration   | Oral use                                       |
| Dosage and administration details:   |  |
| PTM filgotinib 100 mg administered orally once daily with or without food  |  |
| <b>Arm title</b>   | Filgotinib 100 mg From Filgotinib 100 mg (LTE) |
| Arm description:   |  |
| Filgotinib 100 mg tablet orally once daily + PTM filgotinib 200 mg tablet orally once daily for up to 34 weeks. Participants received filgotinib 100 mg in the Main Study. |  |
| Arm type   | Experimental                                   |
| Investigational medicinal product name   | Filgotinib                                     |
| Investigational medicinal product code   |  |
| Other name   | GS-6034  |
| Pharmaceutical forms   | Film-coated tablet                             |
| Routes of administration   | Oral use                                       |
| Dosage and administration details:   |  |
| 100 mg administered once daily with or without food  |  |
| Investigational medicinal product name   | PTM filgotinib                                 |
| Investigational medicinal product code   |  |
| Other name   |  |
| Pharmaceutical forms   | Film-coated tablet                             |
| Routes of administration   | Oral use                                       |
| Dosage and administration details:   |  |
| PTM filgotinib 200 mg administered orally once daily with or without food  |  |
| <b>Arm title</b>   | Filgotinib 200 mg From Adalimumab 40 mg (LTE)  |
| Arm description:   |  |
| Filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily for up to 34 weeks. Participants received adalimumab 40 mg in the Main Study.  |  |
| Arm type   | Experimental                                   |
| Investigational medicinal product name   | Filgotinib                                     |
| Investigational medicinal product code   |  |
| Other name   | GS-6034  |
| Pharmaceutical forms   | Film-coated tablet                             |
| Routes of administration   | Oral use                                       |
| Dosage and administration details:   |  |
| 200 mg administered once daily with or without food  |  |
| Investigational medicinal product name   | PTM filgotinib                                 |
| Investigational medicinal product code   |  |
| Other name   |  |
| Pharmaceutical forms   | Film-coated tablet                             |
| Routes of administration   | Oral use                                       |
| Dosage and administration details:   |  |
| PTM filgotinib 100 mg administered orally once daily with or without food  |  |
| <b>Arm title</b>   | Filgotinib 100 mg From Adalimumab 40 mg (LTE)  |
| Arm description:   |  |
| Filgotinib 100 mg tablet orally once daily + PTM filgotinib 200 mg tablet orally once daily for up to 34 weeks. Participants received adalimumab 40 mg in the Main Study.  |  |
| Arm type   | Experimental                                   |

|  |                                      |
|--|--------------------------------------|
| Investigational medicinal product name   | Filgotinib                           |
| Investigational medicinal product code   |                                      |
| Other name   | GS-6034                              |
| Pharmaceutical forms   | Film-coated tablet                   |
| Routes of administration   | Oral use                             |
| Dosage and administration details:   |                                      |
| 100 mg administered once daily with or without food  |                                      |
| Investigational medicinal product name   | PTM filgotinib                       |
| Investigational medicinal product code   |                                      |
| Other name   |                                      |
| Pharmaceutical forms   | Film-coated tablet                   |
| Routes of administration   | Oral use                             |
| Dosage and administration details:   |                                      |
| PTM filgotinib 200 mg administered orally once daily with or without food  |                                      |
| <b>Arm title</b>   | Filgotinib 200 mg From Placebo (LTE) |
| Arm description:   |                                      |
| Filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily for up to 34 weeks. Participants received placebo in the Main Study. |                                      |
| Arm type   | Experimental                         |
| Investigational medicinal product name   | Filgotinib                           |
| Investigational medicinal product code   |                                      |
| Other name   | GS-6034                              |
| Pharmaceutical forms   | Film-coated tablet                   |
| Routes of administration   | Oral use                             |
| Dosage and administration details:   |                                      |
| 200 mg administered once daily with or without food  |                                      |
| Investigational medicinal product name   | PTM filgotinib                       |
| Investigational medicinal product code   |                                      |
| Other name   |                                      |
| Pharmaceutical forms   | Film-coated tablet                   |
| Routes of administration   | Oral use                             |
| Dosage and administration details:   |                                      |
| PTM filgotinib 100 mg administered orally once daily with or without food  |                                      |
| <b>Arm title</b>   | Filgotinib 100 mg From Placebo (LTE) |
| Arm description:   |                                      |
| Filgotinib 100 mg tablet orally once daily + PTM filgotinib 200 mg tablet orally once daily for up to 34 weeks. Participants received placebo in the Main Study. |                                      |
| Arm type   | Experimental                         |
| Investigational medicinal product name   | Filgotinib                           |
| Investigational medicinal product code   |                                      |
| Other name   | GS-6034                              |
| Pharmaceutical forms   | Film-coated tablet                   |
| Routes of administration   | Oral use                             |
| Dosage and administration details:   |                                      |
| 100 mg administered once daily with or without food  |                                      |
| Investigational medicinal product name   | PTM filgotinib                       |
| Investigational medicinal product code   |                                      |
| Other name   |                                      |
| Pharmaceutical forms   | Film-coated tablet                   |
| Routes of administration   | Oral use                             |
| Dosage and administration details:   |                                      |
| PTM filgotinib 200 mg administered orally once daily with or without food  |                                      |



| <b>Number of subjects in period 2</b> | Filgotinib 200 mg<br>From Filgotinib 200 mg (LTE) | Filgotinib 100 mg<br>From Filgotinib 100 mg (LTE) | Filgotinib 200 mg<br>From Adalimumab 40 mg (LTE) |
|---------------------------------------|---|---|--|
| Started                               | 4   | 3   | 1  |
| Completed                             | 0   | 0   | 0  |
| Not completed                         | 4   | 3   | 1  |
| Adverse event, non-fatal              | -   | -   | -  |
| Study terminated by sponsor           | 4   | 3   | 1  |

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

## Baseline characteristics

### Reporting groups

|  |                                |
|--|--------------------------------|
| Reporting group title  | Filgotinib 200 mg (Main Study) |
| Reporting group description:<br>Filgotinib 200 milligrams (mg) tablet orally once daily + placebo to match (PTM) filgotinib 100 mg tablet orally once daily + PTM adalimumab subcutaneous (SC) injection every two weeks for 16 weeks. |                                |
| Reporting group title  | Filgotinib 100 mg (Main Study) |
| Reporting group description:<br>Filgotinib 100 mg tablet orally once daily + PTM filgotinib 200 mg tablet orally once daily + PTM Adalimumab SC injection every two weeks for 16 weeks.  |                                |
| Reporting group title  | Adalimumab 40 mg (Main Study)  |
| Reporting group description:<br>PTM filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily + Adalimumab 40 mg SC injection every two weeks for 16 weeks.  |                                |
| Reporting group title  | Placebo (Main Study)           |
| Reporting group description:<br>PTM filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily + PTM adalimumab SC injection every two weeks for 16 weeks.  |                                |

| Reporting group values | Filgotinib 200 mg<br>(Main Study) | Filgotinib 100 mg<br>(Main Study) | Adalimumab 40 mg<br>(Main Study) |
|------------------------|-----------------------------------|-----------------------------------|----------------------------------|
| Number of subjects     | 19                                | 19                                | 9                                |
| Age categorical        |                                   |                                   |                                  |
| Units: Subjects        |                                   |                                   |                                  |

|   |        |        |        |
|---|--------|--------|--------|
| Age continuous                            |        |        |        |
| Units: years                              |        |        |        |
| arithmetic mean                           | 49     | 46     | 50     |
| standard deviation                        | ± 13.4 | ± 10.4 | ± 10.4 |
| Gender categorical                        |        |        |        |
| Units: Subjects                           |        |        |        |
| Female                                    | 9      | 7      | 4      |
| Male                                      | 10     | 12     | 5      |
| Race                                      |        |        |        |
| Units: Subjects                           |        |        |        |
| American Indian or Alaska Native          | 0      | 0      | 0      |
| Asian                                     | 1      | 1      | 1      |
| Native Hawaiian or Other Pacific Islander | 0      | 0      | 0      |
| Black or African American                 | 0      | 0      | 0      |
| White                                     | 18     | 18     | 8      |
| More than one race                        | 0      | 0      | 0      |
| Ethnicity                                 |        |        |        |
| Units: Subjects                           |        |        |        |
| Hispanic or Latino                        | 1      | 0      | 0      |
| Not Hispanic or Latino                    | 18     | 19     | 9      |
| Unknown or Not Reported                   | 0      | 0      | 0      |

| Reporting group values | Placebo (Main Study) | Total |  |
|------------------------|----------------------|-------|--|
|------------------------|----------------------|-------|--|

|   |        |    |  |
|---|--------|----|--|
| Number of subjects                        | 20     | 67 |  |
| Age categorical                           |        |    |  |
| Units: Subjects                           |        |    |  |
| Age continuous                            |        |    |  |
| Units: years                              |        |    |  |
| arithmetic mean                           | 47     |    |  |
| standard deviation                        | ± 15.8 | -  |  |
| Gender categorical                        |        |    |  |
| Units: Subjects                           |        |    |  |
| Female                                    | 10     | 30 |  |
| Male                                      | 10     | 37 |  |
| Race                                      |        |    |  |
| Units: Subjects                           |        |    |  |
| American Indian or Alaska Native          | 0      | 0  |  |
| Asian                                     | 0      | 3  |  |
| Native Hawaiian or Other Pacific Islander | 0      | 0  |  |
| Black or African American                 | 0      | 0  |  |
| White                                     | 20     | 64 |  |
| More than one race                        | 0      | 0  |  |
| Ethnicity                                 |        |    |  |
| Units: Subjects                           |        |    |  |
| Hispanic or Latino                        | 1      | 2  |  |
| Not Hispanic or Latino                    | 19     | 65 |  |
| Unknown or Not Reported                   | 0      | 0  |  |

## End points

### End points reporting groups

|  |  |
|--|--|
| Reporting group title  | Filgotinib 200 mg (Main Study)                 |
| Reporting group description:<br>Filgotinib 200 milligrams (mg) tablet orally once daily + placebo to match (PTM) filgotinib 100 mg tablet orally once daily + PTM adalimumab subcutaneous (SC) injection every two weeks for 16 weeks.   |  |
| Reporting group title  | Filgotinib 100 mg (Main Study)                 |
| Reporting group description:<br>Filgotinib 100 mg tablet orally once daily + PTM filgotinib 200 mg tablet orally once daily + PTM Adalimumab SC injection every two weeks for 16 weeks.  |  |
| Reporting group title  | Adalimumab 40 mg (Main Study)                  |
| Reporting group description:<br>PTM filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily + Adalimumab 40 mg SC injection every two weeks for 16 weeks.  |  |
| Reporting group title  | Placebo (Main Study)                           |
| Reporting group description:<br>PTM filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily + PTM adalimumab SC injection every two weeks for 16 weeks.  |  |
| Reporting group title  | Filgotinib 200 mg From Filgotinib 200 mg (LTE) |
| Reporting group description:<br>Long term extension (LTE):<br>Filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily for up to 34 weeks. Participants received filgotinib 200 mg in the Main Study. |  |
| Reporting group title  | Filgotinib 100 mg From Filgotinib 100 mg (LTE) |
| Reporting group description:<br>Filgotinib 100 mg tablet orally once daily + PTM filgotinib 200 mg tablet orally once daily for up to 34 weeks. Participants received filgotinib 100 mg in the Main Study.                               |  |
| Reporting group title  | Filgotinib 200 mg From Adalimumab 40 mg (LTE)  |
| Reporting group description:<br>Filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily for up to 34 weeks. Participants received adalimumab 40 mg in the Main Study.                                |  |
| Reporting group title  | Filgotinib 100 mg From Adalimumab 40 mg (LTE)  |
| Reporting group description:<br>Filgotinib 100 mg tablet orally once daily + PTM filgotinib 200 mg tablet orally once daily for up to 34 weeks. Participants received adalimumab 40 mg in the Main Study.                                |  |
| Reporting group title  | Filgotinib 200 mg From Placebo (LTE)           |
| Reporting group description:<br>Filgotinib 200 mg tablet orally once daily + PTM filgotinib 100 mg tablet orally once daily for up to 34 weeks. Participants received placebo in the Main Study.   |  |
| Reporting group title  | Filgotinib 100 mg From Placebo (LTE)           |
| Reporting group description:<br>Filgotinib 100 mg tablet orally once daily + PTM filgotinib 200 mg tablet orally once daily for up to 34 weeks. Participants received placebo in the Main Study.   |  |

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

|                 |   |
|-----------------|---|
| End point title | Percentage of Participants who Achieved an American College of Rheumatology (ACR) 20% Improvement Response at Week 12 |
|-----------------|---|

#### End point description:

ACR20 response is achieved when the participant has:  $\geq 20\%$  improvement (reduction) from baseline in tender joint count based on 68 joints (TJC68), swollen joint count based on 66 joints (SJC66) and in at

least 3 of the following 5 items: patient's global assessment of disease activity (PGADA) using a visual analogue scale (VAS) on a scale of 0 (very well) to 100 (very poor); physician's global assessment of disease activity (PHGADA) using a VAS on a scale of 0 (no disease activity) to 100 (maximum disease activity); health assessment questionnaire-disability index (HAQ-DI) inclusive of activities scored on a scale of 0 (no disability) to 3 (completely disabled); HAQ-DI pain assessment using VAS on a scale of 0 (no pain) to 100 (serious pain), and high-sensitivity C-reactive protein (hsCRP). Full Analysis Set (FAS) included all randomized participants who took at least 1 dose of study drug.

|                      |         |
|----------------------|---------|
| End point type       | Primary |
| End point timeframe: |         |
| Week 12              |         |

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

## Statistical analyses

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

Notes:

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

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.23 <sup>[2]</sup>                                 |
| Method                                  | Multiple imputation method                            |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 18.4  |

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

Notes:

[2] - The stratification factors (geographic region, concurrent use of csDMARD(s) and/or apremilast at randomization, prior use of bioDMARD(s)) and treatment groups were included in the imputation model as covariates.

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

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

End point description:

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

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

End point timeframe:

Baseline, 4, and 16 weeks

| End point values                              | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|---|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                            | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed                   | 19                             | 19                             | 8                             | 20                   |
| Units: score on a scale                       |                                |                                |                               |                      |
| arithmetic mean (standard deviation)          |                                |                                |                               |                      |
| Baseline                                      | 5.9 (± 1.32)                   | 5.3 (± 0.99)                   | 5.5 (± 1.05)                  | 5.5 (± 1.05)         |
| Change From Baseline at Wk 4<br>N=19,18,8,20  | -1.5 (± 0.62)                  | -1.0 (± 0.99)                  | -1.3 (± 0.66)                 | -0.3 (± 0.80)        |
| Change From Baseline at Wk 16<br>N=18,19,8,20 | -2.5 (± 1.26)                  | -2.0 (± 1.48)                  | -2.6 (± 1.37)                 | -1.0 (± 1.04)        |

## Statistical analyses

No statistical analyses for this end point

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

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

End point description:

MDA is a measure to indicate disease remission, and is based on a composite score of 7 domains. A

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

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

End point timeframe:

Weeks 4, 8, 12, and 16

| End point values                  | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|-----------------------------------|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed       | 19                             | 19                             | 9                             | 20                   |
| Units: percentage of participants |                                |                                |                               |                      |
| number (confidence interval 95%)  |                                |                                |                               |                      |
| Wk 4 N=19,18,9,20                 | 21.1 (0.1 to 42.0)             | 16.7 (0.0 to 36.7)             | 22.2 (0.0 to 54.9)            | 5.0 (0.0 to 17.1)    |
| Wk 8 N=19,19,9,19                 | 26.3 (3.9 to 48.7)             | 31.6 (8.0 to 55.1)             | 22.2 (0.0 to 54.9)            | 15.8 (0.0 to 34.8)   |
| Wk 12 N=18,19,8,19                | 44.4 (18.7 to 70.2)            | 47.4 (22.3 to 72.5)            | 37.5 (0.0 to 77.3)            | 15.8 (0.0 to 34.8)   |
| Wk 16 N=18,19,8,20                | 27.8 (4.3 to 51.2)             | 36.8 (12.5 to 61.2)            | 37.5 (0.0 to 77.3)            | 20.0 (0.0 to 40.0)   |

## Statistical analyses

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

Statistical analysis description:

Week 4

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.17 <sup>[3]</sup>                                 |
| Method                                  | Regression, Logistic                                  |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 16.1  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -9.7  |
| upper limit                             | 41.9  |

Notes:

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

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 4                                  |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.27 <sup>[4]</sup>                                 |
| Method                                  | Regression, Logistic                                  |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 11.7  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -13.3   |
| upper limit                             | 36.6  |

Notes:

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

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 8                                  |   |
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.42 <sup>[5]</sup>                                 |
| Method                                  | Regression, Logistic                                  |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 10.5  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -20.4   |
| upper limit                             | 41.5  |

Notes:

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

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



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

Notes:

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

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 8                                  |   |
| Comparison groups                       | Placebo (Main Study) v Filgotinib 100 mg (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.26 <sup>[7]</sup>                                 |
| Method                                  | Regression, Logistic                                  |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 15.8  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -16   |
| upper limit                             | 47.6  |

Notes:

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

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Comparison groups                       | Placebo (Main Study) v Filgotinib 200 mg (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.58 <sup>[8]</sup>                                 |
| Method                                  | Regression, Logistic                                  |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 7.8   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -24.6   |
| upper limit                             | 40.2  |

Notes:

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

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description: |   |
| Week 12                           |   |
| Comparison groups                 | Placebo (Main Study) v Filgotinib 100 mg (Main Study) |

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

Notes:

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

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 16                                 |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.27 <sup>[10]</sup>                                |
| Method                                  | Regression, Logistic                                  |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 16.8  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -16.2   |
| upper limit                             | 49.9  |

Notes:

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

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

|   |   |
|---|---|
| End point title   | Percentage of Participants Who Achieved Very Low Disease Activity (VLDA) Response at Weeks 4, 8, 12, and 16 |
| End point description:  |   |
| VLDA is a measure to indicate disease remission, and is based on a composite score of 7 domains. A participant is considered as having achieved the VLDA if the participant fulfills all the seven criteria: TJC68 $\leq 1$ ; SJC66 $\leq 1$ ; PASI score $\leq 1$ for participants with psoriasis covering BSA $< 3\%$ [PASI evaluates the severity and extent of psoriasis. In PASI, body is divided into four parts, head and neck, upper limb, trunk and lower limbs. Each area is assessed for erythema, induration and scaling, each rated on a scale of 0 to 4. The total score ranges from 0 (no disease) to 72 (maximal disease)]; PGAPI $\leq 15$ [using VAS on a scale of 0 (no pain) to (serious pain)]; PGADA $\leq 20$ [using VAS on a scale of 0 (very well) to 100 (very poor)]; HAQ-DI score $\leq 0.5$ ; LEI score $\leq 1$ with participants with enthesitis at baseline. Participants in the FAS with available data were analyzed. |   |
| End point type  | Secondary   |
| End point timeframe:  |   |
| Weeks 4, 8, 12, and 16  |   |

| <b>End point values</b>           | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|-----------------------------------|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed       | 19                             | 19                             | 9                             | 20                   |
| Units: percentage of participants |                                |                                |                               |                      |
| number (confidence interval 95%)  |                                |                                |                               |                      |
| Wk 4 N=19,18,9,20                 | 5.3 (0.0 to 17.9)              | 0 (0.0 to 2.8)                 | 0 (0.0 to 5.6)                | 0 (0.0 to 2.5)       |
| Wk 8 N=19,19,9,19                 | 5.3 (0.0 to 17.9)              | 0 (0.0 to 2.6)                 | 0 (0.0 to 5.6)                | 10.5 (0.0 to 27.0)   |
| Wk 12 N=18,19,8,19                | 11.1 (0.0 to 28.4)             | 5.3 (0.0 to 17.9)              | 12.5 (0.0 to 41.7)            | 5.3 (0.0 to 17.9)    |
| Wk 16 N=18,19,9,20                | 5.6 (0.0 to 18.9)              | 10.5 (0.0 to 27.0)             | 11.1 (0.0 to 37.2)            | 0 (0.0 to 2.5)       |

### Statistical analyses

|   |   |
|---|---|
| <b>Statistical analysis title</b>           | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:<br>Week 4 |   |
| Comparison groups                           | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis     | 39  |
| Analysis specification                      | Pre-specified   |
| Analysis type                               | superiority   |
| Parameter estimate                          | Difference in response rates                          |
| Point estimate                              | 5.3   |
| Confidence interval                         |   |
| level                                       | 95 %  |
| sides                                       | 2-sided   |
| lower limit                                 | -9.9  |
| upper limit                                 | 20.4  |

|   |   |
|---|---|
| <b>Statistical analysis title</b>           | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:<br>Week 4 |   |
| Comparison groups                           | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis     | 39  |
| Analysis specification                      | Pre-specified   |
| Analysis type                               | superiority   |
| Parameter estimate                          | Difference in response rates                          |
| Point estimate                              | 0   |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | -5.3    |
| upper limit         | 5.3     |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 8                                  |   |
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | -5.3  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -27.6   |
| upper limit                             | 17.1  |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 8                                  |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | -10.5   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -29.6   |
| upper limit                             | 8.5   |

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Comparison groups                 | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |

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

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 12                                 |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 0   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -19.5   |
| upper limit                             | 19.5  |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 16                                 |   |
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 5.6   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -10.3   |
| upper limit                             | 21.4  |

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Fil 100 mg (Main Study) vs Placebo (Main Study) |
| Statistical analysis description: |   |
| Week 16                           |   |

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 10.5  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -8.4  |
| upper limit                             | 29.5  |

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

|   |  |
|---|--|
| End point title   | Change From Baseline in Disease Activity in Psoriatic Arthritis (DAPSA) at Weeks 2, 4, 8, 12, and 16 |
| End point description:  |  |
| DAPSA is calculated by summing the following components: TJC68; SJC66; PGADA [using VAS on a scale of 0 (very well) to 100 very poor)]; PGAPI [using a VAS on a scale of 0 (no pain) to 100 (serious pain)] and CRP. DAPSA scores 0-4 = remission, 5-14 = low disease activity, 15-28 = moderate disease activity, and >28 = high disease activity. A negative change from baseline indicates improvement. Participants in the FAS with available data were analyzed. |  |
| End point type  | Secondary  |
| End point timeframe:  |  |
| Baseline, 2, 4, 8, 12, and 16 weeks   |  |

| End point values                              | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|---|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                            | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed                   | 19                             | 19                             | 8                             | 20                   |
| Units: score on a scale                       |                                |                                |                               |                      |
| arithmetic mean (standard deviation)          |                                |                                |                               |                      |
| Baseline                                      | 48.0 (± 25.55)                 | 30.3 (± 10.43)                 | 38.8 (± 20.82)                | 33.8 (± 17.55)       |
| Change From Baseline at Wk 2<br>N=19,18,8,19  | -12.5 (± 11.96)                | -5.3 (± 9.12)                  | -10.9 (± 8.39)                | -7.5 (± 11.72)       |
| Change From Baseline at Wk 4<br>N=19,18,8,20  | -19.3 (± 14.30)                | -9.4 (± 12.13)                 | -14.2 (± 10.45)               | -6.5 (± 8.41)        |
| Change From Baseline at Wk 8<br>N=19,19,8,19  | -28.4 (± 15.67)                | -12.4 (± 11.06)                | -17.8 (± 12.96)               | -10.6 (± 8.87)       |
| Change From Baseline at Wk 12<br>N=18,19,7,19 | -27.4 (± 17.09)                | -18.0 (± 11.00)                | -25.2 (± 16.60)               | -9.3 (± 9.81)        |
| Change From Baseline at Wk 16<br>N=18,19,8,20 | -28.1 (± 13.42)                | -17.4 (± 12.16)                | -25.1 (± 14.55)               | -11.3 (± 12.18)      |

## Statistical analyses

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

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

## End point description:

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

|                      |                                     |
|----------------------|-------------------------------------|
| End point type       | Secondary                           |
| End point timeframe: | Baseline, 2, 4, 8, 12, and 16 weeks |

| End point values                           | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|--|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                         | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed                | 8                              | 5                              | 4                             | 4                    |
| Units: score on a scale                    |                                |                                |                               |                      |
| arithmetic mean (standard deviation)       |                                |                                |                               |                      |
| Baseline                                   | 3 ( $\pm$ 1.2)                 | 2 ( $\pm$ 0.8)                 | 2 ( $\pm$ 0.5)                | 2 ( $\pm$ 0.5)       |
| Change From Baseline at Wk 2<br>N=8,5,4,3  | -1 ( $\pm$ 0.5)                | 0 ( $\pm$ 0.0)                 | 0 ( $\pm$ 0.5)                | 0 ( $\pm$ 0.0)       |
| Change From Baseline at Wk 4               | -1 ( $\pm$ 1.0)                | 0 ( $\pm$ 0.5)                 | -1 ( $\pm$ 1.0)               | 0 ( $\pm$ 0.5)       |
| Change From Baseline at Wk 8               | -1 ( $\pm$ 1.0)                | -1 ( $\pm$ 0.7)                | -1 ( $\pm$ 0.8)               | -1 ( $\pm$ 1.0)      |
| Change From Baseline at Wk 12<br>N=7,5,3,4 | -1 ( $\pm$ 1.3)                | -1 ( $\pm$ 1.1)                | -2 ( $\pm$ 0.6)               | 0 ( $\pm$ 1.3)       |
| Change From Baseline at Wk 16              | -1 ( $\pm$ 0.7)                | -1 ( $\pm$ 0.8)                | -2 ( $\pm$ 0.6)               | -1 ( $\pm$ 1.4)      |

**Statistical analyses**

No statistical analyses for this end point

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

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

## End point description:

mNAPSI is used to assess each nail abnormality for each of the participant's nails. Three features or groups of features (pitting, onycholysis together with oil-drop dyschromia, and crumbling) of each fingernail are graded on a scale from 0 (no onycholysis together with oil-drop dyschromia, no pitting, no crumbling) to 3 (>30 onycholysis together with oil-drop dyschromia, >50 pitting, >50% crumbling).

Four features (leukonychia, splinter, hemorrhages, hyperkeratosis, and red spots in the lunula) are graded with the score of 1 = present or 0 = absent for each fingernail. Each finger has a score between 0 and 13. The total mNAPSI score is the sum of all abnormalities individual score across all fingers, and the total mNAPSI score ranges from 0 to 130. Lower numbers indicate fewer nail abnormalities. A negative change from baseline indicates improvement. Participants in the FAS with psoriatic nail involvement at baseline and with available data were analyzed.

|                                  |           |
|----------------------------------|-----------|
| End point type                   | Secondary |
| End point timeframe:             |           |
| Baseline, 4, 8, 12, and 16 weeks |           |

| End point values                             | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|--|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                           | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed                  | 9                              | 11                             | 6                             | 13                   |
| Units: score on a scale                      |                                |                                |                               |                      |
| arithmetic mean (standard deviation)         |                                |                                |                               |                      |
| Baseline                                     | 19 (± 15.1)                    | 15 (± 12.9)                    | 24 (± 32.3)                   | 14 (± 12.9)          |
| Change From Baseline at Wk 4<br>N=9,10,6,13  | -3 (± 3.5)                     | 1 (± 4.5)                      | -3 (± 10.0)                   | 0 (± 8.2)            |
| Change From Baseline at Wk 8<br>N=9,11,6,12  | -3 (± 5.1)                     | -1 (± 5.9)                     | -6 (± 19.4)                   | -2 (± 5.0)           |
| Change From Baseline at Wk 12<br>N=9,11,5,12 | -4 (± 6.0)                     | 0 (± 5.4)                      | -9 (± 23.2)                   | -3 (± 10.6)          |
| Change From Baseline at Wk 16<br>N=8,11,6,13 | 0 (± 10.8)                     | -3 (± 9.6)                     | -14 (± 23.7)                  | -2 (± 9.2)           |

## Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

|                                  |           |
|----------------------------------|-----------|
| End point type                   | Secondary |
| End point timeframe:             |           |
| Baseline, 4, 8, 12, and 16 weeks |           |



| End point values                             | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|--|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                           | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed                  | 10                             | 9                              | 6                             | 11                   |
| Units: score on a scale                      |                                |                                |                               |                      |
| arithmetic mean (standard deviation)         |                                |                                |                               |                      |
| Baseline                                     | 2 (± 1.6)                      | 2 (± 1.4)                      | 2 (± 1.4)                     | 2 (± 1.7)            |
| Change From Baseline at Wk 4                 | -1 (± 0.8)                     | 0 (± 0.7)                      | -1 (± 1.1)                    | 0 (± 1.5)            |
| Change From Baseline at Wk 8<br>N=10,9,6,10  | -1 (± 0.8)                     | -1 (± 1.2)                     | -2 (± 1.5)                    | 0 (± 1.3)            |
| Change From Baseline at Wk 12<br>N=10,9,5,10 | -1 (± 1.4)                     | -1 (± 1.6)                     | -2 (± 1.8)                    | 0 (± 1.2)            |
| Change From Baseline at Wk 16                | -1 (± 1.2)                     | -1 (± 1.5)                     | -2 (± 1.6)                    | 0 (± 1.5)            |

### Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

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

End point timeframe:

Baseline, 4, and 16 weeks

| End point values                             | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|--|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                           | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed                  | 19                             | 19                             | 8                             | 20                   |
| Units: score on a scale                      |                                |                                |                               |                      |
| arithmetic mean (standard deviation)         |                                |                                |                               |                      |
| Baseline                                     | 4.82 (± 1.857)                 | 4.46 (± 2.115)                 | 5.28 (± 1.765)                | 4.44 (± 2.071)       |
| Change From Baseline at Wk 4<br>N=19,18,8,20 | -1.71 (± 1.282)                | -1.39 (± 1.214)                | -1.73 (± 1.645)               | -0.10 (± 1.520)      |
| Change From Baseline at Wk 16                | -2.06 (± 1.314)                | -2.04 (± 1.740)                | -2.56 (± 2.062)               | -0.52 (± 2.176)      |

## Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

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

End point timeframe:

Weeks 4, and 16

| End point values                  | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|-----------------------------------|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed       | 19                             | 19                             | 9                             | 20                   |
| Units: percentage of participants |                                |                                |                               |                      |
| number (confidence interval 95%)  |                                |                                |                               |                      |
| Wk 4 N=19,18,8,20                 | 21.1 (0.1 to 42.0)             | 11.1 (0.0 to 28.4)             | 0 (0.0 to 6.3)                | 5.0 (0.0 to 17.1)    |
| Wk 16 N=18,19,8,20                | 38.9 (13.6 to 64.2)            | 42.1 (17.3 to 66.9)            | 50.0 (9.1 to 90.9)            | 15.0 (0.0 to 33.1)   |

## Statistical analyses

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

Statistical analysis description:

Week 4

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 16.1  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -9.7  |
| upper limit                             | 41.9  |

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

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main St           |
| Statistical analysis description:       |   |
| Week 4                                  |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 6.1   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -16.5   |
| upper limit                             | 28.8  |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 16                                 |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 27.1  |

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

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

|                 |  |
|-----------------|--|
| End point title | Percentage of Participants Who Achieved PASDAS Remission at Weeks 4 and 16 |
|-----------------|--|

End point description:

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

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

End point timeframe:

Weeks 4, and 16

| End point values                  | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|-----------------------------------|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed       | 19                             | 19                             | 9                             | 20                   |
| Units: percentage of participants |                                |                                |                               |                      |
| number (confidence interval 95%)  |                                |                                |                               |                      |
| Wk 4 N=19,18,8,20                 | 0 (0.0 to 2.6)                 | 0 (0.0 to 2.8)                 | 0 (0.0 to 6.3)                | 0 (0.0 to 2.5)       |
| Wk 16 N=18,19,8,20                | 16.7 (0.0 to 36.7)             | 10.5 (0.0 to 27.0)             | 12.5 (0.0 to 41.7)            | 5.0 (0.0 to 17.1)    |

## Statistical analyses

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

Statistical analysis description:

Week 4

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

|   |                              |
|---|------------------------------|
| Number of subjects included in analysis | 39                           |
| Analysis specification                  | Pre-specified                |
| Analysis type                           | superiority                  |
| Parameter estimate                      | Difference in response rates |
| Point estimate                          | 0                            |
| Confidence interval                     |                              |
| level                                   | 95 %                         |
| sides                                   | 2-sided                      |
| lower limit                             | -5.3                         |
| upper limit                             | 5.3                          |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 4                                  |   |
| Comparison groups                       | Placebo (Main Study) v Filgotinib 200 mg (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 0   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -5.1  |
| upper limit                             | 5.1   |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 16                                 |   |
| Comparison groups                       | Placebo (Main Study) v Filgotinib 100 mg (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 5.5   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -16.4   |
| upper limit                             | 27.4  |

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Fil 200 mg (Main Study) vs Placebo (Main Study) |
| Statistical analysis description: |   |
| Week 16                           |   |

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

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

|                 |   |
|-----------------|---|
| End point title | Percentage of Participants Who Achieved an American College of Rheumatology 20% Improvement Response at Weeks 2, 4, 8, 12, and 16 |
|-----------------|---|

### End point description:

ACR20 response is achieved when the participant has:  $\geq 20\%$  improvement (reduction) from baseline in TJC68, SJC66 and in at least 3 of the following 5 items: PGADA using a VAS on a scale of 0 (very well) to 100 (very poor); PHGADA using a VAS on a scale of 0 (no disease activity) to 100 (maximum disease activity); HAQ-DI inclusive of activities scored on a scale of 0 (no disability) to 3 (completely disabled); HAQ-DI pain assessment using VAS on a scale of 0 (no pain) to 100 (serious pain); and hsCRP.

Participants with missing outcomes were set as non-responders. Participants in the FAS with available data were analyzed.

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

### End point timeframe:

Weeks 2, 4, 8, 12, and 16

| End point values                  | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|-----------------------------------|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed       | 19                             | 19                             | 9                             | 20                   |
| Units: percentage of participants |                                |                                |                               |                      |
| number (confidence interval 95%)  |                                |                                |                               |                      |
| Wk 2 N=19,18,9,19                 | 26.3 (3.9 to 48.7)             | 5.6 (0.0 to 18.9)              | 11.1 (0.0 to 37.2)            | 10.5 (0.0 to 27.0)   |
| Wk 4 N=19,18,9,20                 | 52.6 (27.5 to 77.7)            | 27.8 (4.3 to 51.2)             | 33.3 (0.0 to 69.7)            | 10.0 (0.0 to 25.6)   |
| Wk 8 N=19,19,9,19                 | 73.7 (51.3 to 96.1)            | 36.8 (12.5 to 61.2)            | 55.6 (17.5 to 93.6)           | 31.6 (8.0 to 55.1)   |
| Wk 12 N=18,19,8,19                | 77.8 (55.8 to 99.8)            | 63.2 (38.8 to 87.5)            | 75.0 (38.7 to 100.0)          | 42.1 (17.3 to 66.9)  |
| Wk 16 N=18,19,9,20                | 88.9 (71.6 to 100.0)           | 52.6 (27.5 to 77.7)            | 77.8 (45.1 to 100.0)          | 45.0 (20.7 to 69.3)  |

## Statistical analyses

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 2                                  |   |
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.2 <sup>[11]</sup>                                 |
| Method                                  | Regression, Logistic                                  |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 15.8  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -13.6   |
| upper limit                             | 45.2  |

Notes:

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

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 2                                  |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.6 <sup>[12]</sup>                                 |
| Method                                  | Regression, Logistic                                  |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | -5  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -27.8   |
| upper limit                             | 17.8  |

Notes:

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

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 4                                  |   |
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.008 <sup>[13]</sup>                               |
| Method                                  | Regression, Logistic                                  |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 42.6  |

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

Notes:

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

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Fil 100 mg (Main Study) vs Placebo (Main Study) |
|-----------------------------------|---|

Statistical analysis description:

Week 4

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.17 <sup>[14]</sup>                                |
| Method                                  | Regression, Logistic                                  |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 17.8  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -12   |
| upper limit                             | 47.6  |

Notes:

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

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Fil 200 mg (Main Study) vs Placebo (Main Study) |
|-----------------------------------|---|

Statistical analysis description:

Week 8

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.011 <sup>[15]</sup>                               |
| Method                                  | Regression, Logistic                                  |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 42.1  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 8.1   |
| upper limit                             | 76.2  |

Notes:

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

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Fil 100 mg (Main Study) vs Placebo (Main Study) |
|-----------------------------------|---|

Statistical analysis description:

Week 8

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



|   |                              |
|---|------------------------------|
| Number of subjects included in analysis | 39                           |
| Analysis specification                  | Pre-specified                |
| Analysis type                           | superiority                  |
| P-value                                 | = 0.69 <sup>[16]</sup>       |
| Method                                  | Regression, Logistic         |
| Parameter estimate                      | Difference in response rates |
| Point estimate                          | 5.3                          |
| Confidence interval                     |                              |
| level                                   | 95 %                         |
| sides                                   | 2-sided                      |
| lower limit                             | -30.1                        |
| upper limit                             | 40.6                         |

Notes:

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

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 12                                 |   |
| Comparison groups                       | Placebo (Main Study) v Filgotinib 100 mg (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.19 <sup>[17]</sup>                                |
| Method                                  | Regression, Logistic                                  |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 21.1  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -15.2   |
| upper limit                             | 57.4  |

Notes:

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

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 12                                 |   |
| Comparison groups                       | Placebo (Main Study) v Filgotinib 200 mg (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.033 <sup>[18]</sup>                               |
| Method                                  | Regression, Logistic                                  |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 35.7  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 0.9   |
| upper limit                             | 70.4  |

Notes:

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

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

Notes:

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

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

Notes:

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

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

|                 |   |
|-----------------|---|
| End point title | Percentage of Participants Who Achieved an American College of Rheumatology 50% Improvement Response at Weeks 2, 4, 8, 12, and 16 |
|-----------------|---|

End point description:

ACR50 response is achieved when the participant has:  $\geq$  50% improvement (reduction) from baseline in TJC68, SJC66 and in at least 3 of the following 5 items: PGADA using a VAS on a scale of 0 (very well) to 100 (very poor); PHGADA using a VAS on a scale of 0 (no disease activity) to 100 (maximum disease activity); HAQ-DI inclusive of activities scored on a scale of 0 (no disability) to 3 (completely disabled); HAQ-DI pain assessment using VAS on a scale of 0 (no pain) to 100 (serious pain); and hsCRP. Participants with missing outcomes were set as non-responders. Participants in the FAS with available data were analyzed.

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

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

| End point values                  | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|-----------------------------------|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed       | 19                             | 19                             | 9                             | 20                   |
| Units: percentage of participants |                                |                                |                               |                      |
| number (confidence interval 95%)  |                                |                                |                               |                      |
| Wk 2 N=19,18,9,19                 | 5.3 (0.0 to 17.9)              | 0 (0.0 to 2.8)                 | 0 (0.0 to 5.6)                | 5.3 (0.0 to 17.9)    |
| Wk 4 N=19,18,9,20                 | 10.5 (0.0 to 27.0)             | 5.6 (0.0 to 18.9)              | 0 (0.0 to 5.6)                | 5.0 (0.0 to 17.1)    |
| Wk 8 N=19,19,9,19                 | 31.6 (8.0 to 55.1)             | 26.3 (3.9 to 48.7)             | 11.1 (0.0 to 37.2)            | 10.5 (0.0 to 27.0)   |
| Wk 12 N=18,19,8,19                | 55.6 (29.8 to 81.3)            | 42.1 (17.3 to 66.9)            | 37.5 (0.0 to 77.3)            | 10.5 (0.0 to 27.0)   |
| Wk 16 N=18,19,9,20                | 27.8 (4.3 to 51.2)             | 47.4 (22.3 to 72.5)            | 33.3 (0.0 to 69.7)            | 15.0 (0.0 to 33.1)   |

## Statistical analyses

| Statistical analysis title                  | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
|---|---|
| Statistical analysis description:<br>Week 2 |   |
| Comparison groups                           | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis     | 39  |
| Analysis specification                      | Pre-specified   |
| Analysis type                               | superiority   |
| P-value                                     | = 0.98 <sup>[21]</sup>                                |
| Method                                      | Regression, Logistic                                  |
| Parameter estimate                          | Difference in response rates                          |
| Point estimate                              | 0   |
| Confidence interval                         |   |
| level                                       | 95 %  |
| sides                                       | 2-sided   |
| lower limit                                 | -19.5   |
| upper limit                                 | 19.5  |

Notes:

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

| Statistical analysis title | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
|----------------------------|---|
| Comparison groups          | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |

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

Notes:

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

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 4                                  |   |
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.54 <sup>[23]</sup>                                |
| Method                                  | Regression, Logistic                                  |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 5.5   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -16.4   |
| upper limit                             | 27.4  |

Notes:

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

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 4                                  |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.92 <sup>[24]</sup>                                |
| Method                                  | Regression, Logistic                                  |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 0.6   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -19   |
| upper limit                             | 20.1  |

Notes:

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

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 8                                  |   |
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.13 [25]   |
| Method                                  | Regression, Logistic                                  |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 21.1  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -9.3  |
| upper limit                             | 51.4  |

Notes:

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

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 8                                  |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.22 [26]   |
| Method                                  | Regression, Logistic                                  |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 15.8  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -13.6   |
| upper limit                             | 45.2  |

Notes:

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

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description: |   |
| Week 12                           |   |
| Comparison groups                 | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |

|   |                              |
|---|------------------------------|
| Number of subjects included in analysis | 39                           |
| Analysis specification                  | Pre-specified                |
| Analysis type                           | superiority                  |
| P-value                                 | = 0.007 <sup>[27]</sup>      |
| Method                                  | Regression, Logistic         |
| Parameter estimate                      | Difference in response rates |
| Point estimate                          | 45                           |
| Confidence interval                     |                              |
| level                                   | 95 %                         |
| sides                                   | 2-sided                      |
| lower limit                             | 12.8                         |
| upper limit                             | 77.2                         |

Notes:

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

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 12                                 |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.039 <sup>[28]</sup>                               |
| Method                                  | Regression, Logistic                                  |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 31.6  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 0.2   |
| upper limit                             | 63  |

Notes:

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

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 16                                 |   |
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.34 <sup>[29]</sup>                                |
| Method                                  | Regression, Logistic                                  |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 12.8  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -18.4   |
| upper limit                             | 44  |

Notes:

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

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 16                                 |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.04 <sup>[30]</sup>                                |
| Method                                  | Regression, Logistic                                  |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 32.4  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -0.1  |
| upper limit                             | 64.9  |

Notes:

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

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

|  |   |
|--|---|
| End point title  | Percentage of Participants Who Achieved an American College of Rheumatology 70% Improvement Response at Weeks 2, 4, 8, 12, and 16 |
| End point description:   |   |
| ACR70 response is achieved when the participant has: $\geq$ 70% improvement (reduction) from baseline in TJC68, SJC66 and in at least 3 of the following 5 items: PGADA using a VAS on a scale of 0 (very well) to 100 (very poor); PHGADA using a VAS on a scale of 0 (no disease activity) to 100 (maximum disease activity); HAQ-DI inclusive of activities scored on a scale of 0 (no disability) to 3 (completely disabled); HAQ-DI pain assessment using VAS on a scale of 0 (no pain) to 100 (serious pain); and hsCRP. Participants with missing outcomes were set as non-responders. Participants in the FAS with available data were analyzed. |   |
| End point type   | Secondary   |
| End point timeframe:   |   |
| Weeks 2, 4, 8, 12, and 16  |   |

| End point values                  | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|-----------------------------------|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed       | 19                             | 19                             | 9                             | 20                   |
| Units: percentage of participants |                                |                                |                               |                      |
| number (confidence interval 95%)  |                                |                                |                               |                      |
| Wk 2 N=19,18,9,19                 | 5.3 (0.0 to 17.9)              | 0 (0.0 to 2.8)                 | 0 (0.0 to 5.6)                | 0 (0.0 to 2.6)       |
| Wk 4 N=19,18,9,20                 | 5.3 (0.0 to 17.9)              | 0 (0.0 to 2.8)                 | 0 (0.0 to 5.6)                | 0 (0.0 to 2.5)       |

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

## Statistical analyses

| Statistical analysis title              | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
|---|---|
| Statistical analysis description:       |   |
| Week 2                                  |   |
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 5.3   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -10   |
| upper limit                             | 20.6  |

| Statistical analysis title              | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
|---|---|
| Statistical analysis description:       |   |
| Week 2                                  |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 0   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -5.4  |
| upper limit                             | 5.4   |

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



|   |                              |
|---|------------------------------|
| Number of subjects included in analysis | 39                           |
| Analysis specification                  | Pre-specified                |
| Analysis type                           | superiority                  |
| Parameter estimate                      | Difference in response rates |
| Point estimate                          | 5.3                          |
| Confidence interval                     |                              |
| level                                   | 95 %                         |
| sides                                   | 2-sided                      |
| lower limit                             | -9.9                         |
| upper limit                             | 20.4                         |

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

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 4                                  |   |
| Comparison groups                       | Placebo (Main Study) v Filgotinib 100 mg (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 0   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -5.3  |
| upper limit                             | 5.3   |

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Fil 200 mg (Main Study) vs Placebo (Main Study) |
| Statistical analysis description: |   |
| Week 12                           |   |

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

|   |   |
|---|---|
| <b>Statistical analysis title</b>           | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:<br>Week 8 |   |
| Comparison groups                           | Placebo (Main Study) v Filgotinib 100 mg (Main Study) |
| Number of subjects included in analysis     | 39  |
| Analysis specification                      | Pre-specified   |
| Analysis type                               | superiority   |
| Parameter estimate                          | Difference in response rates                          |
| Point estimate                              | 5.3   |
| Confidence interval                         |   |
| level                                       | 95 %  |
| sides                                       | 2-sided   |
| lower limit                                 | -17.1   |
| upper limit                                 | 27.6  |

|  |   |
|--|---|
| <b>Statistical analysis title</b>            | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:<br>Week 12 |   |
| Comparison groups                            | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis      | 39  |
| Analysis specification                       | Pre-specified   |
| Analysis type                                | superiority   |
| Parameter estimate                           | Difference in response rates                          |
| Point estimate                               | 26.3  |
| Confidence interval                          |   |
| level  | 95 %  |
| sides  | 2-sided   |
| lower limit                                  | 1.3   |
| upper limit                                  | 51.4  |

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Fil 200 mg (Main Study) vs Placebo (Main Study) |
|-----------------------------------|---|

Statistical analysis description:

Week 16

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 12.2  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -16.3   |
| upper limit                             | 40.8  |

**Statistical analysis title**

Fil 100 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 16

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 21.6  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -8.2  |
| upper limit                             | 51.4  |

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

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

End point description:

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

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

End point timeframe:

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

| End point values                              | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|---|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                            | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed                   | 19                             | 19                             | 9                             | 20                   |
| Units: tender joint count                     |                                |                                |                               |                      |
| arithmetic mean (standard deviation)          |                                |                                |                               |                      |
| Baseline                                      | 22 ( $\pm$ 14.9)               | 13 ( $\pm$ 8.5)                | 17 ( $\pm$ 11.0)              | 14 ( $\pm$ 11.6)     |
| Change From Baseline at Wk 2<br>N=19,18,9,19  | -6 ( $\pm$ 8.7)                | -1 ( $\pm$ 5.2)                | -5 ( $\pm$ 3.9)               | -3 ( $\pm$ 6.6)      |
| Change From Baseline at Wk 4<br>N=19,18,9,20  | -9 ( $\pm$ 10.3)               | -3 ( $\pm$ 7.9)                | -7 ( $\pm$ 5.3)               | -3 ( $\pm$ 4.6)      |
| Change From Baseline at Wk 8<br>N=19,19,9,19  | -13 ( $\pm$ 9.9)               | -5 ( $\pm$ 6.3)                | -7 ( $\pm$ 7.4)               | -4 ( $\pm$ 4.8)      |
| Change From Baseline at Wk 12<br>N=18,19,8,19 | -13 ( $\pm$ 7.4)               | -7 ( $\pm$ 7.4)                | -10 ( $\pm$ 8.5)              | -4 ( $\pm$ 4.5)      |
| Change From Baseline at Wk 16<br>N=18,19,9,20 | -14 ( $\pm$ 7.7)               | -7 ( $\pm$ 7.9)                | -10 ( $\pm$ 6.1)              | -5 ( $\pm$ 8.3)      |

### Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

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

End point timeframe:

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

| End point values                              | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|---|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                            | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed                   | 19                             | 19                             | 9                             | 20                   |
| Units: swollen joint count                    |                                |                                |                               |                      |
| arithmetic mean (standard deviation)          |                                |                                |                               |                      |
| Baseline                                      | 14 ( $\pm$ 10.3)               | 7 ( $\pm$ 3.3)                 | 11 ( $\pm$ 7.3)               | 8 ( $\pm$ 5.9)       |
| Change From Baseline at Wk 2<br>N=19,18,9,19  | -3 ( $\pm$ 3.8)                | -1 ( $\pm$ 3.5)                | -5 ( $\pm$ 5.2)               | -2 ( $\pm$ 4.7)      |
| Change From Baseline at Wk 4<br>N=19,18,9,20  | -5 ( $\pm$ 6.2)                | -2 ( $\pm$ 2.9)                | -4 ( $\pm$ 7.0)               | -2 ( $\pm$ 3.1)      |
| Change From Baseline at Wk 8<br>N=19,19,9,19  | -9 ( $\pm$ 7.0)                | -3 ( $\pm$ 4.0)                | -6 ( $\pm$ 6.1)               | -3 ( $\pm$ 2.9)      |
| Change From Baseline at Wk 12<br>N=18,19,8,19 | -8 ( $\pm$ 8.9)                | -4 ( $\pm$ 3.1)                | -8 ( $\pm$ 7.3)               | -4 ( $\pm$ 2.9)      |

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

## Statistical analyses

No statistical analyses for this end point

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

|   |  |
|---|--|
| End point title   | Change From Baseline in Individual ACR Component: Patient's Global Assessment of Disease Activity (PGADA) at Weeks 2, 4, 8, 12, and 16 |
| End point description:<br>PGADA is assessed by the participants using a VAS on a scale of 0 (very well) to 100 (very poor). A negative change from baseline indicates improvement. Participants in the FAS with available data were analyzed. |  |
| End point type  | Secondary  |
| End point timeframe:<br>Baseline, 2, 4, 8, 12, and 16 weeks   |  |

| End point values                              | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|---|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                            | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed                   | 19                             | 19                             | 8                             | 20                   |
| Units: score on a scale                       |                                |                                |                               |                      |
| arithmetic mean (standard deviation)          |                                |                                |                               |                      |
| Baseline                                      | 54 (± 26.0)                    | 58 (± 22.8)                    | 47 (± 24.2)                   | 52 (± 24.0)          |
| Change From Baseline at Wk 2<br>N=19,18,8,19  | -15 (± 17.8)                   | -17 (± 26.6)                   | 3 (± 8.6)                     | -10 (± 12.6)         |
| Change From Baseline at Wk 4<br>N=19,18,8,20  | -23 (± 20.3)                   | -23 (± 32.2)                   | -3 (± 11.4)                   | -4 (± 16.6)          |
| Change From Baseline at Wk 8<br>N=19,19,8,19  | -24 (± 22.6)                   | -28 (± 33.8)                   | -4 (± 17.1)                   | -16 (± 23.4)         |
| Change From Baseline at Wk 12<br>N=18,19,7,19 | -27 (± 25.9)                   | -38 (± 29.9)                   | -29 (± 19.7)                  | -9 (± 24.7)          |
| Change From Baseline at Wk 16<br>N=18,19,8,20 | -31 (± 26.4)                   | -34 (± 28.5)                   | -25 (± 25.3)                  | -12 (± 23.5)         |

## Statistical analyses

No statistical analyses for this end point

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

|                 |   |
|-----------------|---|
| End point title | Change From Baseline in Individual ACR Component: Physician's Global Assessment of Disease Activity (PhGADA) at |
|-----------------|---|

## End point description:

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

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

## End point timeframe:

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

| End point values                              | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|---|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                            | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed                   | 19                             | 19                             | 8                             | 20                   |
| Units: score on a scale                       |                                |                                |                               |                      |
| arithmetic mean (standard deviation)          |                                |                                |                               |                      |
| Baseline                                      | 68 (± 16.4)                    | 56 (± 14.3)                    | 65 (± 13.1)                   | 62 (± 13.4)          |
| Change From Baseline at Wk 2<br>N=19,18,8,19  | -17 (± 12.3)                   | -4 (± 11.0)                    | -12 (± 9.2)                   | -8 (± 9.8)           |
| Change From Baseline at Wk 4<br>N=19,18,8,20  | -23 (± 14.5)                   | -12 (± 18.6)                   | -29 (± 14.8)                  | -8 (± 11.5)          |
| Change From Baseline at Wk 8<br>N=19,19,8,19  | -35 (± 15.1)                   | -17 (± 17.4)                   | -35 (± 13.6)                  | -21 (± 13.7)         |
| Change From Baseline at Wk 12<br>N=18,19,7,19 | -36 (± 18.8)                   | -26 (± 22.4)                   | -42 (± 20.8)                  | -21 (± 21.8)         |
| Change From Baseline at Wk 16<br>N=18,19,8,20 | -37 (± 16.4)                   | -27 (± 21.6)                   | -44 (± 21.0)                  | -19 (± 20.2)         |

## Statistical analyses

No statistical analyses for this end point

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

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

## End point description:

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

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

## End point timeframe:

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

| End point values                              | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|---|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                            | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed                   | 19                             | 19                             | 8                             | 20                   |
| Units: score on a scale                       |                                |                                |                               |                      |
| arithmetic mean (standard deviation)          |                                |                                |                               |                      |
| Baseline                                      | 60 ( $\pm$ 24.7)               | 45 ( $\pm$ 22.3)               | 48 ( $\pm$ 24.3)              | 56 ( $\pm$ 24.2)     |
| Change From Baseline at Wk 2<br>N=19,18,8,19  | -16 ( $\pm$ 15.2)              | -4 ( $\pm$ 16.7)               | -5 ( $\pm$ 9.5)               | -8 ( $\pm$ 11.5)     |
| Change From Baseline at Wk 4<br>N=19,18,8,20  | -24 ( $\pm$ 20.9)              | -13 ( $\pm$ 18.6)              | -10 ( $\pm$ 9.8)              | -1 ( $\pm$ 14.3)     |
| Change From Baseline at Wk 8<br>N=19,19,8,19  | -33 ( $\pm$ 20.9)              | -13 ( $\pm$ 23.4)              | -3 ( $\pm$ 17.3)              | -11 ( $\pm$ 25.3)    |
| Change From Baseline at Wk 12<br>N=18,19,7,19 | -33 ( $\pm$ 23.7)              | -19 ( $\pm$ 21.0)              | -28 ( $\pm$ 20.7)             | -8 ( $\pm$ 23.3)     |
| Change From Baseline at Wk 16<br>N=18,19,8,20 | -29 ( $\pm$ 24.5)              | -17 ( $\pm$ 26.5)              | -27 ( $\pm$ 15.2)             | -12 ( $\pm$ 21.7)    |

## Statistical analyses

No statistical analyses for this end point

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

|                        |  |
|------------------------|--|
| End point title        | Change From Baseline in Individual ACR Component: High-Sensitivity C-Reactive Protein (hsCRP) at Weeks 2, 4, 8, 12, and 16   |
| End point description: | The hsCRP is the ACR core set measure of acute phase reactant. It was measured at the central laboratory to help assess the effect of filgotinib on the participant's psoriatic arthritis. A negative change from baseline indicates improvement. Participants in the FAS with available data were analyzed. |
| End point type         | Secondary  |
| End point timeframe:   | Baseline, 2, 4, 8, 12, and 16 weeks  |

| End point values                             | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|--|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                           | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed                  | 19                             | 19                             | 9                             | 20                   |
| Units: mg/L                                  |                                |                                |                               |                      |
| arithmetic mean (standard deviation)         |                                |                                |                               |                      |
| Baseline                                     | 8.08 ( $\pm$ 9.335)            | 3.14 ( $\pm$ 2.673)            | 10.56 ( $\pm$ 16.354)         | 7.11 ( $\pm$ 9.727)  |
| Change From Baseline at Wk 2<br>N=19,18,9,19 | -6.37 ( $\pm$ 8.518)           | -0.10 ( $\pm$ 5.313)           | -7.70 ( $\pm$ 11.874)         | 0.50 ( $\pm$ 4.063)  |
| Change From Baseline at Wk 4<br>N=19,18,9,20 | -6.68 ( $\pm$ 8.998)           | -0.95 ( $\pm$ 2.564)           | -5.99 ( $\pm$ 8.981)          | 3.96 ( $\pm$ 13.594) |
| Change From Baseline at Wk 8<br>N=19,19,9,19 | -5.13 ( $\pm$ 11.271)          | -0.69 ( $\pm$ 4.474)           | -6.40 ( $\pm$ 9.740)          | -1.15 ( $\pm$ 4.979) |

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

## Statistical analyses

No statistical analyses for this end point

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

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

End point description:

The DAS28 (CRP) is a measure of the participant's disease activity calculated using the tender joint count (28 joints), swollen joint count (28 joints), PGADA [using a VAS on a scale of 0 (very well) to 100 (very poor)] and hsCRP for a total possible score of 1 to 9.4. Higher values indicate higher disease activity. A negative change from baseline indicates improvement. Participants in the FAS with available data were analyzed.

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

End point timeframe:

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

| End point values                              | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|---|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                            | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed                   | 19                             | 19                             | 8                             | 20                   |
| Units: score on a scale                       |                                |                                |                               |                      |
| arithmetic mean (standard deviation)          |                                |                                |                               |                      |
| Baseline                                      | 4.9 (± 1.27)                   | 4.2 (± 0.78)                   | 4.5 (± 0.97)                  | 4.4 (± 0.92)         |
| Change From Baseline at Wk 2<br>N=19,18,8,19  | -0.9 (± 0.62)                  | -0.5 (± 0.74)                  | -0.9 (± 0.70)                 | -0.6 (± 0.83)        |
| Change From Baseline at Wk 4<br>N=19,18,8,20  | -1.2 (± 0.63)                  | -0.9 (± 1.04)                  | -1.2 (± 0.60)                 | -0.5 (± 0.65)        |
| Change From Baseline at Wk 8<br>N=19,19,8,19  | -1.8 (± 0.87)                  | -1.2 (± 0.71)                  | -1.2 (± 0.83)                 | -1.0 (± 0.66)        |
| Change From Baseline at Wk 12<br>N=18,19,7,19 | -1.9 (± 0.96)                  | -1.5 (± 0.89)                  | -1.9 (± 0.88)                 | -0.8 (± 0.78)        |
| Change From Baseline at Wk 16<br>N=18,19,8,20 | -1.8 (± 0.62)                  | -1.8 (± 0.97)                  | -2.0 (± 0.71)                 | -0.8 (± 0.92)        |

## Statistical analyses

No statistical analyses for this end point

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

|                 |   |
|-----------------|---|
| End point title | Percentage of Participants Who Achieved DAS28(CRP) LDA at |
|-----------------|---|



## End point description:

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

## End point type

Secondary

## End point timeframe:

Weeks 2, 4, 8, 12, and 16

| End point values                  | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|-----------------------------------|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed       | 19                             | 19                             | 9                             | 20                   |
| Units: percentage of participants |                                |                                |                               |                      |
| number (confidence interval 95%)  |                                |                                |                               |                      |
| Wk 2 N=19,18,9,19                 | 31.6 (8.0 to 55.1)             | 33.3 (8.8 to 57.9)             | 33.3 (0.0 to 69.7)            | 42.1 (17.3 to 66.9)  |
| Wk 4 N=19,18,9,20                 | 36.8 (12.5 to 61.2)            | 44.4 (18.7 to 70.2)            | 55.6 (17.5 to 93.6)           | 25.0 (3.5 to 46.5)   |
| Wk 8 N=19,19,9,19                 | 63.2 (38.8 to 87.5)            | 63.2 (38.8 to 87.5)            | 33.3 (0.0 to 69.7)            | 52.6 (27.5 to 77.7)  |
| Wk 12 N=18,19,8,19                | 66.7 (42.1 to 91.2)            | 68.4 (44.9 to 92.0)            | 62.5 (22.7 to 100.0)          | 36.8 (12.5 to 61.2)  |
| Wk 16 N=18,19,9,20                | 50.0 (24.1 to 75.9)            | 84.2 (65.2 to 100.0)           | 66.7 (30.3 to 100.0)          | 45.0 (20.7 to 69.3)  |

## Statistical analyses

## Statistical analysis title

Fil 200 mg (Main Study) vs Placebo (Main Study)

## Statistical analysis description:

Week 2

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | -10.5   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -46.3   |
| upper limit                             | 25.2  |

## Statistical analysis title

Fil 100 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 2

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | -8.8  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -45.3   |
| upper limit                             | 27.7  |

**Statistical analysis title**

Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 4

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 11.8  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -22.1   |
| upper limit                             | 45.8  |

**Statistical analysis title**

Fil 100 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 4

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 19.4  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -15.6   |
| upper limit                             | 54.5  |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 8                                  |   |
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 10.5  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -26   |
| upper limit                             | 47  |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 12                                 |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 31.6  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -3.8  |
| upper limit                             | 67  |

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

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

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 16                                 |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 39.2  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 6.8   |
| upper limit                             | 71.6  |

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

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

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

|   |  |
|---|--|
| End point title   | Percentage of Participants Who Achieved DAS28 (CRP) Remission at Weeks 2, 4, 8, 12, and 16 |
| End point description:<br>The DAS28 (CRP) is a measure of the participant's disease activity calculated using the tender joint count (28 joints), swollen joint count (28 joints), PGADA (VAS; 0 = very well to 100 = very poor), and hsCRP for a total possible score of 1 to 9.4. Higher values indicate higher disease activity. DAS28 (CRP) remission is defined as DAS28 (CRP) < 2.6. Participants in the FAS with available data were analyzed. |  |
| End point type  | Secondary  |
| End point timeframe:<br>Weeks 2, 4, 8, 12, and 16   |  |

| End point values                  | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|-----------------------------------|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed       | 19                             | 19                             | 9                             | 20                   |
| Units: percentage of participants |                                |                                |                               |                      |
| number (confidence interval 95%)  |                                |                                |                               |                      |
| Wk 2 N=19,18,9,19                 | 10.5 (0.0 to 27.0)             | 11.1 (0.0 to 28.4)             | 22.2 (0.0 to 54.9)            | 10.5 (0.0 to 27.0)   |
| Wk 4 N=19,18,9,20                 | 10.5 (0.0 to 27.0)             | 27.8 (4.3 to 51.2)             | 22.2 (0.0 to 54.9)            | 15.0 (0.0 to 33.1)   |
| Wk 8 N=19,19,9,19                 | 47.4 (22.3 to 72.5)            | 26.3 (3.9 to 48.7)             | 22.2 (0.0 to 54.9)            | 26.3 (3.9 to 48.7)   |
| Wk 12 N=18,19,8,19                | 55.6 (29.8 to 81.3)            | 42.1 (17.3 to 66.9)            | 50.0 (9.1 to 90.9)            | 21.1 (0.1 to 42.0)   |
| Wk 16 N=18,19,9,20                | 44.4 (18.7 to 70.2)            | 52.6 (27.5 to 77.7)            | 44.4 (6.4 to 82.5)            | 20.0 (0.0 to 40.0)   |

## Statistical analyses

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

|   |                              |
|---|------------------------------|
| Number of subjects included in analysis | 39                           |
| Analysis specification                  | Pre-specified                |
| Analysis type                           | superiority                  |
| Parameter estimate                      | Difference in response rates |
| Point estimate                          | 0                            |
| Confidence interval                     |                              |
| level                                   | 95 %                         |
| sides                                   | 2-sided                      |
| lower limit                             | -24.8                        |
| upper limit                             | 24.8                         |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 2                                  |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 0.6   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -24.9   |
| upper limit                             | 26  |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 4                                  |   |
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | -4.5  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -30.5   |
| upper limit                             | 21.5  |

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Fil 100 mg (Main Study) vs Placebo (Main Study) |
| Statistical analysis description: |   |
| Week 4                            |   |

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 12.8  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -18.4   |
| upper limit                             | 44  |

|   |   |
|---|---|
| <b>Statistical analysis title</b>           | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:<br>Week 8 |   |
| Comparison groups                           | Placebo (Main Study) v Filgotinib 100 mg (Main Study) |
| Number of subjects included in analysis     | 39  |
| Analysis specification                      | Pre-specified   |
| Analysis type                               | superiority   |
| Parameter estimate                          | Difference in response rates                          |
| Point estimate                              | 0   |
| Confidence interval                         |   |
| level                                       | 95 %  |
| sides                                       | 2-sided   |
| lower limit                                 | -33.3   |
| upper limit                                 | 33.3  |

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

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Fil 100 mg (Main Study) vs Placebo (Main Study) |
|-----------------------------------|---|

## Statistical analysis description:

Week 12

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

**Statistical analysis title**

Fil 200 mg (Main Study) vs Placebo (Main Study)

## Statistical analysis description:

Week 12

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

**Statistical analysis title**

Fil 200 mg (Main Study) vs Placebo (Main Study)

## Statistical analysis description:

Week 16

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 24.4  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -9.7  |
| upper limit                             | 58.6  |



|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 16                                 |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 32.6  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -1  |
| upper limit                             | 66.2  |

### Secondary: Time to Achieve DAS28 (CRP) LDA

|  |                                 |
|--|---------------------------------|
| End point title  | Time to Achieve DAS28 (CRP) LDA |
| End point description:   |                                 |
| <p>The DAS28 (CRP) is a measure of the participant's disease activity calculated using the TJC (28 joints), SJC (28 joints), PGADA (VAS; 0 = very well to 100 = very poor), and hsCRP for a total possible score of 1 to 9.4. Higher values indicate higher disease activity. DAS28 (CRP) LDA is defined as DAS28 (CRP) <math>\leq</math> 3.2. Time to achieve DAS28 (CRP) LDA is the number of days from the first dose date of study drug administration to the first time when a participant achieves DAS28 (CRP) LDA. Participants in the FAS with available data were analyzed.</p> |                                 |
| End point type   | Secondary                       |
| End point timeframe:   |                                 |
| Up to 16 weeks   |                                 |

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

### Statistical analyses

No statistical analyses for this end point

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

|  |  |
|--|--|
| End point title  | Percentage of Participants Who Achieved DAPSA LDA at Weeks 2, 4, 8, 12, and 16 |
| End point description:   |  |
| DAPSA is calculated by summing the following components: TJC68; SJC66; PGADA [using VAS on a |  |

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

|                           |           |
|---------------------------|-----------|
| End point type            | Secondary |
| End point timeframe:      |           |
| Weeks 2, 4, 8, 12, and 16 |           |

| End point values                  | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|-----------------------------------|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed       | 19                             | 19                             | 9                             | 20                   |
| Units: percentage of participants |                                |                                |                               |                      |
| number (confidence interval 95%)  |                                |                                |                               |                      |
| Wk 2 N=19,18,9,19                 | 15.8 (0.0 to 34.8)             | 11.1 (0.0 to 28.4)             | 22.2 (0.0 to 54.9)            | 31.6 (8.0 to 55.1)   |
| Wk 4 N=19,18,9,20                 | 31.6 (8.0 to 55.1)             | 38.9 (13.6 to 64.2)            | 44.4 (6.4 to 82.5)            | 25.0 (3.5 to 46.5)   |
| Wk 8 N=19,19,9,19                 | 52.6 (27.5 to 77.7)            | 42.1 (17.3 to 66.9)            | 33.3 (0.0 to 69.7)            | 36.8 (12.5 to 61.2)  |
| Wk 12 N=18,19,8,19                | 61.1 (35.8 to 86.4)            | 57.9 (33.1 to 82.7)            | 62.5 (22.7 to 100.0)          | 36.8 (12.5 to 61.2)  |
| Wk 16 N=18,19,9,20                | 44.4 (18.7 to 70.2)            | 63.2 (38.8 to 87.5)            | 55.6 (17.5 to 93.6)           | 40.0 (16.0 to 64.0)  |

## Statistical analyses

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 2                                  |   |
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | -15.8   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -47.6   |
| upper limit                             | 16  |

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description: |   |
| Week 2                            |   |
| Comparison groups                 | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |

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

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 4                                  |   |
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 6.6   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -26.8   |
| upper limit                             | 39.9  |

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

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Fil 100 mg (Main Study) vs Placebo (Main Study) |
| Statistical analysis description: |   |
| Week 4                            |   |

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 13.9  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -20.8   |
| upper limit                             | 48.6  |

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

|   |   |
|---|---|
| <b>Statistical analysis title</b>           | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:<br>Week 8 |   |
| Comparison groups                           | Placebo (Main Study) v Filgotinib 100 mg (Main Study) |
| Number of subjects included in analysis     | 39  |
| Analysis specification                      | Pre-specified   |
| Analysis type                               | superiority   |
| Parameter estimate                          | Difference in response rates                          |
| Point estimate                              | 5.3   |
| Confidence interval                         |   |
| level                                       | 95 %  |
| sides                                       | 2-sided   |
| lower limit                                 | -31   |
| upper limit                                 | 41.6  |

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Fil 200 mg (Main Study) vs Placebo (Main Study) |
|-----------------------------------|---|

Statistical analysis description:

Week 12

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 21.1  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -15.2   |
| upper limit                             | 57.4  |

**Statistical analysis title**

Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 16

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 4.4   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -32.3   |
| upper limit                             | 41.2  |

**Statistical analysis title**

Fil 100 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 16

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 23.2  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -12.5   |
| upper limit                             | 58.8  |

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

|  |  |
|--|--|
| End point title  | Percentage of Participants Who Achieved DAPSA Remission at Weeks 2, 4, 8, 12, and 16 |
| End point description:<br>DAPSA is calculated by summing the following components: TJC68; SJC66; PGADA [using VAS on a scale of 0 (very well) to 100 (very poor)]; PGAPI [using a VAS on a scale of 0 (no pain) to 100 (serious pain)] and CRP. DAPSA scores 0-4 = remission, 5-14 = low disease activity, 15-28 = moderate disease activity, and >28 = high disease activity. DAPSA remission is defined as DAPSA ≤ 4. Participants in the FAS with available data were analyzed. |  |
| End point type   | Secondary  |
| End point timeframe:<br>Weeks 2, 4, 8, 12, and 16  |  |

| End point values                  | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|-----------------------------------|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed       | 19                             | 19                             | 9                             | 20                   |
| Units: percentage of participants |                                |                                |                               |                      |
| number (confidence interval 95%)  |                                |                                |                               |                      |
| Wk 2 N=19,18,9,19                 | 5.3 (0.0 to 17.9)              | 0 (0.0 to 2.8)                 | 0 (0.0 to 5.6)                | 5.3 (0.0 to 17.9)    |
| Wk 4 N=19,18,9,20                 | 5.3 (0.0 to 17.9)              | 5.6 (0.0 to 18.9)              | 0 (0.0 to 5.6)                | 5.0 (0.0 to 17.1)    |
| Wk 8 N=19,19,9,19                 | 10.5 (0.0 to 27.0)             | 5.3 (0.0 to 17.9)              | 0 (0.0 to 5.6)                | 10.5 (0.0 to 27.0)   |
| Wk 12 N=18,19,8,19                | 22.2 (0.2 to 44.2)             | 31.6 (8.0 to 55.1)             | 12.5 (0.0 to 41.7)            | 5.3 (0.0 to 17.9)    |
| Wk 16 N=18,19,9,20                | 16.7 (0.0 to 36.7)             | 21.1 (0.1 to 42.0)             | 22.2 (0.0 to 54.9)            | 10.0 (0.0 to 25.6)   |

## Statistical analyses

|   |   |
|---|---|
| Statistical analysis title                  | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:<br>Week 2 |   |
| Comparison groups                           | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis     | 39  |
| Analysis specification                      | Pre-specified   |
| Analysis type                               | superiority   |
| Parameter estimate                          | Difference in response rates                          |
| Point estimate                              | 0   |
| Confidence interval                         |   |
| level                                       | 95 %  |
| sides                                       | 2-sided   |
| lower limit                                 | -19.5   |
| upper limit                                 | 19.5  |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 2                                  |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | -5.3  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -20.7   |
| upper limit                             | 10.2  |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 4                                  |   |
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 0.3   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -18.7   |
| upper limit                             | 19.3  |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 4                                  |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 0.6   |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | -19     |
| upper limit         | 20.1    |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 8                                  |   |
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 0   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -24.8   |
| upper limit                             | 24.8  |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 8                                  |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | -5.3  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -27.6   |
| upper limit                             | 17.1  |

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description: |   |
| Week 12                           |   |
| Comparison groups                 | Placebo (Main Study) v Filgotinib 100 mg (Main Study) |



|   |                              |
|---|------------------------------|
| Number of subjects included in analysis | 39                           |
| Analysis specification                  | Pre-specified                |
| Analysis type                           | superiority                  |
| Parameter estimate                      | Difference in response rates |
| Point estimate                          | 26.3                         |
| Confidence interval                     |                              |
| level                                   | 95 %                         |
| sides                                   | 2-sided                      |
| lower limit                             | -2.1                         |
| upper limit                             | 54.8                         |

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

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 16                                 |   |
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 6.7   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -20.3   |
| upper limit                             | 33.6  |

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Fil 100 mg (Main Study) vs Placebo (Main Study) |
| Statistical analysis description: |   |
| Week 16                           |   |

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 11.1  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -16.6   |
| upper limit                             | 38.7  |

## Secondary: Time to Achieve DAPSA LDA

|   |                           |
|---|---------------------------|
| End point title   | Time to Achieve DAPSA LDA |
| End point description:  |                           |
| DAPSA is calculated by summing the following components: TJC68; SJC66; PGADA [using VAS on a scale of 0 (very well) to 100 very poor)]; PGAPI [using a VAS on a scale of 0 (no pain) to 100 (serious pain)] and CRP. DAPSA scores 0-4 = remission, 5-14 = low disease activity, 15-28 = moderate disease activity, and >28 = high disease activity. DAPSA LDA is defined as DAPSA ≤ 14. Time to achieve DAPSA LDA is the number of days from the first dose date of study drug administration to the first time when a participant achieves DAPSA LDA. If the DAPSA LDA is not achieved during main study phase, the time to achieve DAPSA LDA will be censored at the last non-missing DAS28 (CRP) assessment date during main study phase. If the component scores of DAPSA LDA are at different dates for a visit, the latest date will be used for the derivation of time to achieve DAPSA LDA. Participants in the FAS with available data were analyzed. 99.999 = Median was not calculated due to less number of participants. |                           |
| End point type  | Secondary                 |
| End point timeframe:  |                           |
| Up to 16 weeks  |                           |

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

## Statistical analyses

No statistical analyses for this end point

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

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

**End point description:**

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

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

**End point timeframe:**

Weeks 2, 4, 8, 12, and 16

| <b>End point values</b>           | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|-----------------------------------|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed       | 19                             | 19                             | 9                             | 20                   |
| Units: percentage of participants |                                |                                |                               |                      |
| number (confidence interval 95%)  |                                |                                |                               |                      |
| Wk 2 N=19,18,9,19                 | 31.6 (8.0 to 55.1)             | 16.7 (0.0 to 36.7)             | 11.1 (0.0 to 37.2)            | 31.6 (8.0 to 55.1)   |
| Wk 4 N=19,18,9,20                 | 57.9 (33.1 to 82.7)            | 38.9 (13.6 to 64.2)            | 44.4 (6.4 to 82.5)            | 30.0 (7.4 to 52.6)   |
| Wk 8 N=19,19,9,19                 | 78.9 (58.0 to 99.9)            | 47.4 (22.3 to 72.5)            | 44.4 (6.4 to 82.5)            | 57.9 (33.1 to 82.7)  |
| Wk 12 N=18,19,8,19                | 72.2 (48.8 to 95.7)            | 68.4 (44.9 to 92.0)            | 75.0 (38.7 to 100.0)          | 47.4 (22.3 to 72.5)  |
| Wk 16 N=18,19,9,20                | 88.9 (71.6 to 100.0)           | 57.9 (33.1 to 82.7)            | 77.8 (45.1 to 100.0)          | 45.0 (20.7 to 69.3)  |

**Statistical analyses**

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Fil 100 mg (Main Study) vs Placebo (Main Study) |
|-----------------------------------|---|

**Statistical analysis description:**

Week 2

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | -14.9   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -47.4   |
| upper limit                             | 17.6  |

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Fil 200 mg (Main Study) vs Placebo (Main Study) |
|-----------------------------------|---|

Statistical analysis description:

Week 2

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 0   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -34.8   |
| upper limit                             | 34.8  |

**Statistical analysis title**

Fil 100 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 4

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 8.9   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -26.6   |
| upper limit                             | 44.3  |

**Statistical analysis title**

Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 4

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 27.9  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -7.2  |
| upper limit                             | 63  |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 8                                  |   |
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 21.1  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -13   |
| upper limit                             | 55.1  |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 8                                  |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | -10.5   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -47.4   |
| upper limit                             | 26.3  |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 12                                 |   |
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 24.9  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -11.1   |
| upper limit                             | 60.8  |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 12                                 |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 21.1  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -14.9   |
| upper limit                             | 57  |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 16                                 |   |
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 43.9  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | 12.4  |
| upper limit                             | 75.4  |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 16                                 |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 12.9  |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | -23.4   |
| upper limit         | 49.1    |

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

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

#### End point description:

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

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

#### End point timeframe:

Baseline, 4, 8, 12, and 16 weeks

| End point values                           | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|--|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                         | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed                | 8                              | 5                              | 4                             | 4                    |
| Units: score on a scale                    |                                |                                |                               |                      |
| arithmetic mean (standard deviation)       |                                |                                |                               |                      |
| Baseline                                   | 9.5 ( $\pm$ 6.70)              | 13.8 ( $\pm$ 14.12)            | 6.5 ( $\pm$ 5.90)             | 9.6 ( $\pm$ 10.60)   |
| Change From Baseline at Wk 4               | -2.2 ( $\pm$ 5.19)             | -5.0 ( $\pm$ 5.14)             | -1.8 ( $\pm$ 1.54)            | -1.1 ( $\pm$ 5.41)   |
| Change From Baseline at Wk 8               | -3.4 ( $\pm$ 4.91)             | -5.5 ( $\pm$ 4.93)             | -3.0 ( $\pm$ 1.98)            | -5.6 ( $\pm$ 7.03)   |
| Change From Baseline at Wk 12<br>N=7,5,3,4 | -3.7 ( $\pm$ 5.65)             | -5.6 ( $\pm$ 6.13)             | -3.0 ( $\pm$ 2.10)            | -4.9 ( $\pm$ 7.12)   |
| Change From Baseline at Wk 16              | -5.5 ( $\pm$ 7.80)             | -7.0 ( $\pm$ 7.69)             | -5.2 ( $\pm$ 4.56)            | -6.4 ( $\pm$ 9.85)   |

### Statistical analyses

No statistical analyses for this end point

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

|   |   |
|---|---|
| End point title   | Percentage of Participants Who Achieved Psoriasis Area and Severity Index 50% Improvement (PASI50) Response at Weeks 4, 8, 12, and 16 in Participants With Psoriasis Covering $\geq 3\%$ of the BSA at Baseline |
| End point description:  |   |
| <p>PASI is assessed in participants with psoriasis covering <math>\geq 3\%</math> of the BSA at Baseline. PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body is divided into 4 regions: the head and neck, trunk, upper limbs, and lower limbs. Each of these areas are assessed separately for the percentage of the area involved and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4, which translates to a numeric score that ranges from 0 (indicates no involvement) to 6 (90 percent [%] to 100% involvement). The PASI produces a numeric score that can range from 0 (no disease) to 72 (maximal disease). For PASI50, the improvement threshold from baseline in PASI score is 50%. A higher score indicates more severe disease. Participants in the FAS with psoriasis covering <math>\geq 3\%</math> of the BSA at baseline and with available data were analyzed.</p> |   |
| End point type  | Secondary   |
| End point timeframe:  |   |
| Weeks 4, 8, 12, and 16  |   |

| End point values                  | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|-----------------------------------|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed       | 8                              | 5                              | 4                             | 4                    |
| Units: percentage of participants |                                |                                |                               |                      |
| number (confidence interval 95%)  |                                |                                |                               |                      |
| Wk 4                              | 37.5 (0.0 to 77.3)             | 40.0 (0.0 to 92.9)             | 50.0 (0.0 to 100.0)           | 0 (0.0 to 12.5)      |
| Wk 8                              | 25.0 (0.0 to 61.3)             | 40.0 (0.0 to 92.9)             | 50.0 (0.0 to 100.0)           | 50.0 (0.0 to 100.0)  |
| Wk 12 N=7,5,3,4                   | 57.1 (13.3 to 100.0)           | 40.0 (0.0 to 92.9)             | 100.0 (83.3 to 100.0)         | 50.0 (0.0 to 100.0)  |
| Wk 16                             | 62.5 (22.7 to 100.0)           | 40.0 (0.0 to 92.9)             | 100.0 (87.5 to 100.0)         | 25.0 (0.0 to 79.9)   |

## Statistical analyses

|   |   |
|---|---|
| Statistical analysis title              | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 4                                  |   |
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 12  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 37.5  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -14.8   |
| upper limit                             | 89.8  |



|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 4                                  |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 9   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 40  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -25.4   |
| upper limit                             | 100   |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 8                                  |   |
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 12  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | -25   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -100  |
| upper limit                             | 51.2  |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 8                                  |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 9   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | -10   |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | -97.7   |
| upper limit         | 77.7    |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 12                                 |   |
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 12  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 7.1   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -73.7   |
| upper limit                             | 88  |

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

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description: |   |
| Week 12                           |   |
| Comparison groups                 | Placebo (Main Study) v Filgotinib 100 mg (Main Study) |

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

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 16                                 |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 9   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 15  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -67.9   |
| upper limit                             | 97.9  |

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

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

End point description:

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

|                        |           |
|------------------------|-----------|
| End point type         | Secondary |
| End point timeframe:   |           |
| Weeks 4, 8, 12, and 16 |           |

| <b>End point values</b>           | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|-----------------------------------|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed       | 8                              | 5                              | 4                             | 4                    |
| Units: percentage of participants |                                |                                |                               |                      |
| number (confidence interval 95%)  |                                |                                |                               |                      |
| Wk 4                              | 12.5 (0.0 to 41.7)             | 20.0 (0.0 to 65.1)             | 0 (0.0 to 12.5)               | 0 (0.0 to 12.5)      |
| Wk 8                              | 25.0 (0.0 to 61.3)             | 40.0 (0.0 to 92.9)             | 25.0 (0.0 to 79.9)            | 0 (0.0 to 12.5)      |
| Wk 12 N=7,5,3,4                   | 42.9 (0.0 to 86.7)             | 40.0 (0.0 to 92.9)             | 66.7 (0.0 to 100.0)           | 0 (0.0 to 12.5)      |
| Wk 16                             | 62.5 (22.7 to 100.0)           | 20.0 (0.0 to 65.1)             | 75.0 (20.1 to 100.0)          | 25.0 (0.0 to 79.9)   |

### Statistical analyses

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 4                                  |   |
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 12  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 12.5  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -29.2   |
| upper limit                             | 54.2  |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 4                                  |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 9   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 20  |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | -37.6   |
| upper limit         | 77.6    |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 8                                  |   |
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 12  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 25  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -23.8   |
| upper limit                             | 73.8  |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 8                                  |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 9   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 40  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -25.4   |
| upper limit                             | 100   |

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description: |   |
| Week 12                           |   |
| Comparison groups                 | Placebo (Main Study) v Filgotinib 100 mg (Main Study) |

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

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

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

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Fil 200 mg (Main Study) vs Placebo (Main Study) |
| Statistical analysis description: |   |
| Week 16                           |   |

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

---

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

---

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

End point description:

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

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

End point timeframe:

Weeks 4, 8, 12, and 16

---

| End point values                  | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|-----------------------------------|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed       | 8                              | 5                              | 4                             | 4                    |
| Units: percentage of participants |                                |                                |                               |                      |
| number (confidence interval 95%)  |                                |                                |                               |                      |
| Wk 4                              | 0 (0.0 to 6.3)                 | 0 (0.0 to 10.0)                | 0 (0.0 to 12.5)               | 0 (0.0 to 12.5)      |
| Wk 8                              | 12.5 (0.0 to 41.7)             | 0 (0.0 to 10.0)                | 25.0 (0.0 to 79.9)            | 0 (0.0 to 12.5)      |
| Wk 12 N=7,5,3,4                   | 14.3 (0.0 to 47.4)             | 20.0 (0.0 to 65.1)             | 66.7 (0.0 to 100.0)           | 0 (0.0 to 12.5)      |
| Wk 16                             | 25.0 (0.0 to 61.3)             | 20.0 (0.0 to 65.1)             | 50.0 (0.0 to 100.0)           | 0 (0.0 to 12.5)      |

## Statistical analyses

| Statistical analysis title              | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
|---|---|
| Statistical analysis description:       |   |
| Week 4                                  |   |
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 12  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 0   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -18.8   |
| upper limit                             | 18.8  |

| Statistical analysis title              | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
|---|---|
| Statistical analysis description:       |   |
| Week 4                                  |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 9   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 0   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -22.5   |
| upper limit                             | 22.5  |

| Statistical analysis title              | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
|---|---|
| Statistical analysis description:       |   |
| Week 8                                  |   |
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 12  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 12.5  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -29.2   |
| upper limit                             | 54.2  |



|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 8                                  |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 9   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 0   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -22.5   |
| upper limit                             | 22.5  |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 12                                 |   |
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 12  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 14.3  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -31.3   |
| upper limit                             | 59.9  |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 12                                 |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 9   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 20  |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | -37.6   |
| upper limit         | 77.6    |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 12                                 |   |
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 12  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 25  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -23.8   |
| upper limit                             | 73.8  |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 16                                 |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 9   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 20  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -37.6   |
| upper limit                             | 77.6  |

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

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

End point description:

PASI is assessed in participants with psoriasis covering  $\geq$  3% of the BSA at Baseline. PASI is a system

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

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

End point timeframe:

Weeks 4, 8, 12, and 16

| End point values                  | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|-----------------------------------|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed       | 8                              | 5                              | 4                             | 4                    |
| Units: percentage of participants |                                |                                |                               |                      |
| number (confidence interval 95%)  |                                |                                |                               |                      |
| Wk 4                              | 0 (0.0 to 6.3)                 | 0 (0.0 to 10.0)                | 0 (0.0 to 12.5)               | 0 (0.0 to 12.5)      |
| Wk 8                              | 0 (0.0 to 6.3)                 | 0 (0.0 to 10.0)                | 25.0 (0.0 to 79.9)            | 0 (0.0 to 12.5)      |
| Wk 12 N=7,5,3,4                   | 14.3 (0.0 to 47.4)             | 0 (0.0 to 10.0)                | 66.7 (0.0 to 100.0)           | 0 (0.0 to 12.5)      |
| Wk 16                             | 12.5 (0.0 to 41.7)             | 20.0 (0.0 to 65.1)             | 25.0 (0.0 to 79.9)            | 0 (0.0 to 12.5)      |

## Statistical analyses

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Fil 200 mg (Main Study) vs Placebo (Main Study) |
|-----------------------------------|---|

Statistical analysis description:

Week 4

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 12  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 0   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -18.8   |
| upper limit                             | 18.8  |

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Fil 100 mg (Main Study) vs Placebo (Main Study) |
|-----------------------------------|---|

Statistical analysis description:

Week 4

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 9   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 0   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -22.5   |
| upper limit                             | 22.5  |

|   |   |
|---|---|
| <b>Statistical analysis title</b>           | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:<br>Week 8 |   |
| Comparison groups                           | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis     | 12  |
| Analysis specification                      | Pre-specified   |
| Analysis type                               | superiority   |
| Parameter estimate                          | Difference in response rates                          |
| Point estimate                              | 0   |
| Confidence interval                         |   |
| level                                       | 95 %  |
| sides                                       | 2-sided   |
| lower limit                                 | -18.8   |
| upper limit                                 | 18.8  |

|   |   |
|---|---|
| <b>Statistical analysis title</b>           | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:<br>Week 8 |   |
| Comparison groups                           | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis     | 9   |
| Analysis specification                      | Pre-specified   |
| Analysis type                               | superiority   |
| Parameter estimate                          | Difference in response rates                          |
| Point estimate                              | 0   |
| Confidence interval                         |   |
| level                                       | 95 %  |
| sides                                       | 2-sided   |
| lower limit                                 | -22.5   |
| upper limit                                 | 22.5  |

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Fil 200 mg (Main Study) vs Placebo (Main Study) |
|-----------------------------------|---|

Statistical analysis description:

Week 12

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 12  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 14.3  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -31.3   |
| upper limit                             | 59.9  |

**Statistical analysis title**

Fil 100 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 12

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 9   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 0   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -22.5   |
| upper limit                             | 22.5  |

**Statistical analysis title**

Fil 200 mg (Main Study) vs Placebo (Main Study)

Statistical analysis description:

Week 16

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 12  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 12.5  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -29.2   |
| upper limit                             | 54.2  |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 16                                 |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 9   |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| Parameter estimate                      | Difference in response rates                          |
| Point estimate                          | 20  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -37.6   |
| upper limit                             | 77.6  |

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

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

End point description:

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

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

End point timeframe:

Baseline, 4, 8, 12, and 16 weeks

| <b>End point values</b>                      | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|--|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                           | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed                  | 10                             | 9                              | 6                             | 11                   |
| Units: score on a scale                      |                                |                                |                               |                      |
| arithmetic mean (standard deviation)         |                                |                                |                               |                      |
| Baseline                                     | 4 (± 3.4)                      | 4 (± 2.4)                      | 4 (± 1.7)                     | 5 (± 4.5)            |
| Change From Baseline at Wk 4                 | -2 (± 2.6)                     | 0 (± 2.0)                      | -2 (± 1.2)                    | 0 (± 3.1)            |
| Change From Baseline at Wk 8<br>N=10,9,6,10  | -2 (± 2.4)                     | -1 (± 1.6)                     | -3 (± 1.9)                    | -2 (± 3.3)           |
| Change From Baseline at Wk 12<br>N=10,9,5,10 | -3 (± 3.5)                     | -2 (± 1.8)                     | -2 (± 1.5)                    | -1 (± 1.7)           |
| Change From Baseline at Wk 16                | -3 (± 3.3)                     | -2 (± 2.6)                     | -3 (± 1.5)                    | -1 (± 3.2)           |

## Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

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

End point timeframe:

Baseline, 4, 8, 12, and 16 weeks

| End point values                     | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|--------------------------------------|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                   | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed          | 6                              | 3                              | 1                             | 5                    |
| Units: score on a scale              |                                |                                |                               |                      |
| arithmetic mean (standard deviation) |                                |                                |                               |                      |
| Baseline                             | 69.5 (± 56.62)                 | 28.9 (± 17.35)                 | 159.1 (± 9999)                | 15.2 (± 19.45)       |
| Change From Baseline at Wk 4         | -13.4 (± 16.81)                | 13.0 (± 19.44)                 | -159.1 (± 9999)               | 13.3 (± 30.64)       |
| Change From Baseline at Wk 8         | -40.8 (± 45.15)                | -2.5 (± 18.34)                 | -159.1 (± 9999)               | 3.6 (± 40.81)        |
| Change From Baseline at Wk 12        | -49.3 (± 40.86)                | -14.0 (± 9.80)                 | -159.1 (± 9999)               | 2.1 (± 44.13)        |
| Change From Baseline at Wk 16        | -40.2 (± 51.12)                | 8.4 (± 41.91)                  | -159.1 (± 9999)               | 2.0 (± 31.30)        |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change From Baseline in Tender Dactylitis Count (TDC) at Weeks 4, 8,

**12, and 16 in Participants With Dactylitis at Baseline**

|   |   |
|---|---|
| End point title   | Change From Baseline in Tender Dactylitis Count (TDC) at Weeks 4, 8, 12, and 16 in Participants With Dactylitis at Baseline |
| End point description:<br>Tender score (0 = no tenderness, 1 = tender, 2 = tender and wince, 3 = tender and withdraw) is collected for Dactylitis Assessments on the Dactylitis Score Sheet that is used for calculation of LDI total score. Tender dactylitis count (TDC) equals the number of tender fingers and toes (tender score >0). For participants with dactylitis status absent for all the fingers and toes, the TDC is set as 0. The total score range of TDC is from 0 to 60, higher scores indicate greater presence of dactylitis. A negative change from baseline indicates improvement. Participants in the FAS with dactylitis at baseline were analyzed. 9999=SD cannot be calculated for one participant. |   |
| End point type  | Secondary   |
| End point timeframe:<br>Baseline, 4, 8, 12, and 16 weeks  |   |

| End point values                     | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|--------------------------------------|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                   | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed          | 6                              | 3                              | 1                             | 5                    |
| Units: tender dactylitis count       |                                |                                |                               |                      |
| arithmetic mean (standard deviation) |                                |                                |                               |                      |
| Baseline                             | 4 (± 4.1)                      | 2 (± 1.0)                      | 6 (± 9999)                    | 1 (± 1.3)            |
| Change From Baseline at Wk 4         | -1 (± 0.9)                     | 1 (± 1.0)                      | -6 (± 9999)                   | 0 (± 1.5)            |
| Change From Baseline at Wk 8         | -3 (± 3.3)                     | 0 (± 1.5)                      | -6 (± 9999)                   | 0 (± 2.1)            |
| Change From Baseline at Wk 12        | -3 (± 3.0)                     | -1 (± 1.5)                     | -6 (± 9999)                   | 0 (± 2.2)            |
| Change From Baseline at Wk 16        | -3 (± 3.3)                     | 0 (± 2.1)                      | -6 (± 9999)                   | 0 (± 1.5)            |

**Statistical analyses**

No statistical analyses for this end point

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

|   |  |
|---|--|
| End point title   | Change From Baseline in Health Assessment Questionnaire - Disability Index (HAQ-DI) Score at Weeks 2, 4, 8, 12, and 16 |
| End point description:<br>The HAQ-DI score is defined as the average of the scores of eight functional categories (dressing and grooming, arising, eating, walking, hygiene, reach, grip, and other activities), usually completed by the participant. Responses in each functional category are collected as 0 (without any difficulty) to 3 (unable to do a task in that area), with or without aids or devices. The eight category scores are averaged into an overall HAQ-DI score on a scale from 0 (no disability) to 3 (completely disabled). When 6 or more categories are non-missing, total possible score is 3. If more than 2 categories are missing, the HAQ-DI score is set to missing. A negative change from baseline indicates improvement (less disability). Participants in the FAS with available data were analyzed. |  |
| End point type  | Secondary  |
| End point timeframe:<br>Baseline, 2, 4, 8, 12, and 16 weeks   |  |



| End point values                              | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|---|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                            | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed                   | 19                             | 19                             | 8                             | 20                   |
| Units: score on a scale                       |                                |                                |                               |                      |
| arithmetic mean (standard deviation)          |                                |                                |                               |                      |
| Baseline                                      | 1.05 (± 0.601)                 | 0.80 (± 0.547)                 | 0.95 (± 0.630)                | 0.92 (± 0.602)       |
| Change From Baseline at Wk 2<br>N=19,18,8,19  | -0.13 (± 0.293)                | -0.09 (± 0.345)                | 0.03 (± 0.332)                | -0.08 (± 0.321)      |
| Change From Baseline at Wk 4<br>N=19,18,8,20  | -0.20 (± 0.264)                | -0.24 (± 0.474)                | -0.16 (± 0.297)               | -0.01 (± 0.337)      |
| Change From Baseline at Wk 8<br>N=19,19,8,19  | -0.37 (± 0.387)                | -0.24 (± 0.516)                | -0.16 (± 0.281)               | -0.12 (± 0.407)      |
| Change From Baseline at Wk 12<br>N=18,19,7,19 | -0.33 (± 0.374)                | -0.20 (± 0.477)                | -0.39 (± 0.274)               | -0.07 (± 0.438)      |
| Change From Baseline at Wk 16<br>N=18,19,8,20 | -0.33 (± 0.407)                | -0.33 (± 0.575)                | -0.34 (± 0.297)               | -0.19 (± 0.487)      |

## Statistical analyses

| Statistical analysis title              | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
|---|---|
| Statistical analysis description:       |   |
| Week 2                                  |   |
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.94 <sup>[31]</sup>                                |
| Method                                  | MMRM  |
| Parameter estimate                      | LS Mean Treatment Difference                          |
| Point estimate                          | -0.01   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -0.22   |
| upper limit                             | 0.2   |

Notes:

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

| Statistical analysis title        | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
|-----------------------------------|---|
| Statistical analysis description: |   |
| Week 2                            |   |
| Comparison groups                 | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |

|   |                              |
|---|------------------------------|
| Number of subjects included in analysis | 39                           |
| Analysis specification                  | Pre-specified                |
| Analysis type                           | superiority                  |
| P-value                                 | = 0.81 <sup>[32]</sup>       |
| Method                                  | MMRM                         |
| Parameter estimate                      | LS Mean Treatment Difference |
| Point estimate                          | 0.03                         |
| Confidence interval                     |                              |
| level                                   | 95 %                         |
| sides                                   | 2-sided                      |
| lower limit                             | -0.18                        |
| upper limit                             | 0.24                         |

Notes:

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

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Fil 200 mg (Main Study) vs Placebo (Main Study) |
|-----------------------------------|---|

Statistical analysis description:

Week 4

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.13 <sup>[33]</sup>                                |
| Method                                  | MMRM  |
| Parameter estimate                      | LS Mean Treatment Difference                          |
| Point estimate                          | -0.17   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -0.39   |
| upper limit                             | 0.05  |

Notes:

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

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Fil 100 mg (Main Study) vs Placebo (Main Study) |
|-----------------------------------|---|

Statistical analysis description:

Week 4

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.073 <sup>[34]</sup>                               |
| Method                                  | MMRM  |
| Parameter estimate                      | LS Mean Treatment Difference                          |
| Point estimate                          | -0.21   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -0.43   |
| upper limit                             | 0.02  |

Notes:

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

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 8                                  |   |
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.083 <sup>[35]</sup>                               |
| Method                                  | MMRM  |
| Parameter estimate                      | LS Mean Treatment Difference                          |
| Point estimate                          | -0.22   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -0.46   |
| upper limit                             | 0.03  |

Notes:

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

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 8                                  |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.28 <sup>[36]</sup>                                |
| Method                                  | MMRM  |
| Parameter estimate                      | LS Mean Treatment Difference                          |
| Point estimate                          | -0.14   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -0.38   |
| upper limit                             | 0.11  |

Notes:

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

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description: |   |
| Week 12                           |   |
| Comparison groups                 | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |

|   |                              |
|---|------------------------------|
| Number of subjects included in analysis | 39                           |
| Analysis specification                  | Pre-specified                |
| Analysis type                           | superiority                  |
| P-value                                 | = 0.038 <sup>[37]</sup>      |
| Method                                  | MMRM                         |
| Parameter estimate                      | LS Mean Treatment Difference |
| Point estimate                          | -0.28                        |
| Confidence interval                     |                              |
| level                                   | 95 %                         |
| sides                                   | 2-sided                      |
| lower limit                             | -0.54                        |
| upper limit                             | -0.02                        |

Notes:

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

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Fil 100 mg (Main Study) vs Placebo (Main Study) |
|-----------------------------------|---|

Statistical analysis description:

Week 12

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.25 <sup>[38]</sup>                                |
| Method                                  | MMRM  |
| Parameter estimate                      | LS Mean Treatment Difference                          |
| Point estimate                          | -0.15   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -0.41   |
| upper limit                             | 0.11  |

Notes:

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

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Fil 200 mg (Main Study) vs Placebo (Main Study) |
|-----------------------------------|---|

Statistical analysis description:

Week 16

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.41 <sup>[39]</sup>                                |
| Method                                  | MMRM  |
| Parameter estimate                      | LS Mean Treatment Difference                          |
| Point estimate                          | -0.11   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -0.39   |
| upper limit                             | 0.16  |

Notes:

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

|  |   |
|--|---|
| <b>Statistical analysis title</b>            | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:<br>Week 16 |   |
| Comparison groups                            | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis      | 39  |
| Analysis specification                       | Pre-specified   |
| Analysis type                                | superiority   |
| P-value                                      | = 0.26 <sup>[40]</sup>                                |
| Method                                       | MMRM  |
| Parameter estimate                           | LS Mean Treatment Difference                          |
| Point estimate                               | -0.16   |
| Confidence interval                          |   |
| level  | 95 %  |
| sides  | 2-sided   |
| lower limit                                  | -0.43   |
| upper limit                                  | 0.12  |

Notes:

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

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

|  |  |
|--|--|
| End point title  | Change From Baseline in Functional Assessment of Chronic Illness Therapy - Fatigue Scale (FACIT-Fatigue) Score at Weeks 4 and 16 |
| End point description:<br>FACIT-Fatigue scale is a brief, 13-item, symptom-specific questionnaire that specifically assesses the self-reported severity of fatigue and its impact upon daily activities and functioning in the past 7 days. The FACIT-Fatigue uses 0 (not at all) to 4 (very much) numeric rating scales for a total possible score of 0 to 52. Higher scores indicate less fatigue. Positive change in value indicates improvement (no or less severity of fatigue). Participants in the FAS with available data were analyzed. |  |
| End point type   | Secondary  |
| End point timeframe:<br>Baseline, 4, and 16 weeks  |  |

| <b>End point values</b>                      | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|--|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                           | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed                  | 19                             | 19                             | 8                             | 20                   |
| Units: score on a scale                      |                                |                                |                               |                      |
| arithmetic mean (standard deviation)         |                                |                                |                               |                      |
| Baseline                                     | 32.5 (± 9.83)                  | 33.9 (± 13.06)                 | 33.4 (± 10.66)                | 31.4 (± 10.37)       |
| Change From Baseline at Wk 4<br>N=19,18,8,20 | 4.6 (± 9.75)                   | 4.1 (± 8.53)                   | 0.5 (± 7.23)                  | 1.6 (± 6.53)         |
| Change From Baseline at Wk 16                | 5.6 (± 9.45)                   | 6.4 (± 10.42)                  | 4.6 (± 9.18)                  | 2.4 (± 9.27)         |

## Statistical analyses

|   |   |
|---|---|
| <b>Statistical analysis title</b>           | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:<br>Week 4 |   |
| Comparison groups                           | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis     | 39  |
| Analysis specification                      | Pre-specified   |
| Analysis type                               | superiority   |
| P-value                                     | = 0.14 <sup>[41]</sup>                                |
| Method                                      | MMRM  |
| Parameter estimate                          | LS Mean Treatment Difference                          |
| Point estimate                              | 3.4   |
| Confidence interval                         |   |
| level                                       | 95 %  |
| sides                                       | 2-sided   |
| lower limit                                 | -1.1  |
| upper limit                                 | 7.9   |

Notes:

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

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

Notes:

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

|  |   |
|--|---|
| <b>Statistical analysis title</b>            | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:<br>Week 16 |   |
| Comparison groups                            | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |

|   |                              |
|---|------------------------------|
| Number of subjects included in analysis | 39                           |
| Analysis specification                  | Pre-specified                |
| Analysis type                           | superiority                  |
| P-value                                 | = 0.15 <sup>[43]</sup>       |
| Method                                  | MMRM                         |
| Parameter estimate                      | LS Mean Treatment Difference |
| Point estimate                          | 3.7                          |
| Confidence interval                     |                              |
| level                                   | 95 %                         |
| sides                                   | 2-sided                      |
| lower limit                             | -1.4                         |
| upper limit                             | 8.7                          |

Notes:

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

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Fil 100 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:       |   |
| Week 16                                 |   |
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.062 <sup>[44]</sup>                               |
| Method                                  | MMRM  |
| Parameter estimate                      | LS Mean Treatment Difference                          |
| Point estimate                          | 4.8   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -0.3  |
| upper limit                             | 9.9   |

Notes:

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

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

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

End point description:

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

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

End point timeframe:

Baseline, 4, and 16 weeks

| End point values                             | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|--|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                           | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed                  | 19                             | 19                             | 8                             | 20                   |
| Units: score on a scale                      |                                |                                |                               |                      |
| arithmetic mean (standard deviation)         |                                |                                |                               |                      |
| Baseline                                     | 49.9 (± 12.48)                 | 50.5 (± 11.43)                 | 44.8 (± 7.67)                 | 48.9 (± 9.27)        |
| Change From Baseline at Wk 4<br>N=19,18,8,20 | 3.3 (± 9.66)                   | 0.4 (± 9.40)                   | 0.6 (± 6.80)                  | -0.4 (± 5.58)        |
| Change From Baseline at Wk 16                | 2.8 (± 10.34)                  | 0.2 (± 9.42)                   | -0.4 (± 5.58)                 | 0.3 (± 5.95)         |

## Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

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

End point timeframe:

Baseline, 4, and 16 weeks

| End point values                             | Filgotinib 200 mg (Main Study) | Filgotinib 100 mg (Main Study) | Adalimumab 40 mg (Main Study) | Placebo (Main Study) |
|--|--------------------------------|--------------------------------|-------------------------------|----------------------|
| Subject group type                           | Reporting group                | Reporting group                | Reporting group               | Reporting group      |
| Number of subjects analysed                  | 19                             | 19                             | 8                             | 20                   |
| Units: score on a scale                      |                                |                                |                               |                      |
| arithmetic mean (standard deviation)         |                                |                                |                               |                      |
| Baseline                                     | 37.1 (± 8.11)                  | 39.2 (± 9.60)                  | 39.2 (± 7.58)                 | 37.2 (± 7.83)        |
| Change From Baseline at Wk 4<br>N=19,18,8,20 | 6.4 (± 5.87)                   | 5.6 (± 7.00)                   | 2.9 (± 7.12)                  | 1.1 (± 5.24)         |
| Change From Baseline at Wk 16                | 8.4 (± 6.86)                   | 7.4 (± 9.80)                   | 8.1 (± 7.73)                  | 4.6 (± 7.85)         |



## Statistical analyses

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

Notes:

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

|   |   |
|---|---|
| <b>Statistical analysis title</b>           | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:<br>Week 4 |   |
| Comparison groups                           | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis     | 39  |
| Analysis specification                      | Pre-specified   |
| Analysis type                               | superiority   |
| P-value                                     | = 0.003 <sup>[46]</sup>                               |
| Method                                      | MMRM  |
| Parameter estimate                          | LS Mean Treatment Difference                          |
| Point estimate                              | 5.3   |
| Confidence interval                         |   |
| level                                       | 95 %  |
| sides                                       | 2-sided   |
| lower limit                                 | 1.9   |
| upper limit                                 | 8.6   |

Notes:

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

|  |   |
|--|---|
| <b>Statistical analysis title</b>            | Fil 200 mg (Main Study) vs Placebo (Main Study)       |
| Statistical analysis description:<br>Week 16 |   |
| Comparison groups                            | Filgotinib 200 mg (Main Study) v Placebo (Main Study) |

|   |                              |
|---|------------------------------|
| Number of subjects included in analysis | 39                           |
| Analysis specification                  | Pre-specified                |
| Analysis type                           | superiority                  |
| P-value                                 | = 0.076 <sup>[47]</sup>      |
| Method                                  | MMRM                         |
| Parameter estimate                      | LS Mean Treatment Difference |
| Point estimate                          | 3.8                          |
| Confidence interval                     |                              |
| level                                   | 95 %                         |
| sides                                   | 2-sided                      |
| lower limit                             | -0.4                         |
| upper limit                             | 8                            |

Notes:

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

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Fil 100 mg (Main Study) vs Placebo (Main Study) |
|-----------------------------------|---|

Statistical analysis description:

Week 16

|   |   |
|---|---|
| Comparison groups                       | Filgotinib 100 mg (Main Study) v Placebo (Main Study) |
| Number of subjects included in analysis | 39  |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority   |
| P-value                                 | = 0.1 <sup>[48]</sup>                                 |
| Method                                  | MMRM  |
| Parameter estimate                      | LS Mean Treatment Difference                          |
| Point estimate                          | 3.5   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -0.7  |
| upper limit                             | 7.7   |

Notes:

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

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Adverse Events: First dose date up to 50 weeks plus 30 days; All-Cause Mortality: Randomization up to 50 weeks plus 30 days

Adverse event reporting additional description:

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

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

### Dictionary used

|                 |        |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

|                    |      |
|--------------------|------|
| Dictionary version | 24.0 |
|--------------------|------|

### Reporting groups

|                       |                                |
|-----------------------|--------------------------------|
| Reporting group title | Filgotinib 200 mg (Main Study) |
|-----------------------|--------------------------------|

Reporting group description:

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

|                       |                                |
|-----------------------|--------------------------------|
| Reporting group title | Filgotinib 100 mg (Main Study) |
|-----------------------|--------------------------------|

Reporting group description:

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

|                       |                               |
|-----------------------|-------------------------------|
| Reporting group title | Adalimumab 40 mg (Main Study) |
|-----------------------|-------------------------------|

Reporting group description:

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

|                       |                      |
|-----------------------|----------------------|
| Reporting group title | Placebo (Main Study) |
|-----------------------|----------------------|

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

|                       |                                      |
|-----------------------|--------------------------------------|
| Reporting group title | Filgotinib 200 mg From Placebo (LTE) |
|-----------------------|--------------------------------------|

Reporting group description:

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

|                       |                                      |
|-----------------------|--------------------------------------|
| Reporting group title | Filgotinib 100 mg From Placebo (LTE) |
|-----------------------|--------------------------------------|

Reporting group description:

Filgotinib 100 mg tablet orally once daily + PTM filgotinib 200 mg tablet orally once daily for up to 34

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

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

| Serious adverse events  | Filgotinib 200 mg<br>From Adalimumab<br>40 mg (LTE) | Filgotinib 100 mg<br>From Adalimumab<br>40 mg (LTE) | Filgotinib 200 mg<br>From Placebo (LTE) |
|---|---|---|---|
| Total subjects affected by serious adverse events                   |   |   |   |
| subjects affected / exposed   | 0 / 1 (0.00%)                                       | 0 / 1 (0.00%)                                       | 1 / 2 (50.00%)                          |
| number of deaths (all causes)                                       | 0   | 0   | 0                                       |
| number of deaths resulting from adverse events                      | 0   | 0   | 0                                       |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |   |   |   |
| Invasive ductal breast carcinoma                                    |   |   |   |
| subjects affected / exposed   | 0 / 1 (0.00%)                                       | 0 / 1 (0.00%)                                       | 1 / 2 (50.00%)                          |
| occurrences causally related to treatment / all                     | 0 / 0   | 0 / 0   | 0 / 1                                   |
| deaths causally related to treatment / all                          | 0 / 0   | 0 / 0   | 0 / 0                                   |
| Infections and infestations   |   |   |   |
| Helicobacter infection  |   |   |   |
| subjects affected / exposed   | 0 / 1 (0.00%)                                       | 0 / 1 (0.00%)                                       | 0 / 2 (0.00%)                           |
| occurrences causally related to treatment / all                     | 0 / 0   | 0 / 0   | 0 / 0                                   |
| deaths causally related to treatment / all                          | 0 / 0   | 0 / 0   | 0 / 0                                   |

| Serious adverse events  | Filgotinib 100 mg<br>From Placebo (LTE) |  |  |
|---|---|--|--|
| Total subjects affected by serious adverse events                   |   |  |  |
| subjects affected / exposed   | 0 / 2 (0.00%)                           |  |  |
| number of deaths (all causes)                                       | 0                                       |  |  |
| number of deaths resulting from adverse events                      | 0                                       |  |  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |   |  |  |
| Invasive ductal breast carcinoma                                    |   |  |  |
| subjects affected / exposed   | 0 / 2 (0.00%)                           |  |  |
| occurrences causally related to treatment / all                     | 0 / 0                                   |  |  |
| deaths causally related to treatment / all                          | 0 / 0                                   |  |  |
| Infections and infestations   |   |  |  |
| Helicobacter infection  |   |  |  |
| subjects affected / exposed   | 0 / 2 (0.00%)                           |  |  |
| occurrences causally related to treatment / all                     | 0 / 0                                   |  |  |
| deaths causally related to treatment / all                          | 0 / 0                                   |  |  |

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

| <b>Non-serious adverse events</b>  | Filgotinib 200 mg<br>(Main Study)   | Filgotinib 100 mg<br>(Main Study)   | Adalimumab 40 mg<br>(Main Study)                                       |
|--|---|---|--|
| Total subjects affected by non-serious adverse events<br>subjects affected / exposed   | 4 / 19 (21.05%)   | 7 / 19 (36.84%)   | 2 / 9 (22.22%)   |
| Vascular disorders<br>Hypertension<br>subjects affected / exposed<br>occurrences (all)   | 1 / 19 (5.26%)<br>1   | 1 / 19 (5.26%)<br>1   | 0 / 9 (0.00%)<br>0   |
| General disorders and administration site conditions<br>Asthenia<br>subjects affected / exposed<br>occurrences (all)<br><br>Fatigue<br>subjects affected / exposed<br>occurrences (all)<br><br>Pyrexia<br>subjects affected / exposed<br>occurrences (all) | 0 / 19 (0.00%)<br>0<br><br>0 / 19 (0.00%)<br>0<br><br>1 / 19 (5.26%)<br>1 | 0 / 19 (0.00%)<br>0<br><br>1 / 19 (5.26%)<br>1<br><br>0 / 19 (0.00%)<br>0 | 0 / 9 (0.00%)<br>0<br><br>0 / 9 (0.00%)<br>0<br><br>0 / 9 (0.00%)<br>0 |
| Respiratory, thoracic and mediastinal disorders<br>Cough<br>subjects affected / exposed<br>occurrences (all)   | 0 / 19 (0.00%)<br>0   | 0 / 19 (0.00%)<br>0   | 0 / 9 (0.00%)<br>0   |
| Psychiatric disorders<br>Initial insomnia<br>subjects affected / exposed<br>occurrences (all)<br><br>Insomnia<br>subjects affected / exposed<br>occurrences (all)  | 0 / 19 (0.00%)<br>0<br><br>0 / 19 (0.00%)<br>0                            | 1 / 19 (5.26%)<br>1<br><br>0 / 19 (0.00%)<br>0                            | 0 / 9 (0.00%)<br>0<br><br>0 / 9 (0.00%)<br>0                           |
| Investigations<br>Aspartate aminotransferase increased<br>subjects affected / exposed<br>occurrences (all)   | 1 / 19 (5.26%)<br>1   | 0 / 19 (0.00%)<br>0   | 0 / 9 (0.00%)<br>0   |
| Injury, poisoning and procedural complications<br>Fall<br>subjects affected / exposed<br>occurrences (all)   | 1 / 19 (5.26%)<br>2   | 0 / 19 (0.00%)<br>0   | 0 / 9 (0.00%)<br>0   |

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

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

| <b>Non-serious adverse events</b>                     | Placebo (Main Study) | Filgotinib 200 mg<br>From Filgotinib 200 mg (LTE) | Filgotinib 100 mg<br>From Filgotinib 100 mg (LTE) |
|---|----------------------|---|---|
| Total subjects affected by non-serious adverse events |                      |   |   |



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

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

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

| <b>Non-serious adverse events</b>                     | Filgotinib 200 mg<br>From Adalimumab<br>40 mg (LTE) | Filgotinib 100 mg<br>From Adalimumab<br>40 mg (LTE) | Filgotinib 200 mg<br>From Placebo (LTE) |
|---|---|---|---|
| Total subjects affected by non-serious adverse events |   |   |   |

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

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

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

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

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

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



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

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date           | Amendment   |
|----------------|---|
| 07 August 2019 | <ul style="list-style-type: none"><li>• Clarified initial DMC data review.</li><li>• Clarified laboratory retesting criteria.</li><li>• Clarified inadequate responder definition.</li><li>• Clarified vaccination recommendations.</li><li>• Optional skin biopsy time points were revised.</li><li>• Inconsistencies to the MRI investigation were corrected.</li><li>• Clarified the primary estimand.</li><li>• Viral monitoring frequency was increased.</li><li>• Urine drug screen panel was revised.</li><li>• Aligned C-reactive protein (CRP) blinding to be consistent throughout protocol.</li><li>• Secondary and exploratory endpoints were recategorized.</li><li>• Clarified stratification at randomization</li><li>• Added optional HLA-B27 sample collection.</li><li>• CTCAE Version 4.03 was updated to Version 5.0.</li><li>• Added follicle-stimulating hormone testing after screening.</li><li>• Updated sample questionnaires for Clinical and Patient Reported Outcomes and corrected inconsistencies with nomenclature.</li><li>• Eligibility criteria was clarified as needed.</li><li>• Inconsistencies regarding timing of the first MRI (at screening) were corrected.</li><li>• Inconsistencies regarding the window for imaging assessments were corrected.</li></ul> |

|               |  |
|---------------|--|
| 17 April 2020 | <ul style="list-style-type: none"> <li>Increased planned number of sites to support enrollment.</li> <li>Removed secondary objective for modified Total Sharp Score (mTSS).</li> <li>Removed restriction on use of Week 16 data.</li> <li>Updated Study Design to end (Main Study) at Week 16, revised last in-clinic visit at</li> <li>Week 120, reduced study duration to 2.25 years, and reduced sample size.</li> <li>Corrected and clarified inclusion and exclusion criteria with respect to cyclosporine removal,</li> <li>region-specific age requirements, and total bilirubin at screening;</li> <li>removed inclusion criteria for x-rays</li> <li>Updated key secondary, other secondary, and exploratory endpoints including the removal of mTSS endpoint.</li> <li>Added description for graphical approach test procedures and safety estimands; updated sample size assumptions and calculations.</li> <li>Updated Preclinical Pharmacology and Toxicology section to align with current IB.</li> <li>Added patient discontinuation requirement for thromboembolic events and for patients with active disease at Week 24.</li> <li>Included biomarker collection visits in Study Procedures Table footnotes and peripheral blood mononuclear cell collection clarification for North America only.</li> <li>Clarified patient could withdraw MRI consent, and updated objectives to match revised collection time point.</li> <li>Removed CRP collection at screening and updated CRP at Day 1 to be unblinded to the sponsor.</li> <li>Updated concomitant medications as a result of shortened Main Study and to include a note for medications that could cause dermatitis and exacerbate psoriasis.</li> <li>Revised timing of rescue therapy with uncontrolled PsA disease activity.</li> <li>Updated AE terminology, Special Situations reporting, SAE and death reporting.</li> <li>Added toxicity management for thromboembolic events.</li> <li>Added more detailed process language for DMC.</li> <li>Updated MACE and thromboembolic events language to include/add more detailed description of adjudication process.</li> <li>Clarified when early termination and safety follow-up visits were to occur.</li> </ul> |
|---------------|--|

Notes:

## Interruptions (globally)

Were there any global interruptions to the trial? Yes

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

Notes:

## Limitations and caveats

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

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

Notes:

