



## Clinical trial results:

### A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy and Safety of 2 Doses of Tofacitinib (CP-690,550) or Adalimumab in Subjects With Active Psoriatic Arthritis

#### Summary

|                          |                         |
|--------------------------|-------------------------|
| EudraCT number           | 2011-003668-55          |
| Trial protocol           | BE CZ ES SK HU DE PL BG |
| Global end of trial date | 18 December 2015        |

#### Results information

|                                |                  |
|--------------------------------|------------------|
| Result version number          | v1 (current)     |
| This version publication date  | 22 December 2016 |
| First version publication date | 22 December 2016 |

#### Trial information

##### Trial identification

|                       |          |
|-----------------------|----------|
| Sponsor protocol code | A3921091 |
|-----------------------|----------|

##### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT01877668 |
| WHO universal trial number (UTN)   | -           |

Notes:

#### Sponsors

|                              |  |
|------------------------------|--|
| Sponsor organisation name    | Pfizer, Inc.   |
| Sponsor organisation address | 235 E 42nd Street, New York, United States, NY 10017   |
| Public contact               | Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com |
| Scientific contact           | Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com |

Notes:

#### Paediatric regulatory details

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

Notes:

## Results analysis stage

|  |                  |
|--|------------------|
| Analysis stage                                       | Final            |
| Date of interim/final analysis                       | 18 December 2015 |
| Is this the analysis of the primary completion data? | Yes              |
| Primary completion date                              | 04 December 2015 |
| Global end of trial reached?                         | Yes              |
| Global end of trial date                             | 18 December 2015 |
| Was the trial ended prematurely?                     | No               |

Notes:

## General information about the trial

Main objective of the trial:

The main objectives of this trial were to compare the efficacy of tofacitinib at doses of 5 mg twice daily (BID) and 10 mg BID versus placebo for the treatment of rheumatological signs and symptoms of psoriatic arthritis (PsA), to compare physical function status, and to compare the safety and tolerability of 2 doses (5 mg BID and 10 mg BID) of tofacitinib versus placebo in participants with active PsA who have had an inadequate response to conventional synthetic disease modifying anti rheumatic drugs.

Protection of trial subjects:

This study was conducted in compliance with the ethical principles originating in or derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonisation Good Clinical Practice Guidelines. In addition, all local regulatory requirements were followed, in particular, those affording greater protection to the safety of trial participants. The final protocol and any amendments were reviewed and approved by the Institutional Review Board(s) and/or Independent Ethics Committee(s) at each of the investigational centres participating in the study.

Background therapy:

Eligible participants remained on a stable dose of 1 conventional synthetic disease-modifying anti-rheumatic drug treatment (ie, methotrexate, sulfasalazine, leflunomide, or others as approved by the Pfizer study clinician) as background therapy.

Evidence for comparator:

Adalimumab was included in a reference arm as an active control. An adalimumab dose of 40 mg subcutaneously administered every 2 weeks is the approved dose for rheumatoid arthritis and psoriasis and was the dose used in this study.

|   |                 |
|---|-----------------|
| Actual start date of recruitment                          | 20 January 2014 |
| 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: 12          |
| Country: Number of subjects enrolled | Belgium: 3             |
| Country: Number of subjects enrolled | Bulgaria: 28           |
| Country: Number of subjects enrolled | Canada: 5              |
| Country: Number of subjects enrolled | Czech Republic: 18     |
| Country: Number of subjects enrolled | France: 1              |
| Country: Number of subjects enrolled | Germany: 11            |
| Country: Number of subjects enrolled | Hungary: 31            |
| Country: Number of subjects enrolled | Mexico: 15             |
| Country: Number of subjects enrolled | Poland: 160            |
| Country: Number of subjects enrolled | Russian Federation: 39 |

|                                      |                    |
|--------------------------------------|--------------------|
| Country: Number of subjects enrolled | Slovakia: 12       |
| Country: Number of subjects enrolled | Spain: 19          |
| Country: Number of subjects enrolled | Taiwan: 6          |
| Country: Number of subjects enrolled | United Kingdom: 15 |
| Country: Number of subjects enrolled | United States: 47  |
| Worldwide total number of subjects   | 422                |
| EEA total number of subjects         | 298                |

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)                      | 384 |
| From 65 to 84 years                       | 38  |
| 85 years and over                         | 0   |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

Of 611 participants screened for entry into the study, 422 received treatment.

### Period 1

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

### Arms

|                              |     |
|------------------------------|-----|
| Are arms mutually exclusive? | Yes |
|------------------------------|-----|

|                  |                                |
|------------------|--------------------------------|
| <b>Arm title</b> | Tofacitinib, 5 mg, twice daily |
|------------------|--------------------------------|

Arm description:

Participants received 1 tofacitinib 5-mg tablet twice daily, 1 placebo tablet twice daily, and subcutaneous placebo administered every 2 weeks.

|  |                    |
|--|--------------------|
| Arm type                               | Experimental       |
| Investigational medicinal product name | Tofacitinib        |
| Investigational medicinal product code | CP-690,550         |
| Other name                             |                    |
| Pharmaceutical forms                   | Film-coated tablet |
| Routes of administration               | Oral use           |

Dosage and administration details:

Tofacitinib 5 mg administered twice daily (with 1 matching placebo tablet) and subcutaneous placebo every 2 weeks during the placebo controlled period (up to Month 3) and the active extension period (from Month 3 to Month 12).

|                  |                                 |
|------------------|---------------------------------|
| <b>Arm title</b> | Tofacitinib, 10 mg, twice daily |
|------------------|---------------------------------|

Arm description:

Participants received 2 tofacitinib 5-mg tablets twice daily and subcutaneous placebo every 2 weeks.

|  |                    |
|--|--------------------|
| Arm type                               | Experimental       |
| Investigational medicinal product name | Tofacitinib        |
| Investigational medicinal product code | CP-690,550         |
| Other name                             |                    |
| Pharmaceutical forms                   | Film-coated tablet |
| Routes of administration               | Oral use           |

Dosage and administration details:

Tofacitinib 10 mg administered twice daily and subcutaneous placebo every 2 weeks during the placebo controlled period (up to Month 3) and the active extension period (from Month 3 to Month 12).

|                  |                                  |
|------------------|----------------------------------|
| <b>Arm title</b> | Adalimumab, 40 mg, every 2 weeks |
|------------------|----------------------------------|

Arm description:

Participants received 2 placebo tablets twice daily and adalimumab, 40 mg, administered subcutaneously every 2 weeks.

|          |                   |
|----------|-------------------|
| Arm type | Active comparator |
|----------|-------------------|

|  |   |
|--|---|
| Investigational medicinal product name | Adalimumab  |
| Investigational medicinal product code |   |
| Other name                             |   |
| Pharmaceutical forms                   | Solution for injection/infusion in pre-filled syringe |
| Routes of administration               | Subcutaneous use                                      |

**Dosage and administration details:**

Placebo tablets administered twice daily and subcutaneous adalimumab 40 mg every 2 weeks during the placebo controlled period (up to Month 3) and the active extension period (from Month 3 to Month 12).

|                  |  |
|------------------|--|
| <b>Arm title</b> | Placebo/Tofacitinib, 5 mg, twice daily |
|------------------|--|

**Arm description:**

Participants received 2 placebo tablets twice daily and subcutaneous placebo every 2 weeks for 3 months. At the end of this period, participants received 1 tofacitinib 5-mg tablet twice daily, 1 placebo tablet twice daily, and subcutaneous placebo every 2 weeks.

|  |                    |
|--|--------------------|
| Arm type                               | Experimental       |
| Investigational medicinal product name | Tofacitinib        |
| Investigational medicinal product code | CP-690,550         |
| Other name                             |                    |
| Pharmaceutical forms                   | Film-coated tablet |
| Routes of administration               | Oral use           |

**Dosage and administration details:**

Placebo tablets administered twice daily and subcutaneous placebo every 2 weeks during the placebo controlled period (up to Month 3) followed by tofacitinib 5 mg administered twice daily (with 1 matching placebo tablet) during the active extension period (from Month 3 to Month 12).

|                  |   |
|------------------|---|
| <b>Arm title</b> | Placebo/Tofacitinib, 10 mg, twice daily |
|------------------|---|

**Arm description:**

Participants received 2 placebo tablets twice daily and subcutaneous placebo every 2 weeks for 3 months. At the end of this period, participants received 2 tofacitinib 5-mg tablets twice daily and subcutaneous placebo every 2 weeks.

|  |                    |
|--|--------------------|
| Arm type                               | Experimental       |
| Investigational medicinal product name | Tofacitinib        |
| Investigational medicinal product code | CP-690,550         |
| Other name                             |                    |
| Pharmaceutical forms                   | Film-coated tablet |
| Routes of administration               | Oral use           |

**Dosage and administration details:**

Placebo tablets administered twice daily and subcutaneous placebo every 2 weeks during the placebo controlled period (up to Month 3) followed by tofacitinib 10 mg administered twice daily during the active extension period (from Month 3 to Month 12).

| <b>Number of subjects in period 1</b> | <b>Tofacitinib, 5 mg, twice daily</b> | <b>Tofacitinib, 10 mg, twice daily</b> | <b>Adalimumab, 40 mg, every 2 weeks</b> |
|---------------------------------------|---------------------------------------|--|---|
| Started                               | 107                                   | 104                                    | 106                                     |
| Completed                             | 96                                    | 96                                     | 94                                      |
| Not completed                         | 11                                    | 8                                      | 12                                      |
| Adverse event, serious fatal          | -                                     | -                                      | -                                       |
| Consent withdrawn by subject          | 2                                     | -                                      | 3                                       |
| No longer met study criteria          | 1                                     | -                                      | 1                                       |
| Not specified                         | 1                                     | 1                                      | 1                                       |
| Adverse event unrelated to study drug | 4                                     | 1                                      | 2                                       |

|                                     |   |   |   |
|-------------------------------------|---|---|---|
| Lost to follow-up                   | - | 2 | 1 |
| Adverse event related to study drug | 2 | 2 | 2 |
| Protocol deviation                  | 1 | 1 | - |
| Insufficient clinical response      | - | 1 | 2 |

| <b>Number of subjects in period 1</b> | Placebo/Tofacitinib,<br>5 mg, twice daily | Placebo/Tofacitinib,<br>10 mg, twice daily |
|---------------------------------------|---|--|
| Started                               | 52  | 53   |
| Completed                             | 44  | 43   |
| Not completed                         | 8   | 10   |
| Adverse event, serious fatal          | 1   | -  |
| Consent withdrawn by subject          | 2   | 2  |
| No longer met study criteria          | -   | -  |
| Not specified                         | 1   | 3  |
| Adverse event unrelated to study drug | -   | 1  |
| Lost to follow-up                     | -   | -  |
| Adverse event related to study drug   | 2   | 1  |
| Protocol deviation                    | -   | 3  |
| Insufficient clinical response        | 2   | -  |

## Baseline characteristics

### Reporting groups

|  |   |
|--|---|
| Reporting group title  | Tofacitinib, 5 mg, twice daily          |
| Reporting group description:<br>Participants received 1 tofacitinib 5-mg tablet twice daily, 1 placebo tablet twice daily, and subcutaneous placebo administered every 2 weeks.  |   |
| Reporting group title  | Tofacitinib, 10 mg, twice daily         |
| Reporting group description:<br>Participants received 2 tofacitinib 5-mg tablets twice daily and subcutaneous placebo every 2 weeks.   |   |
| Reporting group title  | Adalimumab, 40 mg, every 2 weeks        |
| Reporting group description:<br>Participants received 2 placebo tablets twice daily and adalimumab, 40 mg, administered subcutaneously every 2 weeks.  |   |
| Reporting group title  | Placebo/Tofacitinib, 5 mg, twice daily  |
| Reporting group description:<br>Participants received 2 placebo tablets twice daily and subcutaneous placebo every 2 weeks for 3 months. At the end of this period, participants received 1 tofacitinib 5-mg tablet twice daily, 1 placebo tablet twice daily, and subcutaneous placebo every 2 weeks. |   |
| Reporting group title  | Placebo/Tofacitinib, 10 mg, twice daily |
| Reporting group description:<br>Participants received 2 placebo tablets twice daily and subcutaneous placebo every 2 weeks for 3 months. At the end of this period, participants received 2 tofacitinib 5-mg tablets twice daily and subcutaneous placebo every 2 weeks.                               |   |

| Reporting group values                             | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks |
|--|--------------------------------|---------------------------------|----------------------------------|
| Number of subjects                                 | 107                            | 104                             | 106                              |
| Age categorical<br>Units: Subjects                 |                                |                                 |                                  |
| In utero   | 0                              | 0                               | 0                                |
| Preterm newborn infants (gestational age < 37 wks) | 0                              | 0                               | 0                                |
| Newborns (0-27 days)                               | 0                              | 0                               | 0                                |
| Infants and toddlers (28 days-23 months)           | 0                              | 0                               | 0                                |
| Children (2-11 years)                              | 0                              | 0                               | 0                                |
| Adolescents (12-17 years)                          | 0                              | 0                               | 0                                |
| Adults (18-64 years)                               | 95                             | 96                              | 99                               |
| From 65-84 years                                   | 12                             | 8                               | 7                                |
| 85 years and over                                  | 0                              | 0                               | 0                                |
| Age Continuous<br>Units: Years                     |                                |                                 |                                  |
| arithmetic mean                                    | 49.4                           | 46.9                            | 47.4                             |
| standard deviation                                 | ± 12.6                         | ± 12.4                          | ± 11.3                           |
| Gender, Male/Female<br>Units: Subjects             |                                |                                 |                                  |
| Female   | 57                             | 62                              | 50                               |
| Male   | 50                             | 42                              | 56                               |

| Reporting group values | Placebo/Tofacitinib, 5 mg, twice daily | Placebo/Tofacitinib, 10 mg, twice daily | Total |
|------------------------|--|---|-------|
| Number of subjects     | 52                                     | 53                                      | 422   |

|   |        |        |     |
|---|--------|--------|-----|
| Age categorical<br>Units: Subjects                    |        |        |     |
| In utero  | 0      | 0      | 0   |
| Preterm newborn infants<br>(gestational age < 37 wks) | 0      | 0      | 0   |
| Newborns (0-27 days)                                  | 0      | 0      | 0   |
| Infants and toddlers (28 days-23 months)              | 0      | 0      | 0   |
| Children (2-11 years)                                 | 0      | 0      | 0   |
| Adolescents (12-17 years)                             | 0      | 0      | 0   |
| Adults (18-64 years)                                  | 50     | 44     | 384 |
| From 65-84 years                                      | 2      | 9      | 38  |
| 85 years and over                                     | 0      | 0      | 0   |
| Age Continuous<br>Units: Years                        |        |        |     |
| arithmetic mean                                       | 46.1   | 49.3   |     |
| standard deviation                                    | ± 10.4 | ± 13.8 | -   |
| Gender, Male/Female<br>Units: Subjects                |        |        |     |
| Female  | 28     | 28     | 225 |
| Male  | 24     | 25     | 197 |

### Subject analysis sets

|                            |                    |
|----------------------------|--------------------|
| Subject analysis set title | Placebo            |
| Subject analysis set type  | Sub-group analysis |

Subject analysis set description:

Participants received 2 placebo tablets twice daily and subcutaneous placebo every 2 weeks for 3 months.

| Reporting group values                                | Placebo |  |  |
|---|---------|--|--|
| Number of subjects                                    | 105     |  |  |
| Age categorical<br>Units: Subjects                    |         |  |  |
| In utero  | 0       |  |  |
| Preterm newborn infants<br>(gestational age < 37 wks) | 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)                                  | 94      |  |  |
| From 65-84 years                                      | 11      |  |  |
| 85 years and over                                     | 0       |  |  |
| Age Continuous<br>Units: Years                        |         |  |  |
| arithmetic mean                                       | 47.7    |  |  |
| standard deviation                                    | ± 12.3  |  |  |
| Gender, Male/Female<br>Units: Subjects                |         |  |  |
| Female  | 56      |  |  |
| Male  | 49      |  |  |





## End points

### End points reporting groups

|  |   |
|--|---|
| Reporting group title  | Tofacitinib, 5 mg, twice daily          |
| Reporting group description:<br>Participants received 1 tofacitinib 5-mg tablet twice daily, 1 placebo tablet twice daily, and subcutaneous placebo administered every 2 weeks.  |   |
| Reporting group title  | Tofacitinib, 10 mg, twice daily         |
| Reporting group description:<br>Participants received 2 tofacitinib 5-mg tablets twice daily and subcutaneous placebo every 2 weeks.   |   |
| Reporting group title  | Adalimumab, 40 mg, every 2 weeks        |
| Reporting group description:<br>Participants received 2 placebo tablets twice daily and adalimumab, 40 mg, administered subcutaneously every 2 weeks.  |   |
| Reporting group title  | Placebo/Tofacitinib, 5 mg, twice daily  |
| Reporting group description:<br>Participants received 2 placebo tablets twice daily and subcutaneous placebo every 2 weeks for 3 months. At the end of this period, participants received 1 tofacitinib 5-mg tablet twice daily, 1 placebo tablet twice daily, and subcutaneous placebo every 2 weeks. |   |
| Reporting group title  | Placebo/Tofacitinib, 10 mg, twice daily |
| Reporting group description:<br>Participants received 2 placebo tablets twice daily and subcutaneous placebo every 2 weeks for 3 months. At the end of this period, participants received 2 tofacitinib 5-mg tablets twice daily and subcutaneous placebo every 2 weeks.                               |   |
| Subject analysis set title   | Placebo                                 |
| Subject analysis set type  | Sub-group analysis                      |
| Subject analysis set description:<br>Participants received 2 placebo tablets twice daily and subcutaneous placebo every 2 weeks for 3 months.  |   |

### Primary: Percentage of Participants Meeting American College of Rheumatology Response Criteria $\geq 20\%$ (ACR20): Month 3

|  |   |
|--|---|
| End point title  | Percentage of Participants Meeting American College of Rheumatology Response Criteria $\geq 20\%$ (ACR20): Month 3 <sup>[1]</sup> |
| End point description:<br>ACR20 was calculated as a $\geq 20\%$ improvement from baseline in tender/painful and swollen joint counts and $\geq 20\%$ improvement from baseline in 3 of the 5 remaining ACR core set measures: patient's global assessment of arthritis, physician's global assessment of arthritis, patient's assessment of arthritis pain, health assessment questionnaire - disability index (HAQ-DI), and C-reactive protein (CRP). |   |
| End point type   | Primary   |
| End point timeframe:<br>At end of Month 3  |   |

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Since participants received only Placebo up to 3 months in the 'Placebo/Tofacitinib, 5 mg, twice daily' and 'Placebo/Tofacitinib, 10 mg, twice daily' treatment groups, data up to and including 3 months are combined into one 'Placebo' subject analysis set

| <b>End point values</b>           | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo              |
|-----------------------------------|--------------------------------|---------------------------------|----------------------------------|----------------------|
| Subject group type                | Reporting group                | Reporting group                 | Reporting group                  | Subject analysis set |
| Number of subjects analysed       | 107                            | 104                             | 106                              | 105                  |
| Units: Percentage or participants |                                |                                 |                                  |                      |
| number (not applicable)           | 50.47                          | 60.58                           | 51.89                            | 33.33                |

## Statistical analyses

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | Analysis of ACR20                        |
| Comparison groups                       | Tofacitinib, 5 mg, twice daily v Placebo |
| Number of subjects included in analysis | 212                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           |  |
| P-value                                 | = 0.0102                                 |
| Method                                  | Large sample approximation               |
| Parameter estimate                      | Risk difference (RD)                     |
| Point estimate                          | 17.13                                    |
| Confidence interval                     |  |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 4.06                                     |
| upper limit                             | 30.21                                    |
| Variability estimate                    | Standard error of the mean               |
| Dispersion value                        | 6.67                                     |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Analysis of ACR20                         |
| Comparison groups                       | Tofacitinib, 10 mg, twice daily v Placebo |
| Number of subjects included in analysis | 209                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           |   |
| P-value                                 | < 0.0001                                  |
| Method                                  | Large sample approximation                |
| Parameter estimate                      | Risk difference (RD)                      |
| Point estimate                          | 27.24                                     |
| Confidence interval                     |   |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 14.22                                     |
| upper limit                             | 40.26                                     |
| Variability estimate                    | Standard error of the mean                |
| Dispersion value                        | 6.64                                      |

|                                   |                   |
|-----------------------------------|-------------------|
| <b>Statistical analysis title</b> | Analysis of ACR20 |
|-----------------------------------|-------------------|

|   |  |
|---|--|
| Comparison groups                       | Adalimumab, 40 mg, every 2 weeks v Placebo |
| Number of subjects included in analysis | 211  |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           |  |
| P-value                                 | = 0.0055                                   |
| Method                                  | Large sample approximation                 |
| Parameter estimate                      | Risk difference (RD)                       |
| Point estimate                          | 18.55                                      |
| Confidence interval                     |  |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 5.45                                       |
| upper limit                             | 31.66                                      |
| Variability estimate                    | Standard error of the mean                 |
| Dispersion value                        | 6.69                                       |

### Primary: Change From Baseline in Health Assessment Questionnaire - Disability Index (HAQ-DI) Score: Month 3

|                 |   |
|-----------------|---|
| End point title | Change From Baseline in Health Assessment Questionnaire - Disability Index (HAQ-DI) Score: Month 3 <sup>[2]</sup> |
|-----------------|---|

End point description:

The HAQ-DI assesses the difficulty a participant has had in the past week in 8 domains of daily living activities: dressing and grooming, arising, eating, walking, hygiene, reach, grip, and other activities. Each activity category consists of 2-3 items. For each question, level of difficulty is scored from 0 to 3 with 0=no difficulty, 1=some difficulty, 2=much difficulty, and 3=unable to do. The score for each domain is the maximum (worst) score from the items/questions within the domain. Higher score indicates greater disability.

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From Baseline to Month 3

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Since participants received only Placebo up to 3 months in the 'Placebo/Tofacitinib, 5 mg, twice daily' and 'Placebo/Tofacitinib, 10 mg, twice daily' treatment groups, data up to and including 3 months are combined into one 'Placebo' subject analysis set

| End point values                    | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo              |
|-------------------------------------|--------------------------------|---------------------------------|----------------------------------|----------------------|
| Subject group type                  | Reporting group                | Reporting group                 | Reporting group                  | Subject analysis set |
| Number of subjects analysed         | 107                            | 104                             | 106                              | 104                  |
| Units: Units on a scale             |                                |                                 |                                  |                      |
| least squares mean (standard error) | -0.3499 (± 0.04665)            | -0.3998 (± 0.04716)             | -0.3808 (± 0.04767)              | -0.1802 (± 0.05031)  |

### Statistical analyses

|                            |  |
|----------------------------|--|
| Statistical analysis title | Analysis of HAQ-DI                       |
| Comparison groups          | Tofacitinib, 5 mg, twice daily v Placebo |

|   |                            |
|---|----------------------------|
| Number of subjects included in analysis | 211                        |
| Analysis specification                  | Pre-specified              |
| Analysis type                           |                            |
| P-value                                 | = 0.0062                   |
| Method                                  | Mixed models analysis      |
| Parameter estimate                      | Mean difference (net)      |
| Point estimate                          | -0.1697                    |
| Confidence interval                     |                            |
| level                                   | 95 %                       |
| sides                                   | 2-sided                    |
| lower limit                             | -0.291                     |
| upper limit                             | -0.0483                    |
| Variability estimate                    | Standard error of the mean |
| Dispersion value                        | 0.06173                    |

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Analysis of HAQ-DI                        |
| Comparison groups                       | Tofacitinib, 10 mg, twice daily v Placebo |
| Number of subjects included in analysis | 208                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           |   |
| P-value                                 | = 0.0004                                  |
| Method                                  | Mixed models analysis                     |
| Parameter estimate                      | Mean difference (net)                     |
| Point estimate                          | -0.2196                                   |
| Confidence interval                     |   |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | -0.3411                                   |
| upper limit                             | -0.098                                    |
| Variability estimate                    | Standard error of the mean                |
| Dispersion value                        | 0.06184                                   |

|   |  |
|---|--|
| <b>Statistical analysis title</b>       | Analysis of HAQ-DI                         |
| Comparison groups                       | Adalimumab, 40 mg, every 2 weeks v Placebo |
| Number of subjects included in analysis | 210  |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           |  |
| P-value                                 | = 0.0012                                   |
| Method                                  | Mixed models analysis                      |
| Parameter estimate                      | Mean difference (net)                      |
| Point estimate                          | -0.2005                                    |
| Confidence interval                     |  |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | -0.3213                                    |
| upper limit                             | -0.0797                                    |

|                      |                            |
|----------------------|----------------------------|
| Variability estimate | Standard error of the mean |
| Dispersion value     | 0.06145                    |

### Secondary: Change From Baseline in the Van der Heijdel Modified Total Sharp Score (mTSS) for Psoriatic Arthritis at Month 12

|                 |   |
|-----------------|---|
| End point title | Change From Baseline in the Van der Heijdel Modified Total Sharp Score (mTSS) for Psoriatic Arthritis at Month 12 |
|-----------------|---|

End point description:

Assessment of joint damage includes a joint erosion score (range 0-320) and a joint space narrowing (JSN) score (range 0-208). The mTSS is the sum of the erosion and JSN scores (range 0-528). A higher score indicates more severe disease status. If a component score is missing, the mTSS will be missing.

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

End point timeframe:

From Baseline to Month 12

| End point values                    | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|-------------------------------------|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                  | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed         | 98                             | 99                              | 95                               | 48                                     |
| Units: Units on a scale             |                                |                                 |                                  |  |
| least squares mean (standard error) | 0.01 ( $\pm$ 0.067)            | -0.01 ( $\pm$ 0.067)            | -0.07 ( $\pm$ 0.069)             | 0 ( $\pm$ 0.094)                       |

| End point values                    | Placebo/Tofacitinib, 10 mg, twice daily |  |  |  |
|-------------------------------------|---|--|--|--|
| Subject group type                  | Reporting group                         |  |  |  |
| Number of subjects analysed         | 45                                      |  |  |  |
| Units: Units on a scale             |   |  |  |  |
| least squares mean (standard error) | 0.09 ( $\pm$ 0.099)                     |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Participants With Progressed Modified Total Sharp Score (mTSS) at Month 12

|                 |  |
|-----------------|--|
| End point title | Percentage of Participants With Progressed Modified Total Sharp Score (mTSS) at Month 12 |
|-----------------|--|

End point description:

Assessment of joint damage includes a joint erosion score (range 0-320) and a JSN score (range 0-208). The mTSS is the sum of the erosion and JSN scores (range 0-528). A higher score indicates more severe disease status. If a component score is missing, the mTSS will be missing. Progressor is defined as an increase in mTSS >0.5 from baseline.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| At Month 12          |           |

| End point values                  | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|-----------------------------------|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed       | 98                             | 99                              | 95                               | 48                                     |
| Units: Percentage of participants |                                |                                 |                                  |  |
| number (not applicable)           | 4.08                           | 5.05                            | 2.11                             | 4.17                                   |

| End point values                  | Placebo/Tofacitinib, 10 mg, twice daily |  |  |  |
|-----------------------------------|---|--|--|--|
| Subject group type                | Reporting group                         |  |  |  |
| Number of subjects analysed       | 45                                      |  |  |  |
| Units: Percentage of participants |   |  |  |  |
| number (not applicable)           | 8.89                                    |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Participants Meeting American College of Rheumatology Response Criteria $\geq 50\%$ (ACR50) at Week 2 and Months 1, 2, 3, 4, 6, 9, and 12

|                 |   |
|-----------------|---|
| End point title | Percentage of Participants Meeting American College of Rheumatology Response Criteria $\geq 50\%$ (ACR50) at Week 2 and Months 1, 2, 3, 4, 6, 9, and 12 |
|-----------------|---|

End point description:

ACR50 was calculated as a  $\geq 50\%$  improvement from baseline in tender/painful and swollen joint counts and  $\geq 50\%$  improvement from baseline in 3 of the 5 remaining ACR core set measures: patient's global assessment of arthritis, physician's global assessment of arthritis, patient's assessment of arthritis pain, HAQ-DI, and CRP. NA = not applicable, 9999 = results not reported for this group, n=number of responders.

|   |           |
|---|-----------|
| End point type                                | Secondary |
| End point timeframe:                          |           |
| At Week 2 and Months 1, 2, 3, 4, 6, 9, and 12 |           |

| End point values                    | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|-------------------------------------|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                  | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed         | 107                            | 104                             | 106                              | 52                                     |
| Units: Percentage of participants   |                                |                                 |                                  |  |
| number (not applicable)             |                                |                                 |                                  |  |
| Week 2 (n=7, 7, 5, NA, NA, 1)       | 6.54                           | 6.73                            | 4.72                             | 9999                                   |
| Month 1 (n=13, 20, 12, NA, NA, 5)   | 12.15                          | 19.23                           | 11.32                            | 9999                                   |
| Month 2 (n=23, 34, 24, NA, NA, 8)   | 21.5                           | 32.69                           | 22.64                            | 9999                                   |
| Month 3 (n=30, 42, 35, NA, NA, 10)  | 28.04                          | 40.38                           | 33.02                            | 9999                                   |
| Month 4 (n=38, 39, 34, 11, 17, NA)  | 35.51                          | 37.5                            | 32.08                            | 21.15                                  |
| Month 6 (n=41, 48, 45, 17, 14, NA)  | 38.32                          | 46.15                           | 42.45                            | 32.69                                  |
| Month 9 (n=45, 48, 49, 22, 23, NA)  | 42.06                          | 46.15                           | 46.23                            | 42.31                                  |
| Month 12 (n=48, 50, 43, 21, 19, NA) | 44.86                          | 48.08                           | 40.57                            | 40.38                                  |

| End point values                    | Placebo/Tofacitinib, 10 mg, twice daily | Placebo              |  |  |
|-------------------------------------|---|----------------------|--|--|
| Subject group type                  | Reporting group                         | Subject analysis set |  |  |
| Number of subjects analysed         | 53                                      | 105                  |  |  |
| Units: Percentage of participants   |   |                      |  |  |
| number (not applicable)             |   |                      |  |  |
| Week 2 (n=7, 7, 5, NA, NA, 1)       | 9999                                    | 0.95                 |  |  |
| Month 1 (n=13, 20, 12, NA, NA, 5)   | 9999                                    | 4.76                 |  |  |
| Month 2 (n=23, 34, 24, NA, NA, 8)   | 9999                                    | 7.62                 |  |  |
| Month 3 (n=30, 42, 35, NA, NA, 10)  | 9999                                    | 9.52                 |  |  |
| Month 4 (n=38, 39, 34, 11, 17, NA)  | 32.08                                   | 9999                 |  |  |
| Month 6 (n=41, 48, 45, 17, 14, NA)  | 26.42                                   | 9999                 |  |  |
| Month 9 (n=45, 48, 49, 22, 23, NA)  | 43.4                                    | 9999                 |  |  |
| Month 12 (n=48, 50, 43, 21, 19, NA) | 35.85                                   | 9999                 |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants Meeting American College of Rheumatology Response Criteria $\geq 70\%$ (ACR70) at Week 2 and Months 1, 2, 3, 4, 6, 9, and 12

|                 |   |
|-----------------|---|
| End point title | Percentage of Participants Meeting American College of Rheumatology Response Criteria $\geq 70\%$ (ACR70) at Week 2 and Months 1, 2, 3, 4, 6, 9, and 12 |
|-----------------|---|

End point description:

ACR70 was calculated as a  $\geq 70\%$  improvement from baseline in tender/painful and swollen joint counts and  $\geq 70\%$  improvement from baseline in 3 of the 5 remaining ACR core set measures: patient's global assessment of arthritis, physician's global assessment of arthritis, patient's assessment of arthritis pain, HAQ-DI, and CRP. NA = not applicable, 9999 = results not reported for this group, n=number of responders.

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

End point timeframe:

At Week 2 and Months 1, 2, 3, 4, 6, 9, and 12



| End point values                    | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|-------------------------------------|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                  | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed         | 107                            | 104                             | 106                              | 52                                     |
| Units: Percentage of participants   |                                |                                 |                                  |  |
| number (not applicable)             |                                |                                 |                                  |  |
| Week 2 (n=0, 3, 1, NA, NA, 0)       | 0                              | 2.88                            | 0.94                             | 9999                                   |
| Month 1 (n=5, 8, 4, NA, NA, 1)      | 4.67                           | 7.69                            | 3.77                             | 9999                                   |
| Month 2 (n=10, 14, 13, NA, NA, 2)   | 9.35                           | 13.46                           | 12.26                            | 9999                                   |
| Month 3 (n=18, 15, 20, NA, NA, 5)   | 16.82                          | 14.42                           | 18.87                            | 9999                                   |
| Month 4 (n=24, 23, 21, 7, 8, NA)    | 22.43                          | 22.12                           | 19.81                            | 13.46                                  |
| Month 6 (n=19, 33, 32, 10, 7, NA)   | 17.76                          | 31.73                           | 30.19                            | 19.23                                  |
| Month 9 (n=21, 31, 30, 15, 12, NA)  | 19.63                          | 29.81                           | 28.3                             | 28.85                                  |
| Month 12 (n=25, 32, 31, 12, 12, NA) | 23.36                          | 30.77                           | 29.25                            | 23.08                                  |

| End point values                    | Placebo/Tofacitinib, 10 mg, twice daily | Placebo              |  |  |
|-------------------------------------|---|----------------------|--|--|
| Subject group type                  | Reporting group                         | Subject analysis set |  |  |
| Number of subjects analysed         | 53                                      | 105                  |  |  |
| Units: Percentage of participants   |   |                      |  |  |
| number (not applicable)             |   |                      |  |  |
| Week 2 (n=0, 3, 1, NA, NA, 0)       | 9999                                    | 0                    |  |  |
| Month 1 (n=5, 8, 4, NA, NA, 1)      | 9999                                    | 0.95                 |  |  |
| Month 2 (n=10, 14, 13, NA, NA, 2)   | 9999                                    | 1.9                  |  |  |
| Month 3 (n=18, 15, 20, NA, NA, 5)   | 9999                                    | 4.76                 |  |  |
| Month 4 (n=24, 23, 21, 7, 8, NA)    | 15.09                                   | 9999                 |  |  |
| Month 6 (n=19, 33, 32, 10, 7, NA)   | 13.21                                   | 9999                 |  |  |
| Month 9 (n=21, 31, 30, 15, 12, NA)  | 22.64                                   | 9999                 |  |  |
| Month 12 (n=25, 32, 31, 12, 12, NA) | 22.64                                   | 9999                 |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants Meeting American College of Rheumatology Response Criteria $\geq 20\%$ (ACR20) at Week 2 and Months 1, 2, 4, 6, 9, and 12

|                 |  |
|-----------------|--|
| End point title | Percentage of Participants Meeting American College of Rheumatology Response Criteria $\geq 20\%$ (ACR20) at Week 2 and Months 1, 2, 4, 6, 9, and 12 |
|-----------------|--|

End point description:

ACR20 was calculated as a  $\geq 20\%$  improvement from baseline in tender/painful and swollen joint counts and  $\geq 20\%$  improvement from baseline in 3 of the 5 remaining ACR core set measures: patient's global assessment of arthritis, physician's global assessment of arthritis, patient's assessment of arthritis pain, HAQ-DI, and CRP. NA = not applicable, 9999 = results not reported for this group, n=number of

responders.

|  |           |
|--|-----------|
| End point type                             | Secondary |
| End point timeframe:                       |           |
| At Week 2 and Months 1, 2, 4, 6, 9, and 12 |           |

| End point values                    | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|-------------------------------------|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                  | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed         | 107                            | 104                             | 106                              | 52                                     |
| Units: Percentage of participants   |                                |                                 |                                  |  |
| number (not applicable)             |                                |                                 |                                  |  |
| Week 2 (n=24, 33, 23, NA, NA, 6)    | 22.43                          | 31.73                           | 21.7                             | 9999                                   |
| Month 1 (n=37, 50, 30, NA, NA, 11)  | 34.58                          | 48.08                           | 28.3                             | 9999                                   |
| Month 2 (n=47, 57, 62, NA, NA, 28)  | 43.93                          | 54.81                           | 58.49                            | 9999                                   |
| Month 4 (n=65, 60, 61, 27, 28, NA)  | 60.75                          | 57.69                           | 57.55                            | 51.92                                  |
| Month 6 (n=63, 70, 68, 31, 30, NA)  | 58.88                          | 67.31                           | 64.15                            | 59.62                                  |
| Month 9 (n=73, 76, 73, 35, 37, NA)  | 68.22                          | 73.08                           | 68.87                            | 67.31                                  |
| Month 12 (n=73, 73, 64, 35, 31, NA) | 68.22                          | 70.19                           | 60.38                            | 67.31                                  |

| End point values                    | Placebo/Tofacitinib, 10 mg, twice daily | Placebo              |  |  |
|-------------------------------------|---|----------------------|--|--|
| Subject group type                  | Reporting group                         | Subject analysis set |  |  |
| Number of subjects analysed         | 53                                      | 105                  |  |  |
| Units: Percentage of participants   |   |                      |  |  |
| number (not applicable)             |   |                      |  |  |
| Week 2 (n=24, 33, 23, NA, NA, 6)    | 9999                                    | 5.71                 |  |  |
| Month 1 (n=37, 50, 30, NA, NA, 11)  | 9999                                    | 10.48                |  |  |
| Month 2 (n=47, 57, 62, NA, NA, 28)  | 9999                                    | 26.67                |  |  |
| Month 4 (n=65, 60, 61, 27, 28, NA)  | 52.83                                   | 9999                 |  |  |
| Month 6 (n=63, 70, 68, 31, 30, NA)  | 56.6                                    | 9999                 |  |  |
| Month 9 (n=73, 76, 73, 35, 37, NA)  | 69.81                                   | 9999                 |  |  |
| Month 12 (n=73, 73, 64, 35, 31, NA) | 58.49                                   | 9999                 |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Health Assessment Questionnaire - Disability Index (HAQ-DI) Score at Week 2 and Months 1, 2, 4, 6, 9, and 12

|                 |  |
|-----------------|--|
| End point title | Change From Baseline in Health Assessment Questionnaire - Disability Index (HAQ-DI) Score at Week 2 and Months 1, 2, 4, 6, 9, and 12 |
|-----------------|--|

End point description:

The HAQ-DI assesses the difficulty a participant has had in the past week in 8 domains of daily living

activities: dressing and grooming, arising, eating, walking, hygiene, reach, grip, and other activities. Each activity category consists of 2-3 items. For each question, level of difficulty is scored from 0 to 3 with 0=no difficulty, 1=some difficulty, 2=much difficulty, and 3=unable to do. The score for each domain is the maximum (worst) score from the items/questions within the domain. Higher score indicates greater disability. NA = not applicable, 9999 = results not reported for this group, n=number of responders.

|  |           |
|--|-----------|
| End point type   | Secondary |
| End point timeframe:                                     |           |
| From Baseline to Week 2 and Months 1, 2, 4, 6, 9, and 12 |           |

| End point values                       | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|--|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                     | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed            | 107                            | 104                             | 106                              | 52                                     |
| Units: Units on a scale                |                                |                                 |                                  |  |
| least squares mean (standard error)    |                                |                                 |                                  |  |
| Week 2 (n=106, 102, 103, NA, NA, 102)  | -0.1842 (± 0.04131)            | -0.2089 (± 0.04208)             | -0.2129 (± 0.04246)              | 9999 (± 9999)                          |
| Month 1 (n=105, 103, 104, NA, NA, 103) | -0.2048 (± 0.04363)            | -0.2676 (± 0.04426)             | -0.3028 (± 0.04465)              | 9999 (± 9999)                          |
| Month 2 (n=104, 104, 104, NA, NA, 102) | -0.2713 (± 0.04626)            | -0.4009 (± 0.04678)             | -0.3736 (± 0.04719)              | 9999 (± 9999)                          |
| Month 4 (n=102, 100, 102, 50, 50, NA)  | -0.4231 (± 0.04982)            | -0.4407 (± 0.05039)             | -0.3643 (± 0.05069)              | -0.285 (± 0.07075)                     |
| Month 6 (n=100, 100, 99, 48, 48, NA)   | -0.4471 (± 0.05136)            | -0.4611 (± 0.05179)             | -0.4259 (± 0.05227)              | -0.3142 (± 0.07315)                    |
| Month 9 (n=99, 96, 96, 47, 45, NA)     | -0.5119 (± 0.05038)            | -0.4847 (± 0.05096)             | -0.4304 (± 0.05143)              | -0.3843 (± 0.07185)                    |
| Month 12 (n=96, 96, 94, 44, 44, NA)    | -0.5391 (± 0.05324)            | -0.5104 (± 0.05365)             | -0.4478 (± 0.05426)              | -0.4104 (± 0.07646)                    |

| End point values                       | Placebo/Tofacitinib, 10 mg, twice daily | Placebo              |  |  |
|--|---|----------------------|--|--|
| Subject group type                     | Reporting group                         | Subject analysis set |  |  |
| Number of subjects analysed            | 52                                      | 104                  |  |  |
| Units: Units on a scale                |   |                      |  |  |
| least squares mean (standard error)    |   |                      |  |  |
| Week 2 (n=106, 102, 103, NA, NA, 102)  | 9999 (± 9999)                           | -0.0837 (± 0.04549)  |  |  |
| Month 1 (n=105, 103, 104, NA, NA, 103) | 9999 (± 9999)                           | -0.1224 (± 0.04755)  |  |  |
| Month 2 (n=104, 104, 104, NA, NA, 102) | 9999 (± 9999)                           | -0.1682 (± 0.04998)  |  |  |
| Month 4 (n=102, 100, 102, 50, 50, NA)  | -0.3302 (± 0.07128)                     | 9999 (± 9999)        |  |  |
| Month 6 (n=100, 100, 99, 48, 48, NA)   | -0.3841 (± 0.07369)                     | 9999 (± 9999)        |  |  |
| Month 9 (n=99, 96, 96, 47, 45, NA)     | -0.4839 (± 0.07276)                     | 9999 (± 9999)        |  |  |
| Month 12 (n=96, 96, 94, 44, 44, NA)    | -0.4569 (± 0.07704)                     | 9999 (± 9999)        |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change From Baseline in American College of Rheumatology Response Criteria Components: C-reactive Protein Levels at Month 3

|                 |  |
|-----------------|--|
| End point title | Change From Baseline in American College of Rheumatology Response Criteria Components: C-reactive Protein Levels at Month 3 <sup>[3]</sup> |
|-----------------|--|

End point description:

The test for CRP is a laboratory measurement for evaluation of an acute phase reactant of inflammation through the use of an ultrasensitive assay. A decrease in the level of CRP indicates reduction in inflammation and therefore improvement.

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

End point timeframe:

From Baseline to end of Month 3

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Since participants received only Placebo up to 3 months in the 'Placebo/Tofacitinib, 5 mg, twice daily' and 'Placebo/Tofacitinib, 10 mg, twice daily' treatment groups, data up to and including 3 months are combined into one 'Placebo' subject analysis set

| End point values                    | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo                  |
|-------------------------------------|--------------------------------|---------------------------------|----------------------------------|--------------------------|
| Subject group type                  | Reporting group                | Reporting group                 | Reporting group                  | Subject analysis set     |
| Number of subjects analysed         | 101                            | 103                             | 99                               | 101                      |
| Units: mg/L                         |                                |                                 |                                  |                          |
| least squares mean (standard error) | -5.5981 ( $\pm$ 0.80656)       | -6.6004 ( $\pm$ 0.80822)        | -7.8955 ( $\pm$ 0.82547)         | -0.8643 ( $\pm$ 0.86304) |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change From Baseline in American College of Rheumatology Response Criteria Components Score: Patient's Assessment of Arthritis Pain at Month 3

|                 |   |
|-----------------|---|
| End point title | Change From Baseline in American College of Rheumatology Response Criteria Components Score: Patient's Assessment of Arthritis Pain at Month 3 <sup>[4]</sup> |
|-----------------|---|

End point description:

Participants assessed the severity of their arthritis pain using a 100-mm visual analog scale (VAS) by placing a mark on the scale between 0 (no pain) and 100 (most severe pain), which corresponded to the magnitude of their pain.

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

End point timeframe:

From Baseline to end of Month 3

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Since participants received only Placebo up to 3 months in the 'Placebo/Tofacitinib, 5 mg, twice daily' and 'Placebo/Tofacitinib, 10 mg, twice daily' treatment groups, data up to and including 3 months are combined into one 'Placebo' subject analysis set

| End point values                    | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo               |
|-------------------------------------|--------------------------------|---------------------------------|----------------------------------|-----------------------|
| Subject group type                  | Reporting group                | Reporting group                 | Reporting group                  | Subject analysis set  |
| Number of subjects analysed         | 103                            | 103                             | 100                              | 102                   |
| Units: mm                           |                                |                                 |                                  |                       |
| least squares mean (standard error) | -21.49 ( $\pm$ 2.325)          | -27.1 ( $\pm$ 2.342)            | -21.87 ( $\pm$ 2.389)            | -10.22 ( $\pm$ 2.499) |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in American College of Rheumatology Response Criteria Components Score: Patient's Global Assessment of Arthritis at Month 3

|                 |   |
|-----------------|---|
| End point title | Change From Baseline in American College of Rheumatology Response Criteria Components Score: Patient's Global Assessment of Arthritis at Month 3 <sup>[5]</sup> |
|-----------------|---|

End point description:

Participant answered the following question, "Considering all the ways your arthritis affects you, how are you feeling today?" The participant's response was recorded using a 100 mm VAS.

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

End point timeframe:

From Baseline to end of Month 3

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Since participants received only Placebo up to 3 months in the 'Placebo/Tofacitinib, 5 mg, twice daily' and 'Placebo/Tofacitinib, 10 mg, twice daily' treatment groups, data up to and including 3 months are combined into one 'Placebo' subject analysis set

| End point values                    | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo              |
|-------------------------------------|--------------------------------|---------------------------------|----------------------------------|----------------------|
| Subject group type                  | Reporting group                | Reporting group                 | Reporting group                  | Subject analysis set |
| Number of subjects analysed         | 103                            | 103                             | 101                              | 102                  |
| Units: mm                           |                                |                                 |                                  |                      |
| least squares mean (standard error) | -20.08 ( $\pm$ 2.275)          | -25.5 ( $\pm$ 2.291)            | -21.47 ( $\pm$ 2.328)            | -11.4 ( $\pm$ 2.439) |

## Statistical analyses

**Secondary: Change From Baseline in American College of Rheumatology Response Criteria Components Score: Physician's Global Assessment of Arthritis at Month 3**

|                 |   |
|-----------------|---|
| End point title | Change From Baseline in American College of Rheumatology Response Criteria Components Score: Physician's Global Assessment of Arthritis at Month 3 <sup>[6]</sup> |
|-----------------|---|

## End point description:

The blinded investigator or qualified assessor assessed how the participant's overall arthritis appeared at the time of the visit. This was an evaluation based on the participant's disease signs, functional capacity and physical examination, and was independent of the Patient's Global Assessment of Arthritis. The investigator's response was recorded using a 100 mm VAS.

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

## End point timeframe:

From Baseline to end of Month 3

## Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Since participants received only Placebo up to 3 months in the 'Placebo/Tofacitinib, 5 mg, twice daily' and 'Placebo/Tofacitinib, 10 mg, twice daily' treatment groups, data up to and including 3 months are combined into one 'Placebo' subject analysis set

| End point values                    | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo              |
|-------------------------------------|--------------------------------|---------------------------------|----------------------------------|----------------------|
| Subject group type                  | Reporting group                | Reporting group                 | Reporting group                  | Subject analysis set |
| Number of subjects analysed         | 103                            | 101                             | 101                              | 102                  |
| Units: mm                           |                                |                                 |                                  |                      |
| least squares mean (standard error) | -27.44 (± 1.998)               | -33.74 (± 2.021)                | -29.02 (± 2.043)                 | -22.26 (± 2.121)     |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Change From Baseline in American College of Rheumatology Response Criteria Components Score: Swollen Joint Count at Month 3**

|                 |  |
|-----------------|--|
| End point title | Change From Baseline in American College of Rheumatology Response Criteria Components Score: Swollen Joint Count at Month 3 <sup>[7]</sup> |
|-----------------|--|

## End point description:

Swollen joint counts are considered the most specific quantitative clinical measure used to assess the status of participants with inflammatory types of arthritis. Sixty six (66) joints were assessed by a blinded assessor to determine the number of joints that were considered swelling.

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

## End point timeframe:

From Baseline to end of Month 3

## Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Since participants received only Placebo up to 3 months in the 'Placebo/Tofacitinib, 5 mg, twice daily' and 'Placebo/Tofacitinib, 10 mg, twice daily' treatment groups, data up to and including 3 months are combined into one 'Placebo' subject analysis set

| End point values                    | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo              |
|-------------------------------------|--------------------------------|---------------------------------|----------------------------------|----------------------|
| Subject group type                  | Reporting group                | Reporting group                 | Reporting group                  | Subject analysis set |
| Number of subjects analysed         | 103                            | 103                             | 101                              | 102                  |
| Units: Joints                       |                                |                                 |                                  |                      |
| least squares mean (standard error) | -6.5 (± 0.58)                  | -7.6 (± 0.58)                   | -6.5 (± 0.59)                    | -4.8 (± 0.62)        |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change From Baseline in American College of Rheumatology Response Criteria Components Score: Tender/Painful Joint Count at Month 3

|                 |   |
|-----------------|---|
| End point title | Change From Baseline in American College of Rheumatology Response Criteria Components Score: Tender/Painful Joint Count at Month 3 <sup>[8]</sup> |
|-----------------|---|

End point description:

Tender/painful joint counts are considered the most specific quantitative clinical measure used to assess the status of participants with inflammatory types of arthritis. Sixty eight (68) joints were assessed by a blinded assessor to determine the number of joints that were considered tender or painful.

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

End point timeframe:

From Baseline to end of Month 3

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Since participants received only Placebo up to 3 months in the 'Placebo/Tofacitinib, 5 mg, twice daily' and 'Placebo/Tofacitinib, 10 mg, twice daily' treatment groups, data up to and including 3 months are combined into one 'Placebo' subject analysis set

| End point values                    | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo              |
|-------------------------------------|--------------------------------|---------------------------------|----------------------------------|----------------------|
| Subject group type                  | Reporting group                | Reporting group                 | Reporting group                  | Subject analysis set |
| Number of subjects analysed         | 103                            | 103                             | 101                              | 102                  |
| Units: Joints                       |                                |                                 |                                  |                      |
| least squares mean (standard error) | -8.7 (± 1.04)                  | -11 (± 1.05)                    | -7.6 (± 1.07)                    | -6.9 (± 1.1)         |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Participants Meeting Psoriatic Arthritis Response Criteria (PsARC) at Week 2 and Months 1, 2, 3, 4, 6, 9, and 12

|                 |  |
|-----------------|--|
| End point title | Percentage of Participants Meeting Psoriatic Arthritis Response Criteria (PsARC) at Week 2 and Months 1, 2, 3, 4, 6, 9, and 12 |
|-----------------|--|

End point description:

The PsARC covers 4 measures: Tender joint count, swollen joint count, the Physician's Global Assessment of Arthritis, and the Patient's Global Assessment of Arthritis. The PsARC response is defined as improvement in 2 of 4 items, 1 of which must be joint pain or swelling, without worsening in any measure. Improvement criteria: ≥20% improvement in Physician's Global Assessment of Arthritis;

≥20% improvement in Patient's Global Assessment of Arthritis; ≥30% improvement in tender joint count; and ≥30% improvement in swollen joint count. NA = not applicable, 9999 = results not reported for this group, n=number of responders.

|   |           |
|---|-----------|
| End point type                                | Secondary |
| End point timeframe:                          |           |
| At Week 2 and Months 1, 2, 3, 4, 6, 9, and 12 |           |

| End point values                    | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|-------------------------------------|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                  | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed         | 107                            | 104                             | 106                              | 52                                     |
| Units: Percentage of participants   |                                |                                 |                                  |  |
| number (not applicable)             |                                |                                 |                                  |  |
| Week 2 (n=34, 42, 23, NA, NA, 10)   | 31.78                          | 40.38                           | 21.7                             | 9999                                   |
| Month 1 (n=45, 51, 43, NA, NA, 23)  | 42.06                          | 49.04                           | 40.57                            | 9999                                   |
| Month 2 (n=54, 69, 62, NA, NA, 36)  | 50.47                          | 66.35                           | 58.49                            | 9999                                   |
| Month 3 (n=55, 73, 65, NA, NA, 47)  | 51.4                           | 70.19                           | 61.32                            | 9999                                   |
| Month 4 (n=68, 68, 71, 32, 30, NA)  | 63.55                          | 65.38                           | 66.98                            | 61.54                                  |
| Month 6 (n=61, 75, 71, 35, 35, NA)  | 57.01                          | 72.12                           | 66.98                            | 67.31                                  |
| Month 9 (n=75, 73, 71, 36, 37, NA)  | 70.09                          | 70.19                           | 66.98                            | 69.23                                  |
| Month 12 (n=69, 76, 69, 39, 33, NA) | 64.49                          | 73.08                           | 65.09                            | 75                                     |

| End point values                    | Placebo/Tofacitinib, 10 mg, twice daily | Placebo              |  |  |
|-------------------------------------|---|----------------------|--|--|
| Subject group type                  | Reporting group                         | Subject analysis set |  |  |
| Number of subjects analysed         | 53                                      | 105                  |  |  |
| Units: Percentage of participants   |   |                      |  |  |
| number (not applicable)             |   |                      |  |  |
| Week 2 (n=34, 42, 23, NA, NA, 10)   | 9999                                    | 9.52                 |  |  |
| Month 1 (n=45, 51, 43, NA, NA, 23)  | 9999                                    | 21.9                 |  |  |
| Month 2 (n=54, 69, 62, NA, NA, 36)  | 9999                                    | 34.29                |  |  |
| Month 3 (n=55, 73, 65, NA, NA, 47)  | 9999                                    | 44.76                |  |  |
| Month 4 (n=68, 68, 71, 32, 30, NA)  | 56.6                                    | 9999                 |  |  |
| Month 6 (n=61, 75, 71, 35, 35, NA)  | 66.04                                   | 9999                 |  |  |
| Month 9 (n=75, 73, 71, 36, 37, NA)  | 69.81                                   | 9999                 |  |  |
| Month 12 (n=69, 76, 69, 39, 33, NA) | 62.26                                   | 9999                 |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Physician's Global Assessment of Psoriasis (PGA-PsO) Response at Months 1, 3, 6, 9, and 12

|                 |  |
|-----------------|--|
| End point title | Change From Baseline in Physician's Global Assessment of |
|-----------------|--|



End point description:

The PGA-PsO is scored on a 5-point scale, reflecting a global consideration of the erythema, induration, and scaling across all psoriatic lesions. Average erythema, induration, and scaling are rated separately over the whole body according to a 5-point severity scale, scored as 0=none; 1, 2, 3, or 4=most severe. The severity rating scores are summed and the average taken; the total average is rounded to the nearest whole number score to determine the PGA-PsO. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

End point type Secondary

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

| End point values                     | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|--------------------------------------|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                   | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed          | 101                            | 98                              | 102                              | 50                                     |
| Units: Units on a scale              |                                |                                 |                                  |  |
| least squares mean (standard error)  |                                |                                 |                                  |  |
| Month 1 (n=100, 96, 100, NA, NA, 99) | -0.7 (± 0.07)                  | -0.8 (± 0.08)                   | -0.5 (± 0.08)                    | 9999 (± 9999)                          |
| Month 3 (n=98, 97, 98, NA, NA, 98)   | -1 (± 0.08)                    | -1.2 (± 0.08)                   | -1 (± 0.09)                      | 9999 (± 9999)                          |
| Month 6 (n=96, 94, 96, 46, 46, NA)   | -0.9 (± 0.09)                  | -1.3 (± 0.09)                   | -1.2 (± 0.09)                    | -0.7 (± 0.12)                          |
| Month 9 (n=95, 91, 94, 45, 44, NA)   | -1 (± 0.09)                    | -1.5 (± 0.09)                   | -1.2 (± 0.09)                    | -0.7 (± 0.12)                          |
| Month 12 (n=91, 90, 92, 41, 43, NA)  | -1.2 (± 0.09)                  | -1.5 (± 0.09)                   | -1.2 (± 0.09)                    | -0.9 (± 0.13)                          |

| End point values                     | Placebo/Tofacitinib, 10 mg, twice daily | Placebo              |  |  |
|--------------------------------------|---|----------------------|--|--|
| Subject group type                   | Reporting group                         | Subject analysis set |  |  |
| Number of subjects analysed          | 50                                      | 100                  |  |  |
| Units: Units on a scale              |   |                      |  |  |
| least squares mean (standard error)  |   |                      |  |  |
| Month 1 (n=100, 96, 100, NA, NA, 99) | 9999 (± 9999)                           | -0.2 (± 0.08)        |  |  |
| Month 3 (n=98, 97, 98, NA, NA, 98)   | 9999 (± 9999)                           | -0.4 (± 0.09)        |  |  |
| Month 6 (n=96, 94, 96, 46, 46, NA)   | -0.9 (± 0.13)                           | 9999 (± 9999)        |  |  |
| Month 9 (n=95, 91, 94, 45, 44, NA)   | -1.3 (± 0.13)                           | 9999 (± 9999)        |  |  |
| Month 12 (n=91, 90, 92, 41, 43, NA)  | -1.3 (± 0.13)                           | 9999 (± 9999)        |  |  |

Statistical analyses

No statistical analyses for this end point

**Secondary: Percentage of Participants With Psoriasis Area and Severity Index 75 (PASI75) Response at Months 1, 3, 6, 9, and 12**

End point title Percentage of Participants With Psoriasis Area and Severity Index 75 (PASI75) Response at Months 1, 3, 6, 9, and 12

**End point description:**

PASI determines psoriasis severity based on lesion severity & percentage of body surface area (BSA) affected. Lesion severity is assessed for erythema, induration & scaling; each evaluated separately for head & neck, upper limbs, trunk & lower limbs then rated for each body area on a 5 point scale: 0=no involvement; 1=slight; 2=moderate; 3=marked; 4=very marked. BSA involvement is the extent (%) of body area affected by psoriasis & is given a numerical score: 0=no involvement; 1=0-9%; 2=10-29%; 3=30-49%; 4=50-69%; 5=70-89%; 6=90-100%. In each area, the sum of the severity rating scores is multiplied by the score representing the percentage of this area involved by psoriasis, multiplied by a weighting factor (head 0.1; upper limbs 0.2; trunk 0.3; lower limbs 0.4). The sum of the numbers obtained for each of the 4 body areas is the PASI. PASI75 is defined as a 75% reduction from baseline in PASI. NA = not applicable, 9999 = results not reported for this group, n=number of responders.

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

**End point timeframe:**

At Months 1, 3, 6, 9, and 12

| <b>End point values</b>             | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|-------------------------------------|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                  | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed         | 82                             | 70                              | 77                               | 42                                     |
| Units: Percentage of participants   |                                |                                 |                                  |  |
| number (not applicable)             |                                |                                 |                                  |  |
| Month 1 (n=19, 19, 11, NA, NA, 4)   | 23.17                          | 27.14                           | 14.29                            | 9999                                   |
| Month 3 (n=35, 31, 30, NA, NA, 12)  | 42.68                          | 44.29                           | 38.96                            | 9999                                   |
| Month 6 (n=38, 42, 42, 12, 17, NA)  | 46.34                          | 60                              | 54.55                            | 28.57                                  |
| Month 9 (n=36, 48, 45, 14, 20, NA)  | 43.9                           | 68.57                           | 58.44                            | 33.33                                  |
| Month 12 (n=46, 47, 43, 15, 21, NA) | 56.1                           | 67.14                           | 55.84                            | 35.71                                  |

| <b>End point values</b>             | Placebo/Tofacitinib, 10 mg, twice daily | Placebo              |  |  |
|-------------------------------------|---|----------------------|--|--|
| Subject group type                  | Reporting group                         | Subject analysis set |  |  |
| Number of subjects analysed         | 40                                      | 82                   |  |  |
| Units: Percentage of participants   |   |                      |  |  |
| number (not applicable)             |   |                      |  |  |
| Month 1 (n=19, 19, 11, NA, NA, 4)   | 9999                                    | 4.88                 |  |  |
| Month 3 (n=35, 31, 30, NA, NA, 12)  | 9999                                    | 14.63                |  |  |
| Month 6 (n=38, 42, 42, 12, 17, NA)  | 42.5                                    | 9999                 |  |  |
| Month 9 (n=36, 48, 45, 14, 20, NA)  | 50                                      | 9999                 |  |  |
| Month 12 (n=46, 47, 43, 15, 21, NA) | 52.5                                    | 9999                 |  |  |

**Statistical analyses**

No statistical analyses for this end point

### Secondary: Change From Baseline in Dactylitis Severity Score (DSS) at Months 1, 3, 6, 9, and 12

|                 |  |
|-----------------|--|
| End point title | Change From Baseline in Dactylitis Severity Score (DSS) at |
|-----------------|--|

## End point description:

Dactylitis is characterized by swelling of the entire finger or toe. The DSS is a function of finger circumference and tenderness, assessed and summed across all dactylitic digits. The severity of dactylitis is scored on a scale of 0-3, where 0=no tenderness and 3=extreme tenderness in each digit of the hands and feet. The range of total dactylitis scores for a patient is 0-60. Higher score indicates greater degree of tenderness. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

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

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

| End point values                    | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|-------------------------------------|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                  | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed         | 60                             | 60                              | 58                               | 29                                     |
| Units: Units on a scale             |                                |                                 |                                  |  |
| least squares mean (standard error) |                                |                                 |                                  |  |
| Month 1 (n=58, 59, 56, NA, NA, 56)  | -1.8 (± 0.91)                  | -3.1 (± 0.87)                   | -2.1 (± 0.93)                    | 9999 (± 9999)                          |
| Month 3 (n=58, 60, 56, NA, NA, 55)  | -3.5 (± 0.95)                  | -5.5 (± 0.91)                   | -4 (± 0.97)                      | 9999 (± 9999)                          |
| Month 6 (n=58, 59, 55, 28, 25, NA)  | -5.2 (± 1.01)                  | -6.4 (± 0.99)                   | -5.4 (± 1.03)                    | -5.9 (± 1.45)                          |
| Month 9 (n=57, 59, 53, 27, 25, NA)  | -7 (± 0.6)                     | -7.2 (± 0.58)                   | -6.5 (± 0.63)                    | -5.3 (± 0.87)                          |
| Month 12 (n=54, 58, 52, 26, 24, NA) | -7.4 (± 0.65)                  | -7.5 (± 0.62)                   | -6.1 (± 0.67)                    | -6.7 (± 0.93)                          |

| End point values                    | Placebo/Tofacitinib, 10 mg, twice daily | Placebo              |  |  |
|-------------------------------------|---|----------------------|--|--|
| Subject group type                  | Reporting group                         | Subject analysis set |  |  |
| Number of subjects analysed         | 28                                      | 57                   |  |  |
| Units: Units on a scale             |   |                      |  |  |
| least squares mean (standard error) |   |                      |  |  |
| Month 1 (n=58, 59, 56, NA, NA, 56)  | 9999 (± 9999)                           | 0.6 (± 1.02)         |  |  |
| Month 3 (n=58, 60, 56, NA, NA, 55)  | 9999 (± 9999)                           | -2 (± 1.06)          |  |  |
| Month 6 (n=58, 59, 55, 28, 25, NA)  | -5.2 (± 1.5)                            | 9999 (± 9999)        |  |  |
| Month 9 (n=57, 59, 53, 27, 25, NA)  | -7.9 (± 0.89)                           | 9999 (± 9999)        |  |  |
| Month 12 (n=54, 58, 52, 26, 24, NA) | -7.7 (± 0.96)                           | 9999 (± 9999)        |  |  |

## Statistical analyses

No statistical analyses for this end point

**Secondary: Change From Baseline in the Spondyloarthritis Research Consortium of Canada (SPARCC) Enthesitis Index at Months 1, 3, 6, 9, and 12**

|                 |  |
|-----------------|--|
| End point title | Change From Baseline in the Spondyloarthritis Research Consortium of Canada (SPARCC) Enthesitis Index at Months 1, 3, 6, 9, and 12 |
|-----------------|--|

**End point description:**

The SPARCC Enthesitis Index identifies the presence or absence of tenderness at 16 enthesial sites, including the bilateral Achilles tendons, plantar fascia insertion at the calcaneus, patellar tendon insertion at the base of the patella, quadriceps insertion into the superior border of the patella, supraspinatus insertion into the greater tuberosity of the humerus, and medial and lateral epicondyles. On examination, tenderness is recorded as present (1) or absent (0) for each of the 16 sites, with an overall total score ranging from 0 to 16. Higher score indicates a greater number of sites that are affected by enthesitis. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

|  |           |
|--|-----------|
| End point type                             | Secondary |
| End point timeframe:                       |           |
| From Baseline to Months 1, 3, 6, 9, and 12 |           |

| End point values                    | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|-------------------------------------|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                  | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed         | 80                             | 81                              | 82                               | 38                                     |
| Units: Units on a scale             |                                |                                 |                                  |  |
| least squares mean (standard error) |                                |                                 |                                  |  |
| Month 1 (n=79, 80, 80, NA, NA, 78)  | -0.83 (± 0.317)                | -1.27 (± 0.321)                 | -0.95 (± 0.336)                  | 9999 (± 9999)                          |
| Month 3 (n=77, 79, 79, NA, NA, 78)  | -1.84 (± 0.363)                | -2.41 (± 0.364)                 | -1.9 (± 0.375)                   | 9999 (± 9999)                          |
| Month 6 (n=76, 78, 76, 33, 39, NA)  | -2.4 (± 0.34)                  | -2.6 (± 0.34)                   | -2.3 (± 0.35)                    | -2.4 (± 0.5)                           |
| Month 9 (n=75, 75, 73, 34, 37, NA)  | -2.9 (± 0.31)                  | -2.6 (± 0.32)                   | -3 (± 0.33)                      | -2.8 (± 0.46)                          |
| Month 12 (n=72, 73, 72, 31, 37, NA) | -3.2 (± 0.33)                  | -3.1 (± 0.33)                   | -2.8 (± 0.35)                    | -2.5 (± 0.49)                          |

| End point values                    | Placebo/Tofacitinib, 10 mg, twice daily | Placebo              |  |  |
|-------------------------------------|---|----------------------|--|--|
| Subject group type                  | Reporting group                         | Subject analysis set |  |  |
| Number of subjects analysed         | 41                                      | 79                   |  |  |
| Units: Units on a scale             |   |                      |  |  |
| least squares mean (standard error) |   |                      |  |  |
| Month 1 (n=79, 80, 80, NA, NA, 78)  | 9999 (± 9999)                           | -0.58 (± 0.355)      |  |  |
| Month 3 (n=77, 79, 79, NA, NA, 78)  | 9999 (± 9999)                           | -1.17 (± 0.393)      |  |  |
| Month 6 (n=76, 78, 76, 33, 39, NA)  | -2.5 (± 0.48)                           | 9999 (± 9999)        |  |  |
| Month 9 (n=75, 75, 73, 34, 37, NA)  | -3.2 (± 0.44)                           | 9999 (± 9999)        |  |  |
| Month 12 (n=72, 73, 72, 31, 37, NA) | -3.2 (± 0.46)                           | 9999 (± 9999)        |  |  |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Change From Baseline in the Leeds Enthesitis Index (LEI) at Months 1,**

### 3, 6, 9, and 12

|                 |   |
|-----------------|---|
| End point title | Change From Baseline in the Leeds Enthesitis Index (LEI) at Months 1, 3, 6, 9, and 12 |
|-----------------|---|

End point description:

Enthesitis is inflammation in the tendon, ligament, and joint capsule fiber insertion into bone. The LEI assesses enthesitis in 6 sites. Tenderness is recorded as either present (1) or absent (0) for each of the 6 sites, for an total score of 0–6. Higher score indicates a greater number of sites affected by enthesitis. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

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

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

| End point values                    | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|-------------------------------------|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                  | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed         | 74                             | 64                              | 76                               | 31                                     |
| Units: Units on a scale             |                                |                                 |                                  |  |
| least squares mean (standard error) |                                |                                 |                                  |  |
| Month 1 (n=74, 63, 75, NA, NA, 65)  | -0.41 (± 0.192)                | -0.57 (± 0.213)                 | -0.42 (± 0.203)                  | 9999 (± 9999)                          |
| Month 3 (n=70, 63, 73, NA, NA, 63)  | -0.82 (± 0.221)                | -1.46 (± 0.24)                  | -1.1 (± 0.228)                   | 9999 (± 9999)                          |
| Month 6 (n=72, 61, 71, 27, 31, NA)  | -1.3 (± 0.21)                  | -1.2 (± 0.23)                   | -1.3 (± 0.22)                    | -1 (± 0.32)                            |
| Month 9 (n=70, 58, 68, 27, 29, NA)  | -1.4 (± 0.2)                   | -1.3 (± 0.23)                   | -1.5 (± 0.21)                    | -1.4 (± 0.31)                          |
| Month 12 (n=67, 56, 67, 24, 29, NA) | -1.7 (± 0.19)                  | -1.6 (± 0.21)                   | -1.6 (± 0.2)                     | -1.4 (± 0.3)                           |

| End point values                    | Placebo/Tofacitinib, 10 mg, twice daily | Placebo              |  |  |
|-------------------------------------|---|----------------------|--|--|
| Subject group type                  | Reporting group                         | Subject analysis set |  |  |
| Number of subjects analysed         | 34                                      | 65                   |  |  |
| Units: Units on a scale             |   |                      |  |  |
| least squares mean (standard error) |   |                      |  |  |
| Month 1 (n=74, 63, 75, NA, NA, 65)  | 9999 (± 9999)                           | -0.26 (± 0.219)      |  |  |
| Month 3 (n=70, 63, 73, NA, NA, 63)  | 9999 (± 9999)                           | -0.43 (± 0.246)      |  |  |
| Month 6 (n=72, 61, 71, 27, 31, NA)  | -1.3 (± 0.3)                            | 9999 (± 9999)        |  |  |
| Month 9 (n=70, 58, 68, 27, 29, NA)  | -1.7 (± 0.3)                            | 9999 (± 9999)        |  |  |
| Month 12 (n=67, 56, 67, 24, 29, NA) | -1.9 (± 0.28)                           | 9999 (± 9999)        |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change From Baseline in the Short-Form-36 Health Survey Version 2

**(SF-36v2) Acute, Physical Component Summary Score at Months 1, 3, 6, 9, and 12**

|  |  |
|--|--|
| End point title  | Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2) Acute, Physical Component Summary Score at Months 1, 3, 6, 9, and 12 |
| End point description:<br>The SF-36v2 acute is a 36-item measure that evaluates 8 domains: physical functioning, role physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health. The health domains are aggregated into two summary scores known as the physical component summary score and the mental component summary score. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable. |  |
| End point type   | Secondary  |
| End point timeframe:<br>From Baseline to Months 1, 3, 6, 9, and 12   |  |

| End point values                      | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|---------------------------------------|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                    | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed           | 106                            | 104                             | 106                              | 52                                     |
| Units: Units on a scale               |                                |                                 |                                  |  |
| least squares mean (standard error)   |                                |                                 |                                  |  |
| Month 1 (n=105, 103,104, NA, NA, 103) | 3.39 (± 0.638)                 | 4.66 (± 0.645)                  | 4 (± 0.655)                      | 9999 (± 9999)                          |
| Month 3 (n=102, 103,100, NA, NA, 102) | 5.51 (± 0.733)                 | 5.69 (± 0.735)                  | 6.23 (± 0.748)                   | 9999 (± 9999)                          |
| Month 6 (n=100, 100, 98, 48, 48, NA)  | 6.72 (± 0.773)                 | 6.7 (± 0.777)                   | 6.26 (± 0.788)                   | 5.86 (± 1.101)                         |
| Month 9 (n=99, 97, 95, 47, 46, NA)    | 7.52 (± 0.781)                 | 7.21 (± 0.787)                  | 6.91 (± 0.798)                   | 6.16 (± 1.115)                         |
| Month 12 (n=96, 96, 94, 44, 43, NA)   | 7.61 (± 0.806)                 | 7.67 (± 0.81)                   | 6.74 (± 0.822)                   | 5.82 (± 1.16)                          |

| End point values                      | Placebo/Tofacitinib, 10 mg, twice daily | Placebo              |  |  |
|---------------------------------------|---|----------------------|--|--|
| Subject group type                    | Reporting group                         | Subject analysis set |  |  |
| Number of subjects analysed           | 52                                      | 104                  |  |  |
| Units: Units on a scale               |   |                      |  |  |
| least squares mean (standard error)   |   |                      |  |  |
| Month 1 (n=105, 103,104, NA, NA, 103) | 9999 (± 9999)                           | 1.54 (± 0.7)         |  |  |
| Month 3 (n=102, 103,100, NA, NA, 102) | 9999 (± 9999)                           | 2.68 (± 0.785)       |  |  |
| Month 6 (n=100, 100, 98, 48, 48, NA)  | 6.07 (± 1.112)                          | 9999 (± 9999)        |  |  |
| Month 9 (n=99, 97, 95, 47, 46, NA)    | 7.15 (± 1.13)                           | 9999 (± 9999)        |  |  |
| Month 12 (n=96, 96, 94, 44, 43, NA)   | 5.72 (± 1.177)                          | 9999 (± 9999)        |  |  |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute, Mental Component Summary Score at Months 1, 3, 6, 9, and 12**

|  |   |
|--|---|
| End point title  | Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute, Mental Component Summary Score at Months 1, 3, 6, 9, and 12 |
| End point description:   |   |
| The SF-36v2 acute is a 36-item measure that evaluates 8 domains: physical functioning, role physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health. The health domains are aggregated into two summary scores known as the physical component summary score and the mental component summary score. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable. |   |
| End point type   | Secondary   |
| End point timeframe:   |   |
| From Baseline to Months 1, 3, 6, 9, and 12   |   |

| End point values                      | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|---------------------------------------|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                    | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed           | 106                            | 104                             | 106                              | 52                                     |
| Units: Units on a scale               |                                |                                 |                                  |  |
| least squares mean (standard error)   |                                |                                 |                                  |  |
| Month 1 (n=105, 103,104,NA, NA, 103)  | 4.12 (± 0.841)                 | 3.63 (± 0.849)                  | 2.13 (± 0.871)                   | 9999 (± 9999)                          |
| Month 3 (n=102, 103,100, NA, NA, 102) | 4.35 (± 0.909)                 | 4.2 (± 0.909)                   | 3.13 (± 0.938)                   | 9999 (± 9999)                          |
| Month 6 (n=100, 100, 98, 48, 48, NA)  | 5.7 (± 0.927)                  | 5.51 (± 0.93)                   | 4.58 (± 0.955)                   | 4.5 (± 1.319)                          |
| Month 9 (n=99, 97, 95, 47, 46, NA)    | 5.07 (± 0.974)                 | 6.2 (± 0.982)                   | 3.68 (± 1.005)                   | 4.61 (± 1.391)                         |
| Month 12 (n=96, 96, 94, 44, 43, NA)   | 4.82 (± 1.012)                 | 6.26 (± 1.016)                  | 4.81 (± 1.039)                   | 4.51 (± 1.455)                         |

| End point values                      | Placebo/Tofacitinib, 10 mg, twice daily | Placebo              |  |  |
|---------------------------------------|---|----------------------|--|--|
| Subject group type                    | Reporting group                         | Subject analysis set |  |  |
| Number of subjects analysed           | 52                                      | 104                  |  |  |
| Units: Units on a scale               |   |                      |  |  |
| least squares mean (standard error)   |   |                      |  |  |
| Month 1 (n=105, 103,104,NA, NA, 103)  | 9999 (± 9999)                           | 3.19 (± 0.917)       |  |  |
| Month 3 (n=102, 103,100, NA, NA, 102) | 9999 (± 9999)                           | 3.27 (± 0.976)       |  |  |
| Month 6 (n=100, 100, 98, 48, 48, NA)  | 3.62 (± 1.331)                          | 9999 (± 9999)        |  |  |
| Month 9 (n=99, 97, 95, 47, 46, NA)    | 6.03 (± 1.409)                          | 9999 (± 9999)        |  |  |
| Month 12 (n=96, 96, 94, 44, 43, NA)   | 4.43 (± 1.474)                          | 9999 (± 9999)        |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute Components: Physical Functioning Domain at Months 1, 3, 6, 9, and 12

|                 |   |
|-----------------|---|
| End point title | Change From Baseline in the Short-Form-36 Health Survey |
|-----------------|---|

## End point description:

The 10 items of the physical functioning scale represent levels and kinds of limitations between the extremes of physical activities, including lifting and carrying groceries; climbing stairs; bending, kneeling, or stooping; walking moderate distances; self-care limitations. The physical functioning items capture both the presence and extent of physical limitations using a 3-level response continuum. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

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

## End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

| End point values                      | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|---------------------------------------|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                    | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed           | 106                            | 104                             | 106                              | 52                                     |
| Units: Units on a scale               |                                |                                 |                                  |  |
| least squares mean (standard error)   |                                |                                 |                                  |  |
| Month 1 (n=105, 103,104, NA, NA, 103) | 2.43 (± 0.768)                 | 3.89 (± 0.776)                  | 2.81 (± 0.787)                   | 9999 (± 9999)                          |
| Month 3 (n=102, 103,101, NA, NA, 102) | 5.17 (± 0.846)                 | 5.23 (± 0.848)                  | 5.22 (± 0.862)                   | 9999 (± 9999)                          |
| Month 6 (n=100, 100, 99, 48, 48, NA)  | 7.02 (± 0.897)                 | 6.15 (± 0.9)                    | 6.36 (± 0.912)                   | 5.22 (± 1.276)                         |
| Month 9 (n=99, 97, 96, 47, 46, NA)    | 7.43 (± 0.902)                 | 6.67 (± 0.909)                  | 7.01 (± 0.921)                   | 5.69 (± 1.285)                         |
| Month 12 (n=96, 96, 94, 44, 44, NA)   | 7.67 (± 0.899)                 | 7.11 (± 0.903)                  | 6.81 (± 0.917)                   | 6.49 (± 1.292)                         |

| End point values                      | Placebo/Tofacitinib, 10 mg, twice daily | Placebo              |  |  |
|---------------------------------------|---|----------------------|--|--|
| Subject group type                    | Reporting group                         | Subject analysis set |  |  |
| Number of subjects analysed           | 52                                      | 104                  |  |  |
| Units: Units on a scale               |   |                      |  |  |
| least squares mean (standard error)   |   |                      |  |  |
| Month 1 (n=105, 103,104, NA, NA, 103) | 9999 (± 9999)                           | 1.1 (± 0.84)         |  |  |
| Month 3 (n=102, 103,101, NA, NA, 102) | 9999 (± 9999)                           | 2.06 (± 0.91)        |  |  |
| Month 6 (n=100, 100, 99, 48, 48, NA)  | 5.22 (± 1.291)                          | 9999 (± 9999)        |  |  |
| Month 9 (n=99, 97, 96, 47, 46, NA)    | 6.25 (± 1.306)                          | 9999 (± 9999)        |  |  |
| Month 12 (n=96, 96, 94, 44, 44, NA)   | 4.77 (± 1.308)                          | 9999 (± 9999)        |  |  |

## Statistical analyses

No statistical analyses for this end point

**Secondary: Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute Components: Role-Physical Domain at Months 1, 3, 6, 9, and 12**

|                 |  |
|-----------------|--|
| End point title | Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute Components: Role-Physical Domain at Months 1, 3, 6, 9, and 12 |
|-----------------|--|



**End point description:**

The 4-item role-physical scale covers an array of physical health-related role limitations, including: a) limitations in the kind of work or other usual activities; b) reductions in the amount of time spent on work or other usual activities; c) difficulty performing work or other usual activities; and d) accomplishing less. Items in the role-physical scale are answered on a 5-point scale. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

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

**End point timeframe:**

From Baseline to Months 1, 3, 6, 9, and 12

| <b>End point values</b>                | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|--|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                     | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed            | 106                            | 104                             | 106                              | 52                                     |
| Units: Units on a scale                |                                |                                 |                                  |  |
| least squares mean (standard error)    |                                |                                 |                                  |  |
| Month 1 (n=105, 103,104, NA, NA, 103)  | 4.05 (± 0.751)                 | 3.72 (± 0.759)                  | 4.09 (± 0.77)                    | 9999 (± 9999)                          |
| Month 3 (n=102, 103, 100, NA, NA, 102) | 4.45 (± 0.801)                 | 4.79 (± 0.803)                  | 5.21 (± 0.82)                    | 9999 (± 9999)                          |
| Month 6 (n=100, 100, 99, 48, 48, NA)   | 6.02 (± 0.824)                 | 5.21 (± 0.828)                  | 5.48 (± 0.84)                    | 4.97 (± 1.172)                         |
| Month 9 (n=99, 97, 96, 47, 46, NA)     | 6.24 (± 0.853)                 | 6.56 (± 0.861)                  | 5.79 (± 0.872)                   | 4.68 (± 1.217)                         |
| Month 12 (n=96, 96, 94, 44, 44, NA)    | 6.21 (± 0.888)                 | 7.11 (± 0.892)                  | 6.37 (± 0.906)                   | 2.98 (± 1.279)                         |

| <b>End point values</b>                | Placebo/Tofacitinib, 10 mg, twice daily | Placebo              |  |  |
|--|---|----------------------|--|--|
| Subject group type                     | Reporting group                         | Subject analysis set |  |  |
| Number of subjects analysed            | 52                                      | 104                  |  |  |
| Units: Units on a scale                |   |                      |  |  |
| least squares mean (standard error)    |   |                      |  |  |
| Month 1 (n=105, 103,104, NA, NA, 103)  | 9999 (± 9999)                           | 1.98 (± 0.82)        |  |  |
| Month 3 (n=102, 103, 100, NA, NA, 102) | 9999 (± 9999)                           | 3.63 (± 0.862)       |  |  |
| Month 6 (n=100, 100, 99, 48, 48, NA)   | 5.03 (± 1.185)                          | 9999 (± 9999)        |  |  |
| Month 9 (n=99, 97, 96, 47, 46, NA)     | 6.7 (± 1.234)                           | 9999 (± 9999)        |  |  |
| Month 12 (n=96, 96, 94, 44, 44, NA)    | 5.03 (± 1.291)                          | 9999 (± 9999)        |  |  |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute Components: Bodily Pain Domain at Months 1, 3, 6, 9, and 12**

|                 |  |
|-----------------|--|
| End point title | Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute Components: Bodily Pain Domain at Months 1, 3, 6, 9, and 12 |
|-----------------|--|

End point description:

The bodily pain scale comprises of 2 items pertaining to the intensity of bodily pain and extent of interference with normal work activities. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

|  |           |
|--|-----------|
| End point type                             | Secondary |
| End point timeframe:                       |           |
| From Baseline to Months 1, 3, 6, 9, and 12 |           |

| End point values                       | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|--|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                     | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed            | 106                            | 104                             | 106                              | 52                                     |
| Units: Units on a scale                |                                |                                 |                                  |  |
| least squares mean (standard error)    |                                |                                 |                                  |  |
| Month 1 (n=105, 103, 104, NA, NA, 103) | 5.53 (± 0.777)                 | 7.16 (± 0.786)                  | 6.42 (± 0.802)                   | 9999 (± 9999)                          |
| Month 3 (n=102, 103, 101, NA, NA, 102) | 7.75 (± 0.838)                 | 8.05 (± 0.84)                   | 7.52 (± 0.859)                   | 9999 (± 9999)                          |
| Month 6 (n=100, 100, 99, 48, 48, NA)   | 7.76 (± 0.985)                 | 10.65 (± 0.989)                 | 7.76 (± 1.004)                   | 8.55 (± 1.405)                         |
| Month 9 (n=99, 97, 96, 47, 46, NA)     | 9.03 (± 0.953)                 | 10.13 (± 0.96)                  | 8.59 (± 0.977)                   | 8.46 (± 1.362)                         |
| Month 12 (n=96, 96, 94, 44, 43, NA)    | 9.15 (± 0.961)                 | 11.38 (± 0.965)                 | 9.18 (± 0.984)                   | 8.59 (± 1.384)                         |

| End point values                       | Placebo/Tofacitinib, 10 mg, twice daily | Placebo              |  |  |
|--|---|----------------------|--|--|
| Subject group type                     | Reporting group                         | Subject analysis set |  |  |
| Number of subjects analysed            | 52                                      | 104                  |  |  |
| Units: Units on a scale                |   |                      |  |  |
| least squares mean (standard error)    |   |                      |  |  |
| Month 1 (n=105, 103, 104, NA, NA, 103) | 9999 (± 9999)                           | 3.44 (± 0.851)       |  |  |
| Month 3 (n=102, 103, 101, NA, NA, 102) | 9999 (± 9999)                           | 3.77 (± 0.903)       |  |  |
| Month 6 (n=100, 100, 99, 48, 48, NA)   | 8.98 (± 1.425)                          | 9999 (± 9999)        |  |  |
| Month 9 (n=99, 97, 96, 47, 46, NA)     | 10.81 (± 1.389)                         | 9999 (± 9999)        |  |  |
| Month 12 (n=96, 96, 94, 44, 43, NA)    | 8.61 (± 1.413)                          | 9999 (± 9999)        |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute Components: General Health Domain at Months 1, 3, 6, 9, and 12

|                 |   |
|-----------------|---|
| End point title | Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute Components: General Health Domain at Months 1, 3, 6, 9, and 12 |
|-----------------|---|

**End point description:**

The general health scale consists of 5 items including a rating of health and 4 items addressing the respondent's view and expectations of his or her health. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

|  |           |
|--|-----------|
| End point type                             | Secondary |
| End point timeframe:                       |           |
| From Baseline to Months 1, 3, 6, 9, and 12 |           |

| End point values                      | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|---------------------------------------|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                    | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed           | 106                            | 104                             | 106                              | 52                                     |
| Units: Units on a scale               |                                |                                 |                                  |  |
| least squares mean (standard error)   |                                |                                 |                                  |  |
| Month 1 (n=105, 103,104, NA, NA, 103) | 3.29 (± 0.61)                  | 3.87 (± 0.616)                  | 1.96 (± 0.625)                   | 9999 (± 9999)                          |
| Month 3 (n=102, 103,101, NA, NA, 102) | 4.09 (± 0.7)                   | 3.95 (± 0.701)                  | 4.73 (± 0.713)                   | 9999 (± 9999)                          |
| Month 6 (n=100, 100, 99, 48, 48, NA)  | 5.96 (± 0.72)                  | 4.12 (± 0.722)                  | 4.81 (± 0.733)                   | 4.39 (± 1.022)                         |
| Month 9 (n=99, 97, 96, 47, 46, NA)    | 5.93 (± 0.773)                 | 5.18 (± 0.778)                  | 4.09 (± 0.788)                   | 4.72 (± 1.102)                         |
| Month 12 (n=96, 96, 94, 44, 44, NA)   | 5.7 (± 0.811)                  | 4.63 (± 0.815)                  | 4.21 (± 0.825)                   | 4.5 (± 1.164)                          |

| End point values                      | Placebo/Tofacitinib, 10 mg, twice daily | Placebo              |  |  |
|---------------------------------------|---|----------------------|--|--|
| Subject group type                    | Reporting group                         | Subject analysis set |  |  |
| Number of subjects analysed           | 52                                      | 104                  |  |  |
| Units: Units on a scale               |   |                      |  |  |
| least squares mean (standard error)   |   |                      |  |  |
| Month 1 (n=105, 103,104, NA, NA, 103) | 9999 (± 9999)                           | 2.15 (± 0.666)       |  |  |
| Month 3 (n=102, 103,101, NA, NA, 102) | 9999 (± 9999)                           | 2.64 (± 0.748)       |  |  |
| Month 6 (n=100, 100, 99, 48, 48, NA)  | 3.92 (± 1.033)                          | 9999 (± 9999)        |  |  |
| Month 9 (n=99, 97, 96, 47, 46, NA)    | 4.85 (± 1.117)                          | 9999 (± 9999)        |  |  |
| Month 12 (n=96, 96, 94, 44, 44, NA)   | 4.12 (± 1.175)                          | 9999 (± 9999)        |  |  |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute Components: Vitality Domain at Months 1, 3, 6, 9, and 12**

|                 |   |
|-----------------|---|
| End point title | Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute Components: Vitality Domain at Months 1, 3, 6, 9, and 12 |
|-----------------|---|

**End point description:**

This 4-item measure of vitality captures a broad range of subjective evaluations of well-being from

feelings of tiredness and being worn out to feeling full of energy all or most of the time. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

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

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

| End point values                       | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|--|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                     | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed            | 106                            | 104                             | 106                              | 52                                     |
| Units: Units on a scale                |                                |                                 |                                  |  |
| least squares mean (standard error)    |                                |                                 |                                  |  |
| Month 1 (n=105, 103, 104, NA, NA, 103) | 3.64 (± 0.802)                 | 4.59 (± 0.806)                  | 2.42 (± 0.826)                   | 9999 (± 9999)                          |
| Month 3 (n=102, 103, 101, NA, NA, 102) | 5.5 (± 0.889)                  | 5.9 (± 0.887)                   | 4.93 (± 0.909)                   | 9999 (± 9999)                          |
| Month 6 (n=100, 100, 99, 48, 48, NA)   | 6.81 (± 0.969)                 | 7.41 (± 0.97)                   | 5.05 (± 0.989)                   | 5.34 (± 1.378)                         |
| Month 9 (n=99, 97, 96, 47, 46, NA)     | 6.09 (± 1.017)                 | 7.82 (± 1.023)                  | 5.27 (± 1.041)                   | 6.61 (± 1.451)                         |
| Month 12 (n=96, 96, 94, 44, 44, NA)    | 7.01 (± 1.022)                 | 7.02 (± 1.024)                  | 5.12 (± 1.043)                   | 5.62 (± 1.465)                         |

| End point values                       | Placebo/Tofacitinib, 10 mg, twice daily | Placebo              |  |  |
|--|---|----------------------|--|--|
| Subject group type                     | Reporting group                         | Subject analysis set |  |  |
| Number of subjects analysed            | 52                                      | 104                  |  |  |
| Units: Units on a scale                |   |                      |  |  |
| least squares mean (standard error)    |   |                      |  |  |
| Month 1 (n=105, 103, 104, NA, NA, 103) | 9999 (± 9999)                           | 2.16 (± 0.877)       |  |  |
| Month 3 (n=102, 103, 101, NA, NA, 102) | 9999 (± 9999)                           | 3.05 (± 0.954)       |  |  |
| Month 6 (n=100, 100, 99, 48, 48, NA)   | 4.62 (± 1.394)                          | 9999 (± 9999)        |  |  |
| Month 9 (n=99, 97, 96, 47, 46, NA)     | 6.39 (± 1.472)                          | 9999 (± 9999)        |  |  |
| Month 12 (n=96, 96, 94, 44, 44, NA)    | 5.15 (± 1.481)                          | 9999 (± 9999)        |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute Components: Social Functioning Domain at Months 1, 3, 6, 9, and 12

|                 |   |
|-----------------|---|
| End point title | Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute Components: Social Functioning Domain at Months 1, 3, 6, 9, and 12 |
|-----------------|---|

End point description:

This 2-item scale assesses health-related effects on quantity and quality of social activities. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

|  |           |
|--|-----------|
| End point type                             | Secondary |
| End point timeframe:                       |           |
| From Baseline to Months 1, 3, 6, 9, and 12 |           |

| End point values                       | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|--|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                     | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed            | 106                            | 104                             | 106                              | 52                                     |
| Units: Units on a scale                |                                |                                 |                                  |  |
| least squares mean (standard error)    |                                |                                 |                                  |  |
| Month 1 (n=105, 103,104, NA, NA, 103)  | 4.51 (± 0.827)                 | 4.46 (± 0.838)                  | 3.34 (± 0.852)                   | 9999 (± 9999)                          |
| Month 3 (n=102, 103, 101, NA, NA, 102) | 5.95 (± 0.897)                 | 5.22 (± 0.898)                  | 5.26 (± 0.918)                   | 9999 (± 9999)                          |
| Month 6 (n=100, 100, 99, 48, 48, NA)   | 6.97 (± 0.955)                 | 7.08 (± 0.959)                  | 7.1 (± 0.975)                    | 5.44 (± 1.362)                         |
| Month 9 (n=99, 97, 96, 47, 46, NA)     | 7.66 (± 0.947)                 | 7.74 (± 0.957)                  | 5.69 (± 0.972)                   | 5.95 (± 1.355)                         |
| Month 12 (n=96, 96, 94, 44, 44, NA)    | 6.13 (± 0.989)                 | 8.42 (± 0.995)                  | 6.32 (± 1.012)                   | 6.19 (± 1.427)                         |

| End point values                       | Placebo/Tofacitinib, 10 mg, twice daily | Placebo              |  |  |
|--|---|----------------------|--|--|
| Subject group type                     | Reporting group                         | Subject analysis set |  |  |
| Number of subjects analysed            | 52                                      | 104                  |  |  |
| Units: Units on a scale                |   |                      |  |  |
| least squares mean (standard error)    |   |                      |  |  |
| Month 1 (n=105, 103,104, NA, NA, 103)  | 9999 (± 9999)                           | 2.96 (± 0.901)       |  |  |
| Month 3 (n=102, 103, 101, NA, NA, 102) | 9999 (± 9999)                           | 3.63 (± 0.961)       |  |  |
| Month 6 (n=100, 100, 99, 48, 48, NA)   | 6.05 (± 1.373)                          | 9999 (± 9999)        |  |  |
| Month 9 (n=99, 97, 96, 47, 46, NA)     | 8.93 (± 1.373)                          | 9999 (± 9999)        |  |  |
| Month 12 (n=96, 96, 94, 44, 44, NA)    | 6.41 (± 1.445)                          | 9999 (± 9999)        |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute Components: Role-Emotional Domain at Months 1, 3, 6, 9, and 12

|  |   |
|--|---|
| End point title  | Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute Components: Role-Emotional Domain at Months 1, 3, 6, 9, and 12 |
| End point description:   |   |
| The 3-item role-emotional scale assesses mental health-related role limitations in terms of a) time spent in work or other usual activities; b) amount of work or activities accomplished; c) care with which work or other activities were performed. All 3 items are answered on a 5-point scale. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable. |   |
| End point type   | Secondary   |

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

| End point values                       | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|--|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                     | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed            | 106                            | 104                             | 106                              | 52                                     |
| Units: Units on a scale                |                                |                                 |                                  |  |
| least squares mean (standard error)    |                                |                                 |                                  |  |
| Month 1 (n=105, 103, 104, NA, NA, 103) | 4.77 (± 0.96)                  | 3.87 (± 0.971)                  | 2.93 (± 0.991)                   | 9999 (± 9999)                          |
| Month 3 (n=102, 103, 100, NA, NA, 102) | 4.21 (± 1.01)                  | 4.82 (± 1.011)                  | 3.35 (± 1.04)                    | 9999 (± 9999)                          |
| Month 6 (n=100, 100, 98, 48, 48, NA)   | 5.67 (± 1.024)                 | 4.68 (± 1.027)                  | 4.77 (± 1.051)                   | 6.34 (± 1.458)                         |
| Month 9 (n=99, 97, 95, 47, 46, NA)     | 5.13 (± 1.021)                 | 6.13 (± 1.03)                   | 4.87 (± 1.052)                   | 5.89 (± 1.456)                         |
| Month 12 (n=96, 96, 94, 44, 44, NA)    | 5.15 (± 1.048)                 | 6.73 (± 1.053)                  | 6.03 (± 1.075)                   | 4.77 (± 1.509)                         |

| End point values                       | Placebo/Tofacitinib, 10 mg, twice daily | Placebo              |  |  |
|--|---|----------------------|--|--|
| Subject group type                     | Reporting group                         | Subject analysis set |  |  |
| Number of subjects analysed            | 52                                      | 104                  |  |  |
| Units: Units on a scale                |   |                      |  |  |
| least squares mean (standard error)    |   |                      |  |  |
| Month 1 (n=105, 103, 104, NA, NA, 103) | 9999 (± 9999)                           | 4.52 (± 1.042)       |  |  |
| Month 3 (n=102, 103, 100, NA, NA, 102) | 9999 (± 9999)                           | 3.68 (± 1.083)       |  |  |
| Month 6 (n=100, 100, 98, 48, 48, NA)   | 4.56 (± 1.473)                          | 9999 (± 9999)        |  |  |
| Month 9 (n=99, 97, 95, 47, 46, NA)     | 6.52 (± 1.478)                          | 9999 (± 9999)        |  |  |
| Month 12 (n=96, 96, 94, 44, 44, NA)    | 4.94 (± 1.525)                          | 9999 (± 9999)        |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute Components: Mental Health Domain at Months 1, 3, 6, 9, and 12

|                 |  |
|-----------------|--|
| End point title | Change From Baseline in the Short-Form-36 Health Survey Version 2 (SF-36v2), Acute Components: Mental Health Domain at Months 1, 3, 6, 9, and 12 |
|-----------------|--|

End point description:

The 5-item mental health scale includes 1 or more items from each of 4 major mental health dimensions: anxiety, depression, loss of behavioural/emotional control, and psychological well-being. All items are answered on a 5-point scale. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

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

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

| End point values                       | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|--|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                     | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed            | 106                            | 104                             | 106                              | 52                                     |
| Units: Units on a scale                |                                |                                 |                                  |  |
| least squares mean (standard error)    |                                |                                 |                                  |  |
| Month 1 (n=105, 103, 104, NA, NA, 103) | 3.32 (± 0.867)                 | 3.87 (± 0.874)                  | 2.79 (± 0.895)                   | 9999 (± 9999)                          |
| Month 3 (n=102, 103, 101, NA, NA, 102) | 4.45 (± 0.934)                 | 4.23 (± 0.932)                  | 3.95 (± 0.956)                   | 9999 (± 9999)                          |
| Month 6 (n=100, 100, 99, 48, 48, NA)   | 6.11 (± 0.951)                 | 6.38 (± 0.953)                  | 5.35 (± 0.974)                   | 3.7 (± 1.354)                          |
| Month 9 (n=99, 97, 96, 47, 46, NA)     | 5.79 (± 1.022)                 | 6.43 (± 1.028)                  | 4.62 (± 1.048)                   | 3.57 (± 1.461)                         |
| Month 12 (n=96, 96, 94, 44, 44, NA)    | 5.86 (± 1.019)                 | 6.58 (± 1.022)                  | 5.86 (± 1.044)                   | 4.72 (± 1.467)                         |

| End point values                       | Placebo/Tofacitinib, 10 mg, twice daily | Placebo              |  |  |
|--|---|----------------------|--|--|
| Subject group type                     | Reporting group                         | Subject analysis set |  |  |
| Number of subjects analysed            | 52                                      | 104                  |  |  |
| Units: Units on a scale                |   |                      |  |  |
| least squares mean (standard error)    |   |                      |  |  |
| Month 1 (n=105, 103, 104, NA, NA, 103) | 9999 (± 9999)                           | 1.57 (± 0.952)       |  |  |
| Month 3 (n=102, 103, 101, NA, NA, 102) | 9999 (± 9999)                           | 2.62 (± 1.009)       |  |  |
| Month 6 (n=100, 100, 99, 48, 48, NA)   | 3.41 (± 1.372)                          | 9999 (± 9999)        |  |  |
| Month 9 (n=99, 97, 96, 47, 46, NA)     | 5.45 (± 1.483)                          | 9999 (± 9999)        |  |  |
| Month 12 (n=96, 96, 94, 44, 44, NA)    | 4.48 (± 1.483)                          | 9999 (± 9999)        |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Score on EuroQol-5 Dimension Health State Profile (EQ-5D) and Change in Patient's Self-rated Health on a Vertical Visual Analogue Scale (VAS) Recorded on the EQ-5D Questionnaire (EQ-VAS): Mobility at Months 1, 3, 6, 9, and 12

|                 |   |
|-----------------|---|
| End point title | Change From Baseline in Score on EuroQol-5 Dimension Health State Profile (EQ-5D) and Change in Patient's Self-rated Health on a Vertical Visual Analogue Scale (VAS) Recorded on the EQ-5D Questionnaire (EQ-VAS): Mobility at Months 1, 3, 6, 9, and 12 |
|-----------------|---|

End point description:

The EQ-5D is a descriptive system of health-related quality of life states consisting of 5 dimensions

(mobility, self-care, usual activities, pain/discomfort, anxiety/depression) each of which can take 1 of 3 responses. The responses record 3 levels of severity (no problems/some or moderate problems/extreme problems) within a particular EQ-5D dimension. Standard vertical 0 to 100 mm visual analogue scale (similar to a thermometer) for recording an individual's rating for their current health-related quality of life state. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

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

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

| End point values                       | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|--|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                     | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed            | 106                            | 104                             | 106                              | 52                                     |
| Units: Units on a scale                |                                |                                 |                                  |  |
| least squares mean (standard error)    |                                |                                 |                                  |  |
| Month 1 (n=105, 103, 104, NA, NA, 103) | -0.07 (± 0.042)                | -0.19 (± 0.043)                 | -0.15 (± 0.043)                  | 9999 (± 9999)                          |
| Month 3 (n=101, 103, 101, NA, NA, 102) | -0.28 (± 0.047)                | -0.27 (± 0.047)                 | -0.29 (± 0.048)                  | 9999 (± 9999)                          |
| Month 6 (n=100, 100, 99, 48, 48, NA)   | -0.3 (± 0.05)                  | -0.3 (± 0.05)                   | -0.2 (± 0.05)                    | -0.3 (± 0.07)                          |
| Month 9 (n=99, 97, 96, 47, 46, NA)     | -0.3 (± 0.05)                  | -0.3 (± 0.05)                   | -0.3 (± 0.05)                    | -0.3 (± 0.07)                          |
| Month 12 (n=96, 96, 94, 44,44, NA)     | -0.3 (± 0.05)                  | -0.3 (± 0.05)                   | -0.3 (± 0.05)                    | -0.4 (± 0.07)                          |

| End point values                       | Placebo/Tofacitinib, 10 mg, twice daily | Placebo              |  |  |
|--|---|----------------------|--|--|
| Subject group type                     | Reporting group                         | Subject analysis set |  |  |
| Number of subjects analysed            | 52                                      | 104                  |  |  |
| Units: Units on a scale                |   |                      |  |  |
| least squares mean (standard error)    |   |                      |  |  |
| Month 1 (n=105, 103, 104, NA, NA, 103) | 9999 (± 9999)                           | -0.1 (± 0.046)       |  |  |
| Month 3 (n=101, 103, 101, NA, NA, 102) | 9999 (± 9999)                           | -0.11 (± 0.05)       |  |  |
| Month 6 (n=100, 100, 99, 48, 48, NA)   | -0.2 (± 0.07)                           | 9999 (± 9999)        |  |  |
| Month 9 (n=99, 97, 96, 47, 46, NA)     | -0.3 (± 0.07)                           | 9999 (± 9999)        |  |  |
| Month 12 (n=96, 96, 94, 44,44, NA)     | -0.3 (± 0.07)                           | 9999 (± 9999)        |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Score on EQ-5D and Change in Patient's Self-rated Health on a Vertical VAS Recorded on the EQ-VAS: Self-care at Months 1, 3, 6, 9, and 12

|                 |  |
|-----------------|--|
| End point title | Change From Baseline in Score on EQ-5D and Change in |
|-----------------|--|



End point description:

The EQ-5D is a descriptive system of health-related quality of life states consisting of 5 dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) each of which can take 1 of 3 responses. The responses record 3 levels of severity (no problems/some or moderate problems/extreme problems) within a particular EQ-5D dimension. Standard vertical 0 to 100 mm visual analogue scale (similar to a thermometer) for recording an individual's rating for their current health-related quality of life state. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

End point type Secondary

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

| End point values                       | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|--|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                     | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed            | 106                            | 103                             | 106                              | 52                                     |
| Units: Units on a scale                |                                |                                 |                                  |  |
| least squares mean (standard error)    |                                |                                 |                                  |  |
| Month 1 (n=105, 102, 104, NA, NA, 103) | -0.11 (± 0.046)                | -0.16 (± 0.047)                 | -0.16 (± 0.047)                  | 9999 (± 9999)                          |
| Month 3 (n=101, 102, 101, NA, NA, 102) | -0.19 (± 0.047)                | -0.11 (± 0.047)                 | -0.18 (± 0.048)                  | 9999 (± 9999)                          |
| Month 6 (n=100, 99, 99, 48, 48, NA)    | -0.2 (± 0.04)                  | -0.3 (± 0.05)                   | -0.2 (± 0.05)                    | -0.2 (± 0.06)                          |
| Month 9 (n=99, 97, 96, 47, 46, NA)     | -0.2 (± 0.05)                  | -0.2 (± 0.05)                   | -0.3 (± 0.05)                    | -0.2 (± 0.06)                          |
| Month 12 (n=96, 96, 94, 44, 44, NA)    | -0.2 (± 0.05)                  | -0.3 (± 0.05)                   | -0.3 (± 0.05)                    | -0.3 (± 0.07)                          |

| End point values                       | Placebo/Tofacitinib, 10 mg, twice daily | Placebo              |  |  |
|--|---|----------------------|--|--|
| Subject group type                     | Reporting group                         | Subject analysis set |  |  |
| Number of subjects analysed            | 52                                      | 104                  |  |  |
| Units: Units on a scale                |   |                      |  |  |
| least squares mean (standard error)    |   |                      |  |  |
| Month 1 (n=105, 102, 104, NA, NA, 103) | 9999 (± 9999)                           | -0.09 (± 0.05)       |  |  |
| Month 3 (n=101, 102, 101, NA, NA, 102) | 9999 (± 9999)                           | -0.12 (± 0.051)      |  |  |
| Month 6 (n=100, 99, 99, 48, 48, NA)    | -0.3 (± 0.06)                           | 9999 (± 9999)        |  |  |
| Month 9 (n=99, 97, 96, 47, 46, NA)     | -0.3 (± 0.07)                           | 9999 (± 9999)        |  |  |
| Month 12 (n=96, 96, 94, 44, 44, NA)    | -0.2 (± 0.07)                           | 9999 (± 9999)        |  |  |

Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Score on EQ-5D and Change in Patient's Self-rated Health on a Vertical VAS Recorded on the EQ-VAS: Usual Activities at Months 1, 3, 6, 9, and 12

|                 |  |
|-----------------|--|
| End point title | Change From Baseline in Score on EQ-5D and Change in Patient's Self-rated Health on a Vertical VAS Recorded on the EQ-VAS: Usual Activities at Months 1, 3, 6, 9, and 12 |
|-----------------|--|

End point description:

The EQ-5D is a descriptive system of health-related quality of life states consisting of 5 dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) each of which can take 1 of 3 responses. The responses record 3 levels of severity (no problems/some or moderate problems/extreme problems) within a particular EQ-5D dimension. Standard vertical 0 to 100 mm visual analogue scale (similar to a thermometer) for recording an individual's rating for their current health-related quality of life state. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

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

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

| End point values                       | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|--|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                     | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed            | 106                            | 103                             | 106                              | 52                                     |
| Units: Units on a scale                |                                |                                 |                                  |  |
| least squares mean (standard error)    |                                |                                 |                                  |  |
| Month 1 (n=105, 102, 104, NA, NA, 103) | -0.17 (± 0.043)                | -0.19 (± 0.043)                 | -0.21 (± 0.044)                  | 9999 (± 9999)                          |
| Month 3 (n=101, 102, 101, NA, NA, 102) | -0.24 (± 0.049)                | -0.29 (± 0.049)                 | -0.29 (± 0.049)                  | 9999 (± 9999)                          |
| Month 6 (n=100, 99, 99, 48, 47, NA)    | -0.3 (± 0.05)                  | -0.3 (± 0.05)                   | -0.4 (± 0.05)                    | -0.3 (± 0.07)                          |
| Month 9 (n=99, 97, 96, 47, 46, NA)     | -0.3 (± 0.05)                  | -0.4 (± 0.05)                   | -0.4 (± 0.05)                    | -0.3 (± 0.07)                          |
| Month 12 (n=96, 96, 94, 44, 44, NA)    | -0.3 (± 0.05)                  | -0.4 (± 0.05)                   | -0.4 (± 0.05)                    | -0.3 (± 0.07)                          |

| End point values                       | Placebo/Tofacitinib, 10 mg, twice daily | Placebo              |  |  |
|--|---|----------------------|--|--|
| Subject group type                     | Reporting group                         | Subject analysis set |  |  |
| Number of subjects analysed            | 52                                      | 104                  |  |  |
| Units: Units on a scale                |   |                      |  |  |
| least squares mean (standard error)    |   |                      |  |  |
| Month 1 (n=105, 102, 104, NA, NA, 103) | 9999 (± 9999)                           | -0.06 (± 0.047)      |  |  |
| Month 3 (n=101, 102, 101, NA, NA, 102) | 9999 (± 9999)                           | -0.17 (± 0.052)      |  |  |
| Month 6 (n=100, 99, 99, 48, 47, NA)    | -0.3 (± 0.07)                           | 9999 (± 9999)        |  |  |
| Month 9 (n=99, 97, 96, 47, 46, NA)     | -0.4 (± 0.07)                           | 9999 (± 9999)        |  |  |
| Month 12 (n=96, 96, 94, 44, 44, NA)    | -0.3 (± 0.07)                           | 9999 (± 9999)        |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change From Baseline in Score on EQ-5D and Change in Patient's Self-rated Health on a Vertical VAS Recorded on the EQ-VAS: Pain/Discomfort at Months 1, 3, 6, 9, and 12

|                 |   |
|-----------------|---|
| End point title | Change From Baseline in Score on EQ-5D and Change in Patient's Self-rated Health on a Vertical VAS Recorded on the EQ-VAS: Pain/Discomfort at Months 1, 3, 6, 9, and 12 |
|-----------------|---|

End point description:

The EQ-5D is a descriptive system of health-related quality of life states consisting of 5 dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) each of which can take 1 of 3 responses. The responses record 3 levels of severity (no problems/some or moderate problems/extreme problems) within a particular EQ-5D dimension. Standard vertical 0 to 100 mm visual analogue scale (similar to a thermometer) for recording an individual's rating for their current health-related quality of life state. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

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

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

| End point values                       | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|--|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                     | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed            | 106                            | 104                             | 106                              | 52                                     |
| Units: Units on a scale                |                                |                                 |                                  |  |
| least squares mean (standard error)    |                                |                                 |                                  |  |
| Month 1 (n=105, 103, 104, NA, NA, 103) | -0.14 (± 0.039)                | -0.25 (± 0.04)                  | -0.19 (± 0.04)                   | 9999 (± 9999)                          |
| Month 3 (n=101, 103, 101, NA, NA, 102) | -0.25 (± 0.044)                | -0.27 (± 0.044)                 | -0.28 (± 0.045)                  | 9999 (± 9999)                          |
| Month 6 (n=100, 100, 99, 48, 48, NA)   | -0.3 (± 0.05)                  | -0.4 (± 0.05)                   | -0.3 (± 0.05)                    | -0.3 (± 0.07)                          |
| Month 9 (n=99, 97, 96, 47, 46, NA)     | -0.3 (± 0.05)                  | -0.3 (± 0.05)                   | -0.3 (± 0.05)                    | -0.4 (± 0.07)                          |
| Month 12 (n=96, 96, 94, 44, 44, NA)    | -0.3 (± 0.05)                  | -0.4 (± 0.05)                   | -0.3 (± 0.05)                    | -0.2 (± 0.07)                          |

| End point values                       | Placebo/Tofacitinib, 10 mg, twice daily | Placebo              |  |  |
|--|---|----------------------|--|--|
| Subject group type                     | Reporting group                         | Subject analysis set |  |  |
| Number of subjects analysed            | 52                                      | 104                  |  |  |
| Units: Units on a scale                |   |                      |  |  |
| least squares mean (standard error)    |   |                      |  |  |
| Month 1 (n=105, 103, 104, NA, NA, 103) | 9999 (± 9999)                           | -0.08 (± 0.043)      |  |  |
| Month 3 (n=101, 103, 101, NA, NA, 102) | 9999 (± 9999)                           | -0.08 (± 0.047)      |  |  |
| Month 6 (n=100, 100, 99, 48, 48, NA)   | -0.4 (± 0.07)                           | 9999 (± 9999)        |  |  |
| Month 9 (n=99, 97, 96, 47, 46, NA)     | -0.4 (± 0.07)                           | 9999 (± 9999)        |  |  |
| Month 12 (n=96, 96, 94, 44, 44, NA)    | -0.3 (± 0.07)                           | 9999 (± 9999)        |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change From Baseline in Score on EQ-5D and Change in Patient's Self-rated Health on a Vertical VAS Recorded on the EQ-VAS: Anxiety/Depression at Months 1, 3, 6, 9, and 12

|                 |  |
|-----------------|--|
| End point title | Change From Baseline in Score on EQ-5D and Change in Patient's Self-rated Health on a Vertical VAS Recorded on the EQ-VAS: Anxiety/Depression at Months 1, 3, 6, 9, and 12 |
|-----------------|--|

End point description:

The EQ-5D is a descriptive system of health-related quality of life states consisting of 5 dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) each of which can take 1 of 3 responses. The responses record 3 levels of severity (no problems/some or moderate problems/extreme problems) within a particular EQ-5D dimension. Standard vertical 0 to 100 mm visual analogue scale (similar to a thermometer) for recording an individual's rating for their current health-related quality of life state. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

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

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

| End point values                       | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|--|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                     | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed            | 106                            | 104                             | 106                              | 52                                     |
| Units: Units on a scale                |                                |                                 |                                  |  |
| least squares mean (standard error)    |                                |                                 |                                  |  |
| Month 1 (n=105, 103, 104, NA, NA, 103) | -0.25 (± 0.051)                | -0.22 (± 0.052)                 | -0.27 (± 0.053)                  | 9999 (± 9999)                          |
| Month 3 (n=101, 103, 100, NA, NA, 102) | -0.25 (± 0.055)                | -0.17 (± 0.055)                 | -0.32 (± 0.056)                  | 9999 (± 9999)                          |
| Month 6 (n=100, 100, 99, 48, 48, NA)   | -0.3 (± 0.05)                  | -0.3 (± 0.05)                   | -0.3 (± 0.05)                    | -0.3 (± 0.08)                          |
| Month 9 (n=99, 97, 96, 47, 46, NA)     | -0.3 (± 0.05)                  | -0.4 (± 0.05)                   | -0.4 (± 0.06)                    | -0.2 (± 0.08)                          |
| Month 12 (n=96, 96, 94, 44, 44, NA)    | -0.3 (± 0.05)                  | -0.4 (± 0.05)                   | -0.4 (± 0.06)                    | -0.2 (± 0.08)                          |

| End point values                    | Placebo/Tofacitinib, 10 mg, twice daily | Placebo              |  |  |
|-------------------------------------|---|----------------------|--|--|
| Subject group type                  | Reporting group                         | Subject analysis set |  |  |
| Number of subjects analysed         | 52                                      | 104                  |  |  |
| Units: Units on a scale             |   |                      |  |  |
| least squares mean (standard error) |   |                      |  |  |

|  |               |                 |  |  |
|--|---------------|-----------------|--|--|
| Month 1 (n=105, 103, 104, NA, NA, 103) | 9999 (± 9999) | -0.21 (± 0.056) |  |  |
| Month 3 (n=101, 103, 100, NA, NA, 102) | 9999 (± 9999) | -0.21 (± 0.059) |  |  |
| Month 6 (n=100, 100, 99, 48, 48, NA)   | -0.2 (± 0.08) | 9999 (± 9999)   |  |  |
| Month 9 (n=99, 97, 96, 47, 46, NA)     | -0.3 (± 0.08) | 9999 (± 9999)   |  |  |
| Month 12 (n=96, 96, 94, 44, 44, NA)    | -0.3 (± 0.08) | 9999 (± 9999)   |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Score on EQ-5D and Change in Patient's Self-rated Health on a Vertical VAS Recorded on the EQ-VAS: Patient's Health State Today at Months 1, 3, 6, 9, and 12

|                 |  |
|-----------------|--|
| End point title | Change From Baseline in Score on EQ-5D and Change in Patient's Self-rated Health on a Vertical VAS Recorded on the EQ-VAS: Patient's Health State Today at Months 1, 3, 6, 9, and 12 |
|-----------------|--|

End point description:

The EQ-5D is a descriptive system of health-related quality of life states consisting of 5 dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) each of which can take 1 of 3 responses. The responses record 3 levels of severity (no problems/some or moderate problems/extreme problems) within a particular EQ-5D dimension. Standard vertical 0 to 100 mm visual analogue scale (similar to a thermometer) for recording an individual's rating for their current health-related quality of life state. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

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

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

| End point values                       | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|--|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                     | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed            | 106                            | 104                             | 106                              | 52                                     |
| Units: mm                              |                                |                                 |                                  |  |
| least squares mean (standard error)    |                                |                                 |                                  |  |
| Month 1 (n=105, 103, 104, NA, NA, 103) | 10.75 (± 1.859)                | 10.81 (± 1.88)                  | 10.27 (± 1.917)                  | 9999 (± 9999)                          |
| Month 3 (n=101, 103, 101, NA, NA, 101) | 14 (± 2.1)                     | 15.83 (± 2.092)                 | 13.1 (± 2.138)                   | 9999 (± 9999)                          |
| Month 6 (n=100, 100, 99, 48, 48, NA)   | 19.5 (± 2.08)                  | 15.7 (± 2.09)                   | 15.5 (± 2.12)                    | 14.7 (± 2.97)                          |
| Month 9 (n=99, 97, 96, 47, 46, NA)     | 19.2 (± 2.21)                  | 15.9 (± 2.23)                   | 18.2 (± 2.26)                    | 12.8 (± 3.16)                          |
| Month 12 (n=96, 96, 94, 44, 44, NA)    | 20.7 (± 2.09)                  | 19.8 (± 2.09)                   | 16.5 (± 2.14)                    | 16 (± 3.02)                            |

|                  |   |         |  |  |
|------------------|---|---------|--|--|
| End point values | Placebo/Tofacitinib, 10 mg, twice daily | Placebo |  |  |
|------------------|---|---------|--|--|

|  |                 |                      |  |  |
|--|-----------------|----------------------|--|--|
| Subject group type                     | Reporting group | Subject analysis set |  |  |
| Number of subjects analysed            | 52              | 104                  |  |  |
| Units: mm                              |                 |                      |  |  |
| least squares mean (standard error)    |                 |                      |  |  |
| Month 1 (n=105, 103, 104, NA, NA, 103) | 9999 (± 9999)   | 6.59 (± 2.027)       |  |  |
| Month 3 (n=101, 103, 101, NA, NA, 101) | 9999 (± 9999)   | 6.37 (± 2.242)       |  |  |
| Month 6 (n=100, 100, 99, 48, 48, NA)   | 16.6 (± 3)      | 9999 (± 9999)        |  |  |
| Month 9 (n=99, 97, 96, 47, 46, NA)     | 21.5 (± 3.21)   | 9999 (± 9999)        |  |  |
| Month 12 (n=96, 96, 94, 44, 44, NA)    | 19.8 (± 3.05)   | 9999 (± 9999)        |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Functional Assessment of Chronic Illness Therapy Fatigue (FACIT-F) Scores: Total Score at Months 1, 3, 6, 9, and 12

|                 |   |
|-----------------|---|
| End point title | Change From Baseline in Functional Assessment of Chronic Illness Therapy Fatigue (FACIT-F) Scores: Total Score at Months 1, 3, 6, 9, and 12 |
|-----------------|---|

End point description:

FACIT-F is a 13-item questionnaire, with each item score ranging from 0 to 4. Three endpoints are derived: change in FACIT-F total score, change in FACIT-F experience domain score, and change in FACIT-F impact domain score. FACIT-F total score (range 0-52) is calculated by summing the 13 items. FACIT-F experience domain score (range 0-20) is calculated by summing 5 items : I feel fatigued, I feel weak all over, I feel listless ("washed out"), I feel tired, and I have energy, while FACIT-F impact domain score (range 0-32) is calculated by summing the remaining 8 items. All responses are added with equal weight to obtain the total score. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

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

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

| End point values                       | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|--|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                     | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed            | 106                            | 104                             | 106                              | 52                                     |
| Units: Units on a scale                |                                |                                 |                                  |  |
| least squares mean (standard error)    |                                |                                 |                                  |  |
| Month 1 (n=105, 103, 104, NA, NA, 103) | 5.2 (± 0.77)                   | 4.4 (± 0.78)                    | 4.2 (± 0.79)                     | 9999 (± 9999)                          |
| Month 3 (n=102, 102, 101, NA, NA, 102) | 7 (± 0.85)                     | 6 (± 0.85)                      | 6 (± 0.87)                       | 9999 (± 9999)                          |
| Month 6 (n=100, 100, 99, 48, 48, NA)   | 7.9 (± 0.89)                   | 8 (± 0.89)                      | 6.5 (± 0.91)                     | 6.5 (± 1.26)                           |
| Month 9 (n=99, 97, 96, 47, 46, NA)     | 7.9 (± 0.92)                   | 7.4 (± 0.92)                    | 6.5 (± 0.94)                     | 5.5 (± 1.31)                           |
| Month 12 (n=96, 96, 94, 44, 44, NA)    | 8.5 (± 0.95)                   | 8.4 (± 0.95)                    | 6.9 (± 0.97)                     | 5.7 (± 1.36)                           |

| End point values                       | Placebo/Tofacitinib, 10 mg, twice daily | Placebo              |  |  |
|--|---|----------------------|--|--|
| Subject group type                     | Reporting group                         | Subject analysis set |  |  |
| Number of subjects analysed            | 52                                      | 104                  |  |  |
| Units: Units on a scale                |   |                      |  |  |
| least squares mean (standard error)    |   |                      |  |  |
| Month 1 (n=105, 103, 104, NA, NA, 103) | 9999 (± 9999)                           | 2.7 (± 0.84)         |  |  |
| Month 3 (n=102, 102, 101, NA, NA, 102) | 9999 (± 9999)                           | 3.3 (± 0.91)         |  |  |
| Month 6 (n=100, 100, 99, 48, 48, NA)   | 7.2 (± 1.28)                            | 9999 (± 9999)        |  |  |
| Month 9 (n=99, 97, 96, 47, 46, NA)     | 8.4 (± 1.33)                            | 9999 (± 9999)        |  |  |
| Month 12 (n=96, 96, 94, 44, 44, NA)    | 7.6 (± 1.38)                            | 9999 (± 9999)        |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Functional Assessment of Chronic Illness Therapy Fatigue (FACIT-F) Scores: Experience Domain Score at Months 1, 3, 6, 9, and 12

|                 |   |
|-----------------|---|
| End point title | Change From Baseline in Functional Assessment of Chronic Illness Therapy Fatigue (FACIT-F) Scores: Experience Domain Score at Months 1, 3, 6, 9, and 12 |
|-----------------|---|

End point description:

FACIT-F is a 13-item questionnaire, with each item score ranging from 0 to 4. Three endpoints are derived: change in FACIT-F total score, change in FACIT-F experience domain score, and change in FACIT-F impact domain score. FACIT-F total score (range 0-52) is calculated by summing the 13 items. FACIT-F experience domain score (range 0-20) is calculated by summing 5 items : I feel fatigued, I feel weak all over, I feel listless ("washed out"), I feel tired, and I have energy, while FACIT-F impact domain score (range 0-32) is calculated by summing the remaining 8 items. All responses are added with equal weight to obtain the total score. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

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

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

| End point values                       | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|--|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                     | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed            | 106                            | 104                             | 106                              | 52                                     |
| Units: Units on a scale                |                                |                                 |                                  |  |
| least squares mean (standard error)    |                                |                                 |                                  |  |
| Month 1 (n=105, 103, 104, NA, NA, 103) | 2.4 (± 0.35)                   | 2.1 (± 0.35)                    | 2.1 (± 0.36)                     | 9999 (± 9999)                          |

|  |              |              |              |               |
|--|--------------|--------------|--------------|---------------|
| Month 3 (n=102, 102, 101, NA, NA, 102) | 3.3 (± 0.38) | 2.8 (± 0.38) | 2.9 (± 0.39) | 9999 (± 9999) |
| Month 6 (n=100, 100, 99,48, 48, NA)    | 3.6 (± 0.4)  | 3.3 (± 0.4)  | 3.2 (± 0.41) | 3 (± 0.57)    |
| Month 9 (n=99, 97, 96, 47, 46, NA)     | 3.6 (± 0.42) | 3.3 (± 0.42) | 3.3 (± 0.43) | 2.7 (± 0.59)  |
| Month 12 (n=96, 96, 94, 44, 44, NA)    | 3.9 (± 0.44) | 3.7 (± 0.44) | 3.2 (± 0.45) | 2.7 (± 0.63)  |

| End point values                       | Placebo/Tofacitinib, 10 mg, twice daily | Placebo              |  |  |
|--|---|----------------------|--|--|
| Subject group type                     | Reporting group                         | Subject analysis set |  |  |
| Number of subjects analysed            | 52                                      | 104                  |  |  |
| Units: Units on a scale                |   |                      |  |  |
| least squares mean (standard error)    |   |                      |  |  |
| Month 1 (n=105, 103, 104, NA, NA, 103) | 9999 (± 9999)                           | 1.2 (± 0.38)         |  |  |
| Month 3 (n=102, 102, 101, NA, NA, 102) | 9999 (± 9999)                           | 1.6 (± 0.41)         |  |  |
| Month 6 (n=100, 100, 99,48, 48, NA)    | 3.3 (± 0.58)                            | 9999 (± 9999)        |  |  |
| Month 9 (n=99, 97, 96, 47, 46, NA)     | 3.9 (± 0.6)                             | 9999 (± 9999)        |  |  |
| Month 12 (n=96, 96, 94, 44, 44, NA)    | 3.4 (± 0.63)                            | 9999 (± 9999)        |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Functional Assessment of Chronic Illness Therapy Fatigue (FACIT-F) Scores: Impact Domain Score at Months 1, 3, 6, 9, and 12

|                 |   |
|-----------------|---|
| End point title | Change From Baseline in Functional Assessment of Chronic Illness Therapy Fatigue (FACIT-F) Scores: Impact Domain Score at Months 1, 3, 6, 9, and 12 |
|-----------------|---|

End point description:

FACIT-F is a 13-item questionnaire, with each item score ranging from 0 to 4. Three endpoints are derived: change in FACIT-F total score, change in FACIT-F experience domain score, and change in FACIT-F impact domain score. FACIT-F total score (range 0-52) is calculated by summing the 13 items. FACIT-F experience domain score (range 0-20) is calculated by summing 5 items : I feel fatigued, I feel weak all over, I feel listless ("washed out"), I feel tired, and I have energy, while FACIT-F impact domain score (range 0-32) is calculated by summing the remaining 8 items. All responses are added with equal weight to obtain the total score. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

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

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12



| End point values                       | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|--|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                     | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed            | 106                            | 104                             | 106                              | 52                                     |
| Units: Units on a scale                |                                |                                 |                                  |  |
| least squares mean (standard error)    |                                |                                 |                                  |  |
| Month 1 (n=105, 103, 104, NA, NA, 103) | 2.9 (± 0.47)                   | 2.3 (± 0.48)                    | 2.1 (± 0.49)                     | 9999 (± 9999)                          |
| Month 3 (n=102, 102, 101, NA, NA, 102) | 3.8 (± 0.52)                   | 3.2 (± 0.52)                    | 3.2 (± 0.53)                     | 9999 (± 9999)                          |
| Month 6 (n=100, 100, 99, 48, 48, NA)   | 4.3 (± 0.53)                   | 4.7 (± 0.53)                    | 3.4 (± 0.54)                     | 3.5 (± 0.75)                           |
| Month 9 (n=99, 97, 96, 47, 46, NA)     | 4.3 (± 0.55)                   | 4.1 (± 0.55)                    | 3.3 (± 0.56)                     | 2.8 (± 0.78)                           |
| Month 12 (n=96, 96, 94, 44, 44, NA)    | 4.6 (± 0.57)                   | 4.7 (± 0.57)                    | 3.7 (± 0.58)                     | 2.9 (± 0.82)                           |

| End point values                       | Placebo/Tofacitinib, 10 mg, twice daily | Placebo              |  |  |
|--|---|----------------------|--|--|
| Subject group type                     | Reporting group                         | Subject analysis set |  |  |
| Number of subjects analysed            | 52                                      | 104                  |  |  |
| Units: Units on a scale                |   |                      |  |  |
| least squares mean (standard error)    |   |                      |  |  |
| Month 1 (n=105, 103, 104, NA, NA, 103) | 9999 (± 9999)                           | 1.5 (± 0.52)         |  |  |
| Month 3 (n=102, 102, 101, NA, NA, 102) | 9999 (± 9999)                           | 1.8 (± 0.56)         |  |  |
| Month 6 (n=100, 100, 99, 48, 48, NA)   | 4 (± 0.76)                              | 9999 (± 9999)        |  |  |
| Month 9 (n=99, 97, 96, 47, 46, NA)     | 4.6 (± 0.8)                             | 9999 (± 9999)        |  |  |
| Month 12 (n=96, 96, 94, 44, 44, NA)    | 4.3 (± 0.82)                            | 9999 (± 9999)        |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Scores Evaluating Spondylitis Using the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) at Months 1, 3, 6, 9, and 12

|                 |  |
|-----------------|--|
| End point title | Change From Baseline in Scores Evaluating Spondylitis Using the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) at Months 1, 3, 6, 9, and 12 |
|-----------------|--|

End point description:

BASDAI is a validated self-assessment tool used to determine disease activity in participants with ankylosing spondylitis. Utilizing a visual analog scale of 0-10 (0=none and 10=very severe) participants answer 6 questions measuring discomfort, pain, and fatigue. The final BASDAI score averages the individual assessments for a final score ranging 0-10. NA = not applicable, 9999 = results not reported for this group, n=number of participants evaluable.

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

End point timeframe:

From Baseline to Months 1, 3, 6, 9, and 12

| End point values                    | Tofacitinib, 5 mg, twice daily | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Placebo/Tofacitinib, 5 mg, twice daily |
|-------------------------------------|--------------------------------|---------------------------------|----------------------------------|--|
| Subject group type                  | Reporting group                | Reporting group                 | Reporting group                  | Reporting group                        |
| Number of subjects analysed         | 24                             | 21                              | 10                               | 10                                     |
| Units: cm                           |                                |                                 |                                  |  |
| least squares mean (standard error) |                                |                                 |                                  |  |
| Month 1 (n=24, 21, 10, NA, NA, 22)  | -1.23 (± 0.537)                | -1.6 (± 0.508)                  | -2.3 (± 0.673)                   | 9999 (± 9999)                          |
| Month 3 (n=24, 21, 10, NA, NA, 22)  | -1.83 (± 0.579)                | -2.78 (± 0.559)                 | -2.93 (± 0.753)                  | 9999 (± 9999)                          |
| Month 6 (n=23, 21, 10, 9, 11, NA)   | -2.24 (± 0.58)                 | -2.35 (± 0.56)                  | -3.58 (± 0.758)                  | -2.85 (± 0.778)                        |
| Month 9 (n=23, 20, 10, 9, 9, NA)    | -2.06 (± 0.575)                | -2.71 (± 0.558)                 | 2.66 (± 0.747)                   | -3 (± 0.77)                            |
| Month 12 (n=23, 19, 10, 9, 9, NA)   | -2.5 (± 0.594)                 | -3.3 (± 0.587)                  | -2.42 (± 0.779)                  | -2.31 (± 0.808)                        |

| End point values                    | Placebo/Tofacitinib, 10 mg, twice daily | Placebo              |  |  |
|-------------------------------------|---|----------------------|--|--|
| Subject group type                  | Reporting group                         | Subject analysis set |  |  |
| Number of subjects analysed         | 12                                      | 22                   |  |  |
| Units: cm                           |   |                      |  |  |
| least squares mean (standard error) |   |                      |  |  |
| Month 1 (n=24, 21, 10, NA, NA, 22)  | 9999 (± 9999)                           | -1.27 (± 0.581)      |  |  |
| Month 3 (n=24, 21, 10, NA, NA, 22)  | 9999 (± 9999)                           | -1.6 (± 0.624)       |  |  |
| Month 6 (n=23, 21, 10, 9, 11, NA)   | -3.31 (± 0.744)                         | 9999 (± 9999)        |  |  |
| Month 9 (n=23, 20, 10, 9, 9, NA)    | -3.35 (± 0.761)                         | 9999 (± 9999)        |  |  |
| Month 12 (n=23, 19, 10, 9, 9, NA)   | -2.67 (± 0.806)                         | 9999 (± 9999)        |  |  |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Adverse events (AEs) were assessed from first administration of study treatment through last visit. Serious AEs (SAEs) were assessed from informed consent through and including 28 calendar days after last administration of investigational product.

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

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 18.1 |
|--------------------|------|

### Reporting groups

|                       |                                 |
|-----------------------|---------------------------------|
| Reporting group title | Tofacitinib, 10 mg, twice daily |
|-----------------------|---------------------------------|

Reporting group description:

Participants received 2 tofacitinib 5-mg tablets twice daily and subcutaneous placebo every 2 weeks.

|                       |                                  |
|-----------------------|----------------------------------|
| Reporting group title | Adalimumab, 40 mg, every 2 weeks |
|-----------------------|----------------------------------|

Reporting group description:

Participants received 2 placebo tablets twice daily and adalimumab, 40 mg, administered subcutaneously every 2 weeks.

|                       |                                |
|-----------------------|--------------------------------|
| Reporting group title | Tofacitinib, 5 mg, twice daily |
|-----------------------|--------------------------------|

Reporting group description:

Participants received 1 tofacitinib 5-mg tablet twice daily, 1 placebo tablet twice daily, and subcutaneous placebo administered every 2 weeks.

|                       |   |
|-----------------------|---|
| Reporting group title | Placebo/Tofacitinib, 10 mg, twice daily |
|-----------------------|---|

Reporting group description:

Participants received 2 placebo tablets twice daily and subcutaneous placebo every 2 weeks for 3 months. At the end of this period, participants received 2 tofacitinib 5-mg tablets twice daily and subcutaneous placebo every 2 weeks

|                       |  |
|-----------------------|--|
| Reporting group title | Placebo/Tofacitinib, 5 mg, twice daily |
|-----------------------|--|

Reporting group description:

Participants received 2 placebo tablets twice daily and subcutaneous placebo every 2 weeks for 3 months. At the end of this period, participants received 1 tofacitinib 5-mg tablet twice daily, 1 placebo tablet twice daily, and subcutaneous placebo every 2 weeks.

| Serious adverse events  | Tofacitinib, 10 mg, twice daily | Adalimumab, 40 mg, every 2 weeks | Tofacitinib, 5 mg, twice daily |
|---|---------------------------------|----------------------------------|--------------------------------|
| Total subjects affected by serious adverse events                   |                                 |                                  |                                |
| subjects affected / exposed   | 4 / 104 (3.85%)                 | 9 / 106 (8.49%)                  | 8 / 107 (7.48%)                |
| 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) |                                 |                                  |                                |
| Bladder transitional cell carcinoma                                 |                                 |                                  |                                |
| subjects affected / exposed   | 0 / 104 (0.00%)                 | 0 / 106 (0.00%)                  | 1 / 107 (0.93%)                |
| occurrences causally related to treatment / all                     | 0 / 0                           | 0 / 0                            | 0 / 1                          |
| deaths causally related to treatment / all                          | 0 / 0                           | 0 / 0                            | 0 / 0                          |
| Infected neoplasm   |                                 |                                  |                                |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 104 (0.00%) | 0 / 106 (0.00%) | 1 / 107 (0.93%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Invasive ductal breast carcinoma                |                 |                 |                 |
| subjects affected / exposed                     | 0 / 104 (0.00%) | 0 / 106 (0.00%) | 1 / 107 (0.93%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Squamous cell carcinoma of the vulva            |                 |                 |                 |
| subjects affected / exposed                     | 0 / 104 (0.00%) | 0 / 106 (0.00%) | 1 / 107 (0.93%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Vascular disorders                              |                 |                 |                 |
| Deep vein thrombosis                            |                 |                 |                 |
| subjects affected / exposed                     | 0 / 104 (0.00%) | 0 / 106 (0.00%) | 0 / 107 (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           |
| Hypertension                                    |                 |                 |                 |
| subjects affected / exposed                     | 1 / 104 (0.96%) | 0 / 106 (0.00%) | 0 / 107 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Reproductive system and breast disorders        |                 |                 |                 |
| Cystocele                                       |                 |                 |                 |
| subjects affected / exposed                     | 1 / 104 (0.96%) | 0 / 106 (0.00%) | 0 / 107 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Postmenopausal haemorrhage                      |                 |                 |                 |
| subjects affected / exposed                     | 0 / 104 (0.00%) | 1 / 106 (0.94%) | 0 / 107 (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           |
| Rectocele                                       |                 |                 |                 |
| subjects affected / exposed                     | 1 / 104 (0.96%) | 0 / 106 (0.00%) | 0 / 107 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| Uterine polyp                                   |                 |                 |                 |
| subjects affected / exposed                     | 0 / 104 (0.00%) | 0 / 106 (0.00%) | 0 / 107 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Respiratory, thoracic and mediastinal disorders |                 |                 |                 |
| Bronchial hyperreactivity                       |                 |                 |                 |
| subjects affected / exposed                     | 1 / 104 (0.96%) | 0 / 106 (0.00%) | 0 / 107 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Bronchospasm                                    |                 |                 |                 |
| subjects affected / exposed                     | 1 / 104 (0.96%) | 0 / 106 (0.00%) | 0 / 107 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Dyspnoea exertional                             |                 |                 |                 |
| subjects affected / exposed                     | 0 / 104 (0.00%) | 1 / 106 (0.94%) | 0 / 107 (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           |
| Hypoxia   |                 |                 |                 |
| subjects affected / exposed                     | 1 / 104 (0.96%) | 0 / 106 (0.00%) | 0 / 107 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Injury, poisoning and procedural complications  |                 |                 |                 |
| Joint injury                                    |                 |                 |                 |
| subjects affected / exposed                     | 0 / 104 (0.00%) | 1 / 106 (0.94%) | 1 / 107 (0.93%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Cardiac disorders                               |                 |                 |                 |
| Atrial fibrillation                             |                 |                 |                 |
| subjects affected / exposed                     | 0 / 104 (0.00%) | 1 / 106 (0.94%) | 0 / 107 (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           |
| Bradycardia                                     |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 104 (0.00%) | 1 / 106 (0.94%) | 0 / 107 (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           |
| Cardiac arrest                                  |                 |                 |                 |
| subjects affected / exposed                     | 0 / 104 (0.00%) | 0 / 106 (0.00%) | 0 / 107 (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           |
| Nervous system disorders                        |                 |                 |                 |
| Migraine  |                 |                 |                 |
| subjects affected / exposed                     | 0 / 104 (0.00%) | 0 / 106 (0.00%) | 1 / 107 (0.93%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Transient ischaemic attack                      |                 |                 |                 |
| subjects affected / exposed                     | 0 / 104 (0.00%) | 1 / 106 (0.94%) | 0 / 107 (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           |
| Gastrointestinal disorders                      |                 |                 |                 |
| Abdominal hernia                                |                 |                 |                 |
| subjects affected / exposed                     | 0 / 104 (0.00%) | 0 / 106 (0.00%) | 0 / 107 (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           |
| Chronic gastritis                               |                 |                 |                 |
| subjects affected / exposed                     | 0 / 104 (0.00%) | 1 / 106 (0.94%) | 0 / 107 (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           |
| Diverticulum                                    |                 |                 |                 |
| subjects affected / exposed                     | 0 / 104 (0.00%) | 0 / 106 (0.00%) | 0 / 107 (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           |
| Nausea  |                 |                 |                 |
| subjects affected / exposed                     | 0 / 104 (0.00%) | 0 / 106 (0.00%) | 1 / 107 (0.93%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Hepatobiliary disorders                         |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| Bile duct stone                                 |                 |                 |                 |
| subjects affected / exposed                     | 0 / 104 (0.00%) | 1 / 106 (0.94%) | 0 / 107 (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           |
| Skin and subcutaneous tissue disorders          |                 |                 |                 |
| Angioedema                                      |                 |                 |                 |
| subjects affected / exposed                     | 0 / 104 (0.00%) | 0 / 106 (0.00%) | 1 / 107 (0.93%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Dermal cyst                                     |                 |                 |                 |
| subjects affected / exposed                     | 1 / 104 (0.96%) | 0 / 106 (0.00%) | 0 / 107 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Renal and urinary disorders                     |                 |                 |                 |
| Calculus urinary                                |                 |                 |                 |
| subjects affected / exposed                     | 0 / 104 (0.00%) | 0 / 106 (0.00%) | 1 / 107 (0.93%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Nephropathy                                     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 104 (0.00%) | 0 / 106 (0.00%) | 0 / 107 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Musculoskeletal and connective tissue disorders |                 |                 |                 |
| Intervertebral disc disorder                    |                 |                 |                 |
| subjects affected / exposed                     | 0 / 104 (0.00%) | 1 / 106 (0.94%) | 0 / 107 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Musculoskeletal chest pain                      |                 |                 |                 |
| subjects affected / exposed                     | 0 / 104 (0.00%) | 1 / 106 (0.94%) | 0 / 107 (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           |
| Psoriatic arthropathy                           |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 104 (0.00%) | 0 / 106 (0.00%) | 1 / 107 (0.93%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Spondylolisthesis                               |                 |                 |                 |
| subjects affected / exposed                     | 0 / 104 (0.00%) | 0 / 106 (0.00%) | 0 / 107 (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                     |                 |                 |                 |
| Appendicitis                                    |                 |                 |                 |
| subjects affected / exposed                     | 0 / 104 (0.00%) | 0 / 106 (0.00%) | 0 / 107 (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           |
| Herpes simplex                                  |                 |                 |                 |
| subjects affected / exposed                     | 0 / 104 (0.00%) | 1 / 106 (0.94%) | 0 / 107 (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           |
| Influenza                                       |                 |                 |                 |
| subjects affected / exposed                     | 1 / 104 (0.96%) | 0 / 106 (0.00%) | 0 / 107 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Pneumonia                                       |                 |                 |                 |
| subjects affected / exposed                     | 0 / 104 (0.00%) | 0 / 106 (0.00%) | 0 / 107 (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           |
| Pyoderma streptococcal                          |                 |                 |                 |
| subjects affected / exposed                     | 0 / 104 (0.00%) | 1 / 106 (0.94%) | 0 / 107 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Metabolism and nutrition disorders              |                 |                 |                 |
| Dehydration                                     |                 |                 |                 |
| subjects affected / exposed                     | 1 / 104 (0.96%) | 0 / 106 (0.00%) | 0 / 107 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |



| <b>Serious adverse events</b>                                       | Placebo/Tofacitinib,<br>10 mg, twice daily | Placebo/Tofacitinib,<br>5 mg, twice daily |  |
|---|--|---|--|
| Total subjects affected by serious adverse events                   |  |   |  |
| subjects affected / exposed   | 4 / 53 (7.55%)                             | 3 / 52 (5.77%)                            |  |
| number of deaths (all causes)                                       | 0  | 1   |  |
| number of deaths resulting from adverse events                      | 0  | 1   |  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |  |   |  |
| Bladder transitional cell carcinoma                                 |  |   |  |
| subjects affected / exposed   | 0 / 53 (0.00%)                             | 0 / 52 (0.00%)                            |  |
| occurrences causally related to treatment / all                     | 0 / 0                                      | 0 / 0                                     |  |
| deaths causally related to treatment / all                          | 0 / 0                                      | 0 / 0                                     |  |
| Infected neoplasm   |  |   |  |
| subjects affected / exposed   | 0 / 53 (0.00%)                             | 0 / 52 (0.00%)                            |  |
| occurrences causally related to treatment / all                     | 0 / 0                                      | 0 / 0                                     |  |
| deaths causally related to treatment / all                          | 0 / 0                                      | 0 / 0                                     |  |
| Invasive ductal breast carcinoma                                    |  |   |  |
| subjects affected / exposed   | 0 / 53 (0.00%)                             | 0 / 52 (0.00%)                            |  |
| occurrences causally related to treatment / all                     | 0 / 0                                      | 0 / 0                                     |  |
| deaths causally related to treatment / all                          | 0 / 0                                      | 0 / 0                                     |  |
| Squamous cell carcinoma of the vulva                                |  |   |  |
| subjects affected / exposed   | 0 / 53 (0.00%)                             | 0 / 52 (0.00%)                            |  |
| occurrences causally related to treatment / all                     | 0 / 0                                      | 0 / 0                                     |  |
| deaths causally related to treatment / all                          | 0 / 0                                      | 0 / 0                                     |  |
| Vascular disorders  |  |   |  |
| Deep vein thrombosis  |  |   |  |
| subjects affected / exposed   | 1 / 53 (1.89%)                             | 0 / 52 (0.00%)                            |  |
| occurrences causally related to treatment / all                     | 0 / 1                                      | 0 / 0                                     |  |
| deaths causally related to treatment / all                          | 0 / 0                                      | 0 / 0                                     |  |
| Hypertension  |  |   |  |
| subjects affected / exposed   | 0 / 53 (0.00%)                             | 0 / 52 (0.00%)                            |  |
| occurrences causally related to treatment / all                     | 0 / 0                                      | 0 / 0                                     |  |
| deaths causally related to treatment / all                          | 0 / 0                                      | 0 / 0                                     |  |
| Reproductive system and breast disorders                            |  |   |  |
| Cystocele   |  |   |  |

|   |                |                |  |
|---|----------------|----------------|--|
| subjects affected / exposed                     | 0 / 53 (0.00%) | 0 / 52 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Postmenopausal haemorrhage                      |                |                |  |
| subjects affected / exposed                     | 0 / 53 (0.00%) | 0 / 52 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Rectocele                                       |                |                |  |
| subjects affected / exposed                     | 0 / 53 (0.00%) | 0 / 52 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Uterine polyp                                   |                |                |  |
| subjects affected / exposed                     | 1 / 53 (1.89%) | 0 / 52 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Respiratory, thoracic and mediastinal disorders |                |                |  |
| Bronchial hyperreactivity                       |                |                |  |
| subjects affected / exposed                     | 0 / 53 (0.00%) | 0 / 52 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Bronchospasm                                    |                |                |  |
| subjects affected / exposed                     | 0 / 53 (0.00%) | 0 / 52 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Dyspnoea exertional                             |                |                |  |
| subjects affected / exposed                     | 0 / 53 (0.00%) | 0 / 52 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Hypoxia   |                |                |  |
| subjects affected / exposed                     | 0 / 53 (0.00%) | 0 / 52 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Injury, poisoning and procedural complications  |                |                |  |

|   |                |                |  |
|---|----------------|----------------|--|
| Joint injury                                    |                |                |  |
| subjects affected / exposed                     | 0 / 53 (0.00%) | 0 / 52 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Cardiac disorders                               |                |                |  |
| Atrial fibrillation                             |                |                |  |
| subjects affected / exposed                     | 0 / 53 (0.00%) | 0 / 52 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Bradycardia                                     |                |                |  |
| subjects affected / exposed                     | 0 / 53 (0.00%) | 0 / 52 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Cardiac arrest                                  |                |                |  |
| subjects affected / exposed                     | 0 / 53 (0.00%) | 1 / 52 (1.92%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 1 / 1          |  |
| Nervous system disorders                        |                |                |  |
| Migraine  |                |                |  |
| subjects affected / exposed                     | 0 / 53 (0.00%) | 0 / 52 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Transient ischaemic attack                      |                |                |  |
| subjects affected / exposed                     | 0 / 53 (0.00%) | 0 / 52 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Gastrointestinal disorders                      |                |                |  |
| Abdominal hernia                                |                |                |  |
| subjects affected / exposed                     | 1 / 53 (1.89%) | 0 / 52 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Chronic gastritis                               |                |                |  |

|   |                |                |  |
|---|----------------|----------------|--|
| subjects affected / exposed                     | 0 / 53 (0.00%) | 0 / 52 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Diverticulum                                    |                |                |  |
| subjects affected / exposed                     | 1 / 53 (1.89%) | 0 / 52 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Nausea  |                |                |  |
| subjects affected / exposed                     | 0 / 53 (0.00%) | 0 / 52 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Hepatobiliary disorders                         |                |                |  |
| Bile duct stone                                 |                |                |  |
| subjects affected / exposed                     | 0 / 53 (0.00%) | 0 / 52 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Skin and subcutaneous tissue disorders          |                |                |  |
| Angioedema                                      |                |                |  |
| subjects affected / exposed                     | 0 / 53 (0.00%) | 0 / 52 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Dermal cyst                                     |                |                |  |
| subjects affected / exposed                     | 0 / 53 (0.00%) | 0 / 52 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Renal and urinary disorders                     |                |                |  |
| Calculus urinary                                |                |                |  |
| subjects affected / exposed                     | 0 / 53 (0.00%) | 0 / 52 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Nephropathy                                     |                |                |  |
| subjects affected / exposed                     | 1 / 53 (1.89%) | 0 / 52 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |

|   |                |                |  |
|---|----------------|----------------|--|
| Musculoskeletal and connective tissue disorders |                |                |  |
| Intervertebral disc disorder                    |                |                |  |
| subjects affected / exposed                     | 0 / 53 (0.00%) | 0 / 52 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Musculoskeletal chest pain                      |                |                |  |
| subjects affected / exposed                     | 0 / 53 (0.00%) | 0 / 52 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Psoriatic arthropathy                           |                |                |  |
| subjects affected / exposed                     | 0 / 53 (0.00%) | 0 / 52 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Spondylolisthesis                               |                |                |  |
| subjects affected / exposed                     | 1 / 53 (1.89%) | 0 / 52 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Infections and infestations                     |                |                |  |
| Appendicitis                                    |                |                |  |
| subjects affected / exposed                     | 0 / 53 (0.00%) | 1 / 52 (1.92%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 1 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Herpes simplex                                  |                |                |  |
| subjects affected / exposed                     | 0 / 53 (0.00%) | 0 / 52 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Influenza                                       |                |                |  |
| subjects affected / exposed                     | 0 / 53 (0.00%) | 0 / 52 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Pneumonia                                       |                |                |  |
| subjects affected / exposed                     | 0 / 53 (0.00%) | 1 / 52 (1.92%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 1 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |

|   |                |                |  |
|---|----------------|----------------|--|
| Pyoderma streptococcal<br>subjects affected / exposed | 0 / 53 (0.00%) | 0 / 52 (0.00%) |  |
| occurrences causally related to<br>treatment / all    | 0 / 0          | 0 / 0          |  |
| deaths causally related to<br>treatment / all         | 0 / 0          | 0 / 0          |  |
| Metabolism and nutrition disorders                    |                |                |  |
| Dehydration   |                |                |  |
| subjects affected / exposed                           | 0 / 53 (0.00%) | 0 / 52 (0.00%) |  |
| occurrences causally related to<br>treatment / all    | 0 / 0          | 0 / 0          |  |
| deaths causally related to<br>treatment / all         | 0 / 0          | 0 / 0          |  |

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

| <b>Non-serious adverse events</b>                        | Tofacitinib, 10 mg,<br>twice daily | Adalimumab, 40 mg,<br>every 2 weeks | Tofacitinib, 5 mg,<br>twice daily |
|--|------------------------------------|-------------------------------------|-----------------------------------|
| Total subjects affected by non-serious<br>adverse events |                                    |                                     |                                   |
| subjects affected / exposed                              | 43 / 104 (41.35%)                  | 43 / 106 (40.57%)                   | 31 / 107 (28.97%)                 |
| Investigations   |                                    |                                     |                                   |
| Alanine aminotransferase increased                       |                                    |                                     |                                   |
| subjects affected / exposed                              | 3 / 104 (2.88%)                    | 8 / 106 (7.55%)                     | 3 / 107 (2.80%)                   |
| occurrences (all)  | 3                                  | 11                                  | 3                                 |
| Aspartate aminotransferase<br>increased                  |                                    |                                     |                                   |
| subjects affected / exposed                              | 1 / 104 (0.96%)                    | 7 / 106 (6.60%)                     | 0 / 107 (0.00%)                   |
| occurrences (all)  | 1                                  | 8                                   | 0                                 |
| Blood creatine phosphokinase<br>increased                |                                    |                                     |                                   |
| subjects affected / exposed                              | 5 / 104 (4.81%)                    | 3 / 106 (2.83%)                     | 5 / 107 (4.67%)                   |
| occurrences (all)  | 5                                  | 3                                   | 7                                 |
| Nervous system disorders                                 |                                    |                                     |                                   |
| Headache   |                                    |                                     |                                   |
| subjects affected / exposed                              | 11 / 104 (10.58%)                  | 7 / 106 (6.60%)                     | 5 / 107 (4.67%)                   |
| occurrences (all)  | 17                                 | 10                                  | 6                                 |
| Gastrointestinal disorders                               |                                    |                                     |                                   |
| Abdominal pain   |                                    |                                     |                                   |
| subjects affected / exposed                              | 1 / 104 (0.96%)                    | 2 / 106 (1.89%)                     | 1 / 107 (0.93%)                   |
| occurrences (all)  | 1                                  | 2                                   | 1                                 |
| Nausea   |                                    |                                     |                                   |

|  |                         |                         |                        |
|--|-------------------------|-------------------------|------------------------|
| subjects affected / exposed<br>occurrences (all)   | 4 / 104 (3.85%)<br>4    | 6 / 106 (5.66%)<br>6    | 3 / 107 (2.80%)<br>3   |
| Musculoskeletal and connective tissue disorders<br>Spinal pain<br>subjects affected / exposed<br>occurrences (all) | 1 / 104 (0.96%)<br>1    | 3 / 106 (2.83%)<br>3    | 2 / 107 (1.87%)<br>2   |
| Infections and infestations<br>Nasopharyngitis<br>subjects affected / exposed<br>occurrences (all)                 | 12 / 104 (11.54%)<br>13 | 11 / 106 (10.38%)<br>14 | 8 / 107 (7.48%)<br>9   |
| Pharyngitis<br>subjects affected / exposed<br>occurrences (all)  | 6 / 104 (5.77%)<br>6    | 7 / 106 (6.60%)<br>9    | 5 / 107 (4.67%)<br>5   |
| Upper respiratory tract infection<br>subjects affected / exposed<br>occurrences (all)                              | 11 / 104 (10.58%)<br>11 | 8 / 106 (7.55%)<br>9    | 10 / 107 (9.35%)<br>13 |
| Urinary tract infection<br>subjects affected / exposed<br>occurrences (all)  | 4 / 104 (3.85%)<br>5    | 4 / 106 (3.77%)<br>4    | 2 / 107 (1.87%)<br>4   |

| <b>Non-serious adverse events</b>  | Placebo/Tofacitinib,<br>10 mg, twice daily | Placebo/Tofacitinib,<br>5 mg, twice daily |  |
|--|--|---|--|
| Total subjects affected by non-serious adverse events<br>subjects affected / exposed                     | 22 / 53 (41.51%)                           | 15 / 52 (28.85%)                          |  |
| Investigations<br>Alanine aminotransferase increased<br>subjects affected / exposed<br>occurrences (all) | 1 / 53 (1.89%)<br>1                        | 3 / 52 (5.77%)<br>3                       |  |
| Aspartate aminotransferase increased<br>subjects affected / exposed<br>occurrences (all)                 | 1 / 53 (1.89%)<br>1                        | 1 / 52 (1.92%)<br>1                       |  |
| Blood creatine phosphokinase increased<br>subjects affected / exposed<br>occurrences (all)               | 5 / 53 (9.43%)<br>6                        | 1 / 52 (1.92%)<br>1                       |  |
| Nervous system disorders   |  |   |  |

|  |                     |                     |  |
|--|---------------------|---------------------|--|
| Headache<br>subjects affected / exposed<br>occurrences (all)   | 4 / 53 (7.55%)<br>7 | 2 / 52 (3.85%)<br>3 |  |
| Gastrointestinal disorders<br>Abdominal pain<br>subjects affected / exposed<br>occurrences (all)                   | 3 / 53 (5.66%)<br>4 | 0 / 52 (0.00%)<br>0 |  |
| Nausea<br>subjects affected / exposed<br>occurrences (all)   | 1 / 53 (1.89%)<br>3 | 0 / 52 (0.00%)<br>0 |  |
| Musculoskeletal and connective tissue disorders<br>Spinal pain<br>subjects affected / exposed<br>occurrences (all) | 0 / 53 (0.00%)<br>0 | 3 / 52 (5.77%)<br>4 |  |
| Infections and infestations<br>Nasopharyngitis<br>subjects affected / exposed<br>occurrences (all)                 | 4 / 53 (7.55%)<br>4 | 4 / 52 (7.69%)<br>5 |  |
| Pharyngitis<br>subjects affected / exposed<br>occurrences (all)  | 3 / 53 (5.66%)<br>3 | 0 / 52 (0.00%)<br>0 |  |
| Upper respiratory tract infection<br>subjects affected / exposed<br>occurrences (all)                              | 5 / 53 (9.43%)<br>6 | 5 / 52 (9.62%)<br>5 |  |
| Urinary tract infection<br>subjects affected / exposed<br>occurrences (all)  | 4 / 53 (7.55%)<br>4 | 1 / 52 (1.92%)<br>1 |  |



## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date             | Amendment  |
|------------------|--|
| 14 May 2013      | This amendment included country-specific requirement for participants in Taiwan to be >20 years old for inclusion, updated footnotes of schedule of activities to show that collection of banked biospecimens were not mandatory per regulatory feedback, exclusion criterion 6d revised absolute lymphocyte count from $<0.5 \times 10^9/L$ ( $<500 \text{ mm}^3$ ) to $<1.0 \times 10^9/L$ ( $<1000 \text{ mm}^3$ ) as exclusion criterion per regulatory feedback (EU Competent Authorities that participated in the Voluntary Harmonization Procedure for Clinical Trial Applications).  |
| 13 December 2013 | Inclusion criterion 1: clarified PsA criteria for enrollment to state that a participant had signs and symptoms consistent with the diagnosis of PsA for at least 6 months. Inclusion criterion 6: standardised washout of biologics to 6 months per regulatory agency request (Canada Health Ministry). Addition of 'localised' infection to exclusion criterion 15 per regulatory agency request (German BfArM). Addition of new exclusion criterion (26) for participants at risk of gastrointestinal perforation per latest Investigator's Brochure. Clarification of use of sexual abstinence as contraceptive method only when consistent with preferred and usual participant lifestyle, per regulatory agency request (UK Ethics Committee). Added contraception advice for adalimumab: participants were advised to use effective contraception for 5 months following administration of the injectable medication or as per local adalimumab label/summary of product characteristics. |

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported