



## Clinical trial results:

### A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Baricitinib (LY3009104) in Patients with Inadequate Response to Conventional Disease-Modifying Antirheumatic Drugs with Moderately to Severely Active Rheumatoid Arthritis

#### Summary

|                          |                            |
|--------------------------|----------------------------|
| EudraCT number           | 2012-002339-27             |
| Trial protocol           | HU BE DE IT PT GB CZ SK ES |
| Global end of trial date | 19 December 2014           |

#### Results information

|                                |               |
|--------------------------------|---------------|
| Result version number          | v1 (current)  |
| This version publication date  | 26 March 2017 |
| First version publication date | 26 March 2017 |

#### Trial information

##### Trial identification

|                       |       |
|-----------------------|-------|
| Sponsor protocol code | 14059 |
|-----------------------|-------|

##### Additional study identifiers

|                                    |   |
|------------------------------------|---|
| ISRCTN number                      | -   |
| ClinicalTrials.gov id (NCT number) | NCT01721057                                   |
| WHO universal trial number (UTN)   | -   |
| Other trial identifiers            | Trial Number: 14059, Trial Alias: I4V-MC-JADX |

Notes:

#### Sponsors

|                              |   |
|------------------------------|---|
| Sponsor organisation name    | Eli Lilly and Company   |
| Sponsor organisation address | Lilly Corporate Center, Indianapolis, IN, United States, 46285            |
| Public contact               | Available Mon-Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 877-CTLilly,  |
| Scientific contact           | Available Mon-Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 877-285-4559, |

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                       | 19 December 2014 |
| Is this the analysis of the primary completion data? | No               |
| Global end of trial reached?                         | Yes              |
| Global end of trial date                             | 19 December 2014 |
| Was the trial ended prematurely?                     | No               |

Notes:

## General information about the trial

Main objective of the trial:

The purpose of this study is to determine whether baricitinib 4 milligram (mg) once daily (QD) is superior to placebo in the treatment of participants with moderately to severely active Rheumatoid Arthritis (RA) who have had inadequate response to or are intolerant to at least 1 conventional disease-modifying antirheumatic drug (cDMARD)(cDMARD-IR [inadequate response] participants) and who have not received a biologic disease-modifying antirheumatic drug (DMARD).

Protection of trial subjects:

This study was conducted in accordance with ICH Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy:

Participants continued to take background conventional disease-modifying antirheumatic drug (cDMARD) therapy throughout study.

Evidence for comparator: -

|   |                  |
|---|------------------|
| Actual start date of recruitment                          | 01 December 2012 |
| 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 | Argentina: 64          |
| Country: Number of subjects enrolled | Australia: 15          |
| Country: Number of subjects enrolled | Belgium: 11            |
| Country: Number of subjects enrolled | Canada: 28             |
| Country: Number of subjects enrolled | Croatia: 4             |
| Country: Number of subjects enrolled | Czech Republic: 15     |
| Country: Number of subjects enrolled | Germany: 9             |
| Country: Number of subjects enrolled | Hungary: 20            |
| Country: Number of subjects enrolled | India: 58              |
| Country: Number of subjects enrolled | Italy: 10              |
| Country: Number of subjects enrolled | Japan: 21              |
| Country: Number of subjects enrolled | Korea, Republic of: 17 |
| Country: Number of subjects enrolled | Mexico: 22             |
| Country: Number of subjects enrolled | Poland: 51             |
| Country: Number of subjects enrolled | Portugal: 5            |
| Country: Number of subjects enrolled | Romania: 6             |

|                                      |                        |
|--------------------------------------|------------------------|
| Country: Number of subjects enrolled | Russian Federation: 20 |
| Country: Number of subjects enrolled | Slovakia: 11           |
| Country: Number of subjects enrolled | Spain: 34              |
| Country: Number of subjects enrolled | Taiwan: 82             |
| Country: Number of subjects enrolled | United Kingdom: 5      |
| Country: Number of subjects enrolled | United States: 176     |
| Worldwide total number of subjects   | 684                    |
| EEA total number of subjects         | 181                    |

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)                      | 587 |
| From 65 to 84 years                       | 97  |
| 85 years and over                         | 0   |

## Subject disposition

### Recruitment

Recruitment details:

All started participants received at least one dose of study drug.

### Pre-assignment

Screening details:

Participants who did not respond (nonresponders) to study drug were eligible for rescue treatment beginning at Week 16.

Nonresponders were defined as lack of improvement of at least 20% in both tender joint count and swollen joint count at both Weeks 14 and 16 compared to baseline.

### Period 1

|                              |  |
|------------------------------|--|
| Period 1 title               | Treatment Period (Weeks 0 to 24)       |
| Is this the baseline period? | Yes                                    |
| Allocation method            | Randomised - controlled                |
| Blinding used                | Double blind                           |
| Roles blinded                | Subject, Investigator, Carer, Assessor |

### Arms

|                              |         |
|------------------------------|---------|
| Are arms mutually exclusive? | Yes     |
| <b>Arm title</b>             | Placebo |

Arm description:

Placebo administered orally (PO) once daily (QD) through Week 24. Participants continued to take background conventional disease-modifying antirheumatic drug (cDMARD) therapy throughout study. Starting at Week 16, participants who were nonresponders were rescued with baricitinib 4 mg PO, QD.

All started participants received at least one dose of study drug.

|  |                     |
|--|---------------------|
| Arm type                               | Placebo             |
| Investigational medicinal product name | Baricitinib Placebo |
| Investigational medicinal product code |                     |
| Other name                             |                     |
| Pharmaceutical forms                   | Tablet              |
| Routes of administration               | Oral use            |

Dosage and administration details:

Placebo administered orally (PO) once daily (QD) through Week 24. Participants continued to take background cDMARD therapy throughout study.

|                  |                  |
|------------------|------------------|
| <b>Arm title</b> | Baricitinib 2 mg |
|------------------|------------------|

Arm description:

Baricitinib 2 mg PO QD through Week 24. Participants continued to take background cDMARD therapy throughout study. Starting at Week 16, participants who were nonresponders were rescued with baricitinib 4 mg PO, QD.

|  |              |
|--|--------------|
| Arm type                               | Experimental |
| Investigational medicinal product name | Baricitinib  |
| Investigational medicinal product code |              |
| Other name                             | LY3009104    |
| Pharmaceutical forms                   | Tablet       |
| Routes of administration               | Oral use     |

Dosage and administration details:

Baricitinib 4 mg PO QD through week 24.

Participants continued to take background cDMARD therapy throughout study.

|  |                  |
|--|------------------|
| <b>Arm title</b>   | Baricitinib 4 mg |
| Arm description:<br>Baricitinib 4 mg PO QD through Week 24. Participants continued to take background cDMARD therapy throughout study. Starting at Week 16, participants who were nonresponders were rescued with baricitinib 4 mg PO, QD. |                  |
| Arm type   | Experimental     |
| Investigational medicinal product name   | Baricitinib      |
| Investigational medicinal product code   |                  |
| Other name   | LY3009104        |
| Pharmaceutical forms   | Tablet           |
| Routes of administration   | Oral use         |

Dosage and administration details:

Baricitinib 4 mg PO QD through Week 24.

Participants continued to take background cDMARD therapy throughout study.

| <b>Number of subjects in period 1</b> | Placebo           | Baricitinib 2 mg  | Baricitinib 4 mg  |
|---------------------------------------|-------------------|-------------------|-------------------|
| Started                               | 228               | 229               | 227               |
| Rescue Week 16-24                     | 55 <sup>[1]</sup> | 21 <sup>[2]</sup> | 15 <sup>[3]</sup> |
| Completed                             | 199               | 209               | 203               |
| Not completed                         | 29                | 20                | 24                |
| Adverse event, serious fatal          | 2                 | -                 | -                 |
| Consent withdrawn by subject          | 11                | 5                 | 8                 |
| Physician decision                    | -                 | 1                 | 3                 |
| Adverse event, non-fatal              | 8                 | 10                | 12                |
| Lost to follow-up                     | 1                 | -                 | -                 |
| Lack of efficacy                      | 7                 | 4                 | 1                 |

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Participants who were nonresponders based on tender/swollen joint count were entered into the rescue milestone calculation.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Participants who were nonresponders based on tender/swollen joint count were entered into the rescue milestone calculation.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Participants who were nonresponders based on tender/swollen joint count were entered into the rescue milestone calculation.

|   |  |
|---|--|
| <b>Period 2</b>   |  |
| Period 2 title  | Follow Up                              |
| Is this the baseline period?  | No                                     |
| Allocation method   | Randomised - controlled                |
| Blinding used   | Double blind                           |
| Roles blinded   | Subject, Investigator, Carer, Assessor |
| <b>Arms</b>   |  |
| Are arms mutually exclusive?  | Yes                                    |
| <b>Arm title</b>  | Placebo-Follow Up                      |
| Arm description:  |  |
| No study drug received. Participants return for safety follow-up visit 28 days after the last dose of study drug. |  |
| Arm type  | No intervention                        |
| No investigational medicinal product assigned in this arm   |  |
| <b>Arm title</b>  | Baricitinib 2 mg- Follow Up            |
| Arm description:  |  |
| No study drug received. Participants return for safety follow-up visit 28 days after the last dose of study drug. |  |
| Arm type  | No intervention                        |
| No investigational medicinal product assigned in this arm   |  |
| <b>Arm title</b>  | Baricitinib 4 mg- Follow Up            |
| Arm description:  |  |
| No study drug received. Participants return for safety follow-up visit 28 days after the last dose of study drug. |  |
| Includes participants who were rescued to Baricitinib 4 mg.   |  |
| Arm type  | No intervention                        |
| No investigational medicinal product assigned in this arm   |  |

| <b>Number of subjects in period 2<sup>[4]</sup></b> | Placebo-Follow Up | Baricitinib 2 mg- Follow Up | Baricitinib 4 mg- Follow Up |
|---|-------------------|-----------------------------|-----------------------------|
| Started   | 17                | 19                          | 22                          |
| Completed   | 17                | 19                          | 22                          |

Notes:

[4] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Includes participants who entered the post-treatment follow-up period

## Baseline characteristics

### Reporting groups

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

Reporting group description:

Placebo administered orally (PO) once daily (QD) through Week 24. Participants continued to take background conventional disease-modifying antirheumatic drug (cDMARD) therapy throughout study. Starting at Week 16, participants who were nonresponders were rescued with baricitinib 4 mg PO, QD.

All started participants received at least one dose of study drug.

|                       |                  |
|-----------------------|------------------|
| Reporting group title | Baricitinib 2 mg |
|-----------------------|------------------|

Reporting group description:

Baricitinib 2 mg PO QD through Week 24. Participants continued to take background cDMARD therapy throughout study. Starting at Week 16, participants who were nonresponders were rescued with baricitinib 4 mg PO, QD.

|                       |                  |
|-----------------------|------------------|
| Reporting group title | Baricitinib 4 mg |
|-----------------------|------------------|

Reporting group description:

Baricitinib 4 mg PO QD through Week 24. Participants continued to take background cDMARD therapy throughout study. Starting at Week 16, participants who were nonresponders were rescued with baricitinib 4 mg PO, QD.

| Reporting group values                             | Placebo | Baricitinib 2 mg | Baricitinib 4 mg |
|--|---------|------------------|------------------|
| Number of subjects                                 | 228     | 229              | 227              |
| Age categorical                                    |         |                  |                  |
| Units: Subjects                                    |         |                  |                  |
| In utero   | 0       | 0                | 0                |
| Preterm newborn infants (gestational age < 37 wks) | 0       | 0                | 0                |
| Newborns (0-27 days)                               | 0       | 0                | 0                |
| Infants and toddlers (28 days-23 months)           | 0       | 0                | 0                |
| Children (2-11 years)                              | 0       | 0                | 0                |
| Adolescents (12-17 years)                          | 0       | 0                | 0                |
| Adults (18-64 years)                               | 197     | 196              | 194              |
| From 65-84 years                                   | 31      | 33               | 33               |
| 85 years and over                                  | 0       | 0                | 0                |
| Age Continuous                                     |         |                  |                  |
| Units: years                                       |         |                  |                  |
| arithmetic mean                                    | 51.4    | 52.2             | 51.8             |
| standard deviation                                 | ± 12.5  | ± 12.3           | ± 12.1           |
| Gender, Male/Female                                |         |                  |                  |
| Units: participants                                |         |                  |                  |
| Female   | 189     | 184              | 187              |
| Male   | 39      | 45               | 40               |
| Ethnicity (NIH/OMB)                                |         |                  |                  |
| Units: Subjects                                    |         |                  |                  |
| Hispanic or Latino                                 | 12      | 15               | 17               |
| Not Hispanic or Latino                             | 45      | 43               | 43               |
| Unknown or Not Reported                            | 171     | 171              | 167              |
| Race (NIH/OMB)                                     |         |                  |                  |

|   |        |        |        |
|---|--------|--------|--------|
| Units: Subjects                             |        |        |        |
| American Indian or Alaska Native            | 3      | 2      | 9      |
| Asian                                       | 60     | 61     | 59     |
| Native Hawaiian or Other Pacific Islander   | 1      | 0      | 0      |
| Black or African American                   | 10     | 9      | 9      |
| White                                       | 153    | 156    | 148    |
| More than one race                          | 1      | 1      | 1      |
| Unknown or Not Reported                     | 0      | 0      | 1      |
| Region of Enrollment                        |        |        |        |
| Units: Subjects                             |        |        |        |
| Argentina                                   | 25     | 21     | 18     |
| Australia                                   | 8      | 1      | 6      |
| Belgium                                     | 1      | 4      | 6      |
| Canada                                      | 10     | 10     | 8      |
| Croatia                                     | 0      | 2      | 2      |
| Czech Republic                              | 7      | 5      | 3      |
| Germany                                     | 4      | 2      | 3      |
| Hungary                                     | 7      | 8      | 5      |
| India                                       | 19     | 19     | 20     |
| Italy                                       | 3      | 3      | 4      |
| Japan                                       | 8      | 6      | 7      |
| Korea, Republic of                          | 6      | 7      | 4      |
| Mexico                                      | 3      | 8      | 11     |
| Poland                                      | 18     | 13     | 20     |
| Portugal                                    | 2      | 2      | 1      |
| Romania                                     | 1      | 3      | 2      |
| Russian Federation                          | 4      | 10     | 6      |
| Slovakia                                    | 3      | 5      | 3      |
| Spain                                       | 14     | 10     | 10     |
| Taiwan                                      | 26     | 28     | 28     |
| United Kingdom                              | 1      | 4      | 0      |
| United States                               | 58     | 58     | 60     |
| Duration of Rheumatoid Arthritis            |        |        |        |
| n= 228, 225, 225 and 678                    |        |        |        |
| Units: years                                |        |        |        |
| arithmetic mean                             | 7.2    | 7.6    | 7.7    |
| standard deviation                          | ± 7.5  | ± 7.6  | ± 7.9  |
| Tender Joint Count of 68 Evaluable Joints   |        |        |        |
| Units: Number of Joints                     |        |        |        |
| arithmetic mean                             | 24.3   | 23.5   | 24.3   |
| standard deviation                          | ± 15   | ± 14.1 | ± 14   |
| Swollen Joint Count of 66 Evaluable Joints  |        |        |        |
| Units: Number of Joints                     |        |        |        |
| arithmetic mean                             | 13.1   | 13.6   | 13.5   |
| standard deviation                          | ± 7.2  | ± 8.7  | ± 6.9  |
| High Sensitivity C-Reactive Protein (hsCRP) |        |        |        |
| Units: milligram per Liter (mg/L)           |        |        |        |
| arithmetic mean                             | 17.7   | 18.2   | 14.2   |
| standard deviation                          | ± 20.4 | ± 21.5 | ± 14.5 |



|   |       |  |  |
|---|-------|--|--|
| <b>Reporting group values</b>                         | Total |  |  |
| Number of subjects                                    | 684   |  |  |
| 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)                                  | 587   |  |  |
| From 65-84 years                                      | 97    |  |  |
| 85 years and over                                     | 0     |  |  |
| Age Continuous<br>Units: years                        |       |  |  |
| arithmetic mean                                       |       |  |  |
| standard deviation                                    | -     |  |  |
| Gender, Male/Female<br>Units: participants            |       |  |  |
| Female  | 560   |  |  |
| Male  | 124   |  |  |
| Ethnicity (NIH/OMB)<br>Units: Subjects                |       |  |  |
| Hispanic or Latino                                    | 44    |  |  |
| Not Hispanic or Latino                                | 131   |  |  |
| Unknown or Not Reported                               | 509   |  |  |
| Race (NIH/OMB)<br>Units: Subjects                     |       |  |  |
| American Indian or Alaska Native                      | 14    |  |  |
| Asian   | 180   |  |  |
| Native Hawaiian or Other Pacific Islander             | 1     |  |  |
| Black or African American                             | 28    |  |  |
| White   | 457   |  |  |
| More than one race                                    | 3     |  |  |
| Unknown or Not Reported                               | 1     |  |  |
| Region of Enrollment<br>Units: Subjects               |       |  |  |
| Argentina   | 64    |  |  |
| Australia   | 15    |  |  |
| Belgium   | 11    |  |  |
| Canada  | 28    |  |  |
| Croatia   | 4     |  |  |
| Czech Republic  | 15    |  |  |
| Germany   | 9     |  |  |
| Hungary   | 20    |  |  |
| India   | 58    |  |  |
| Italy   | 10    |  |  |
| Japan   | 21    |  |  |

|   |     |  |  |
|---|-----|--|--|
| Korea, Republic of                          | 17  |  |  |
| Mexico                                      | 22  |  |  |
| Poland                                      | 51  |  |  |
| Portugal                                    | 5   |  |  |
| Romania                                     | 6   |  |  |
| Russian Federation                          | 20  |  |  |
| Slovakia                                    | 11  |  |  |
| Spain                                       | 34  |  |  |
| Taiwan                                      | 82  |  |  |
| United Kingdom                              | 5   |  |  |
| United States                               | 176 |  |  |
| Duration of Rheumatoid Arthritis            |     |  |  |
| n= 228, 225, 225 and 678                    |     |  |  |
| Units: years                                |     |  |  |
| arithmetic mean                             |     |  |  |
| standard deviation                          | -   |  |  |
| Tender Joint Count of 68 Evaluable Joints   |     |  |  |
| Units: Number of Joints                     |     |  |  |
| arithmetic mean                             |     |  |  |
| standard deviation                          | -   |  |  |
| Swollen Joint Count of 66 Evaluable Joints  |     |  |  |
| Units: Number of Joints                     |     |  |  |
| arithmetic mean                             |     |  |  |
| standard deviation                          | -   |  |  |
| High Sensitivity C-Reactive Protein (hsCRP) |     |  |  |
| Units: milligram per Liter (mg/L)           |     |  |  |
| arithmetic mean                             |     |  |  |
| standard deviation                          | -   |  |  |

## End points

### End points reporting groups

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

Reporting group description:

Placebo administered orally (PO) once daily (QD) through Week 24. Participants continued to take background conventional disease-modifying antirheumatic drug (cDMARD) therapy throughout study. Starting at Week 16, participants who were nonresponders were rescued with baricitinib 4 mg PO, QD.

All started participants received at least one dose of study drug.

|                       |                  |
|-----------------------|------------------|
| Reporting group title | Baricitinib 2 mg |
|-----------------------|------------------|

Reporting group description:

Baricitinib 2 mg PO QD through Week 24. Participants continued to take background cDMARD therapy throughout study. Starting at Week 16, participants who were nonresponders were rescued with baricitinib 4 mg PO, QD.

|                       |                  |
|-----------------------|------------------|
| Reporting group title | Baricitinib 4 mg |
|-----------------------|------------------|

Reporting group description:

Baricitinib 4 mg PO QD through Week 24. Participants continued to take background cDMARD therapy throughout study. Starting at Week 16, participants who were nonresponders were rescued with baricitinib 4 mg PO, QD.

|                       |                   |
|-----------------------|-------------------|
| Reporting group title | Placebo-Follow Up |
|-----------------------|-------------------|

Reporting group description:

No study drug received. Participants return for safety follow-up visit 28 days after the last dose of study drug.

|                       |                             |
|-----------------------|-----------------------------|
| Reporting group title | Baricitinib 2 mg- Follow Up |
|-----------------------|-----------------------------|

Reporting group description:

No study drug received. Participants return for safety follow-up visit 28 days after the last dose of study drug.

|                       |                             |
|-----------------------|-----------------------------|
| Reporting group title | Baricitinib 4 mg- Follow Up |
|-----------------------|-----------------------------|

Reporting group description:

No study drug received. Participants return for safety follow-up visit 28 days after the last dose of study drug.

Includes participants who were rescued to Baricitinib 4 mg.

|                            |                                |
|----------------------------|--------------------------------|
| Subject analysis set title | PK population 2 mg Baricitinib |
|----------------------------|--------------------------------|

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

Subject analysis set description:

All randomized participants who received at least 1 dose of 2 mg baricitinib with evaluable PK data.

|                            |                                |
|----------------------------|--------------------------------|
| Subject analysis set title | PK Population 4 mg Baricitinib |
|----------------------------|--------------------------------|

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

Subject analysis set description:

All randomized participants who received at least 1 dose of 4 mg baricitinib with evaluable PK data.

### Primary: Percentage of Participants Achieving American College of Rheumatology 20% Improvement (ACR20)

|                 |   |
|-----------------|---|
| End point title | Percentage of Participants Achieving American College of Rheumatology 20% Improvement (ACR20) |
|-----------------|---|

End point description:

ACR20 Responder Index is a composite of clinical, laboratory, and functional measures in rheumatoid arthritis (RA). "ACR20 Responder" is a participant who has at least 20% improvement in both tender and swollen joint counts and in at least 3 of the following 5 criteria: Physician's Global Assessment of Disease Activity, Patient's Global Assessment of Disease Activity using visual analog scale (VAS), Health Assessment Questionnaire - Disability Index (HAQ-DI), participant's assessment of pain, and high-sensitivity C-reactive protein (hsCRP). Participants with missing responses and participants who discontinue study or drug or are rescued before analysis timepoint are deemed non-responders.

Analysis Population Description: All randomized participants who received at least 1 dose of the study drug. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using non-responder imputation (NRI).

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

| End point values                  | Placebo         | Baricitinib 2 mg | Baricitinib 4 mg |  |
|-----------------------------------|-----------------|------------------|------------------|--|
| Subject group type                | Reporting group | Reporting group  | Reporting group  |  |
| Number of subjects analysed       | 228             | 229              | 227              |  |
| Units: percentage of participants |                 |                  |                  |  |
| number (not applicable)           | 39.5            | 65.9             | 61.7             |  |

## Statistical analyses

|   |                                |
|---|--------------------------------|
| Statistical analysis title              | Statistical Analysis for ACR20 |
| Comparison groups                       | Baricitinib 4 mg v Placebo     |
| Number of subjects included in analysis | 455                            |
| Analysis specification                  | Pre-specified                  |
| Analysis type                           | superiority                    |
| P-value                                 | = 0.001                        |
| Method                                  | Regression, Logistic           |

## Secondary: Change from Baseline in the Health Assessment Questionnaire-Disability Index (HAQ-DI) Score

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

End point description:

The HAQ-DI questionnaire assesses the participant's self-perception on the degree of difficulty (0 [without any difficulty], 1 [with some difficulty], 2 [with much difficulty], and 3 [unable to do]) when dressing and grooming, arising, eating, walking, hygiene, reaching, gripping, and performing other daily activities. Scores for each functional area were averaged to calculate the HAQ-DI score, which ranged from 0 (no disability) to 3 (worst disability). A decrease in HAQ-DI score indicated an improvement in the participant's condition.

Analysis Population Description: All randomized participants who received at least 1 dose of the study drug. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using modified baseline observation carried forward (mBOCF).

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Baseline, Week 12    |           |

| End point values                     | Placebo         | Baricitinib 2 mg | Baricitinib 4 mg |  |
|--------------------------------------|-----------------|------------------|------------------|--|
| Subject group type                   | Reporting group | Reporting group  | Reporting group  |  |
| Number of subjects analysed          | 228             | 229              | 227              |  |
| Units: units on a scale              |                 |                  |                  |  |
| arithmetic mean (standard deviation) | -0.3 (± 0.45)   | -0.52 (± 0.59)   | -0.52 (± 0.6)    |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in the Disease Activity Score Based on a 28-Joint Count and High-Sensitivity C-Reactive Protein (DAS28-hsCRP)

|                 |  |
|-----------------|--|
| End point title | Change from Baseline in the Disease Activity Score Based on a 28-Joint Count and High-Sensitivity C-Reactive Protein (DAS28-hsCRP) |
|-----------------|--|

End point description:

Disease Activity Score (DAS) modified to include 28 joint count (DAS28) consisted of composite score of following variables: tender joint count (TJC28), swollen joint count (SJC28), C-reactive protein (CRP) (milligrams per liter), and Patient's Global Assessment of Disease Activity using visual analog scale (VAS) (participant global VAS). DAS28 was calculated using following formula:  $\text{DAS28-CRP} = 0.56 \times \sqrt{\text{TJC28}} + 0.28 \times \sqrt{\text{SJC28}} + 0.36 \times \ln(\text{CRP} + 1) + 0.014 \times \text{Patient's Global VAS} + 0.96$ . Scores ranged 1.0-9.4, where lower scores indicated less disease activity.

Analysis Population Description All randomized participants who received at least 1 dose of the study drug. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using mBOCF.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Baseline, Week 12    |           |

| End point values                     | Placebo         | Baricitinib 2 mg | Baricitinib 4 mg |  |
|--------------------------------------|-----------------|------------------|------------------|--|
| Subject group type                   | Reporting group | Reporting group  | Reporting group  |  |
| Number of subjects analysed          | 228             | 229              | 227              |  |
| Units: units on a scale              |                 |                  |                  |  |
| arithmetic mean (standard deviation) | -1.05 (± 1.23)  | -1.83 (± 1.22)   | -1.91 (± 1.21)   |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants Achieving Simplified Disease Activity Index (SDAI) ≤3.3

|                 |  |
|-----------------|--|
| End point title | Percentage of Participants Achieving Simplified Disease Activity Index (SDAI) ≤3.3 |
|-----------------|--|

End point description:

SDAI is a tool for measurement of disease activity in RA that integrates TJC28, SJC28, acute phase

response using C-reactive protein (milligrams per liter), Participant's Global Assessment of Disease Activity using VAS centimeters (cm), and Physician's Global Assessment of Disease Activity using VAS (cm). The SDAI is calculated by summing the values of the 5 components. Lower scores indicated less disease activity. An index-based definition of remission occurs with an SDAI score  $\leq 3.3$ .

**Analysis Population Description** All randomized participants who received at least 1 dose of the study drug. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using NRI.

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

| End point values                  | Placebo         | Baricitinib 2 mg | Baricitinib 4 mg |  |
|-----------------------------------|-----------------|------------------|------------------|--|
| Subject group type                | Reporting group | Reporting group  | Reporting group  |  |
| Number of subjects analysed       | 228             | 229              | 227              |  |
| Units: percentage of participants |                 |                  |                  |  |
| number (not applicable)           | 0.9             | 9.2              | 8.8              |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Mean Duration of Morning Joint Stiffness (MJS) in the Prior 7 Days as Collected in Electronic Daily Diaries

|                 |   |
|-----------------|---|
| End point title | Mean Duration of Morning Joint Stiffness (MJS) in the Prior 7 Days as Collected in Electronic Daily Diaries |
|-----------------|---|

End point description:

Participants reported the duration of their morning joint stiffness (MJS) in hours and minutes into daily electronic diaries. If MJS duration was longer than 12 hours (720 minutes), it was truncated to 720 minutes for statistical presentations and analyses. The average value across the 7 days preceding each visit is calculated. A decrease in duration of MJS indicated an improvement in the participant's condition.

**Analysis Population Description:** All randomized participants who received at least 1 dose of the study drug and had at least 4 entries within any post-baseline 7-day window are included in the analysis.

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

| End point values                 | Placebo           | Baricitinib 2 mg | Baricitinib 4 mg    |  |
|----------------------------------|-------------------|------------------|---------------------|--|
| Subject group type               | Reporting group   | Reporting group  | Reporting group     |  |
| Number of subjects analysed      | 221               | 223              | 222                 |  |
| Units: minutes                   |                   |                  |                     |  |
| median (confidence interval 95%) | 60 (50.7 to 76.7) | 44.4 (30 to 60)  | 34.6 (23.7 to 51.4) |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Mean Severity of Morning Joint Stiffness Numeric Rating Scale (NRS) in the Prior 7 Days as Collected in Electronic Diaries

|                 |  |
|-----------------|--|
| End point title | Mean Severity of Morning Joint Stiffness Numeric Rating Scale (NRS) in the Prior 7 Days as Collected in Electronic Diaries |
|-----------------|--|

End point description:

Participants rated the severity of their MJS by selecting a number from 0 to 10 that best described their overall level of MJS from the time they woke up, where 0 represents "no joint stiffness" and 10 represents "joint stiffness as bad as you can imagine". Participants reported their severity daily in electronic diaries. The average value across the 7 days preceding each visit is calculated. A decrease in severity rating indicated an improvement in the participant's condition.

Analysis Population Description: All randomized participants who received at least 1 dose of the study drug and had at least 4 entries within any post-baseline 7-day window are included in the analysis.

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

End point timeframe:

Week 12

| End point values                     | Placebo         | Baricitinib 2 mg | Baricitinib 4 mg |  |
|--------------------------------------|-----------------|------------------|------------------|--|
| Subject group type                   | Reporting group | Reporting group  | Reporting group  |  |
| Number of subjects analysed          | 221             | 223              | 222              |  |
| Units: units on a scale              |                 |                  |                  |  |
| arithmetic mean (standard deviation) | 4.2 (± 2.3)     | 3.5 (± 2.5)      | 3.4 (± 2.2)      |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Mean Worst Tiredness Numeric Rating Scale (NRS) in the Prior 7 Days as Collected in Electronic Diaries

|                 |  |
|-----------------|--|
| End point title | Mean Worst Tiredness Numeric Rating Scale (NRS) in the Prior 7 Days as Collected in Electronic Diaries |
|-----------------|--|

End point description:

Participants rated their tiredness by selecting a number from 0 to 10 that best described their level of worst tiredness during the past 24 hours, where 0 represents "no tiredness" and 10 represents "as bad as you can imagine". Participants reported their worst tiredness in daily electronic diaries. The average value across the 7 days preceding each visit is calculated. A decrease in tiredness severity rating indicated an improvement in the participant's condition.

Analysis Population Description: All randomized participants who received at least 1 dose of the study drug and had at least 4 entries within any post-baseline 7-day window are included in the analysis.

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

| End point values                     | Placebo         | Baricitinib 2 mg | Baricitinib 4 mg |  |
|--------------------------------------|-----------------|------------------|------------------|--|
| Subject group type                   | Reporting group | Reporting group  | Reporting group  |  |
| Number of subjects analysed          | 221             | 223              | 222              |  |
| Units: units on a scale              |                 |                  |                  |  |
| arithmetic mean (standard deviation) | 4.5 (± 2.2)     | 4 (± 2.5)        | 4 (± 2.3)        |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Mean Worst Joint Pain Numeric Rating Scale (NRS) in the Prior 7 days as Collected in Electronic Diaries

|                 |   |
|-----------------|---|
| End point title | Mean Worst Joint Pain Numeric Rating Scale (NRS) in the Prior 7 days as Collected in Electronic Diaries |
|-----------------|---|

End point description:

Participants rated their joint pain by selecting a number from 0 to 10 that best described their worst joint pain during the last 24 hours, where 0 represents "no pain" and 10 represents "pain as bad as you can imagine". Participants reported their worst joint pain in daily electronic diaries. The average value across the 7 days preceding each visit is calculated. A decrease in joint pain severity rating indicated an improvement in the participant's condition.

Analysis Population Description: All randomized participants who received at least 1 dose of the study drug and had at least 4 entries within any post-baseline 7-day window are included in the analysis.

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

| End point values                     | Placebo         | Baricitinib 2 mg | Baricitinib 4 mg |  |
|--------------------------------------|-----------------|------------------|------------------|--|
| Subject group type                   | Reporting group | Reporting group  | Reporting group  |  |
| Number of subjects analysed          | 221             | 223              | 222              |  |
| Units: units on a scale              |                 |                  |                  |  |
| arithmetic mean (standard deviation) | 4.7 (± 2.2)     | 3.9 (± 2.5)      | 3.8 (± 2.2)      |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Participants Achieving American College of Rheumatology



## 50% (ACR50) Response

|                 |  |
|-----------------|--|
| End point title | Percentage of Participants Achieving American College of Rheumatology 50% (ACR50) Response |
|-----------------|--|

End point description:

ACR50 Responder Index is composite of clinical, laboratory, and functional measures in RA. "ACR50 Responder" is a participant who has at least 50% improvement in both tender and swollen joint counts and in at least 3 of the following 5 criteria:

Physician's Global Assessment of Disease Activity, Patient's Global Assessment of Disease Activity, HAQ-DI, participant's assessment of pain, and hsCRP. Participants with missing responses and participants who discontinue study or drug or are rescued before analysis timepoint are deemed non-responders.

Analysis Population Description: All randomized participants who received at least 1 dose of the study drug. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using NRI.

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

End point timeframe:

Week 12, Week 24

| End point values                  | Placebo         | Baricitinib 2 mg | Baricitinib 4 mg |  |
|-----------------------------------|-----------------|------------------|------------------|--|
| Subject group type                | Reporting group | Reporting group  | Reporting group  |  |
| Number of subjects analysed       | 228             | 229              | 227              |  |
| Units: percentage of participants |                 |                  |                  |  |
| number (not applicable)           |                 |                  |                  |  |
| Week 12                           | 12.7            | 33.6             | 33.5             |  |
| Week 24                           | 21.5            | 41.5             | 44.1             |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants Achieving American College of Rheumatology 70% (ACR70) Response

|                 |  |
|-----------------|--|
| End point title | Percentage of Participants Achieving American College of Rheumatology 70% (ACR70) Response |
|-----------------|--|

End point description:

ACR70 Responder Index is composite of clinical, laboratory, and functional measures in RA. "ACR70 Responder" is a participant who has at least 70% improvement in both tender and swollen joint counts and in at least 3 of the following 5 criteria: Physician's Global Assessment of Disease Activity, Patient's Global Assessment of Disease Activity, HAQ-DI, participant's assessment of pain, and hsCRP.

Participants with missing responses and participants who discontinue study or drug or are rescued before analysis timepoint are deemed non-responders.

Analysis Population Description: All randomized participants who received at least 1 dose of the study drug. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using NRI.

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

End point timeframe:

Week 12, Week 24

| End point values                  | Placebo         | Baricitinib 2 mg | Baricitinib 4 mg |  |
|-----------------------------------|-----------------|------------------|------------------|--|
| Subject group type                | Reporting group | Reporting group  | Reporting group  |  |
| Number of subjects analysed       | 228             | 229              | 227              |  |
| Units: percentage of participants |                 |                  |                  |  |
| number (not applicable)           |                 |                  |                  |  |
| Week 12                           | 3.1             | 17.9             | 18.1             |  |
| Week 24                           | 7.9             | 25.3             | 24.2             |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Measures of Clinical Disease Activity Index (CDAI) Score

|                 |  |
|-----------------|--|
| End point title | Change From Baseline in Measures of Clinical Disease Activity Index (CDAI) Score |
|-----------------|--|

End point description:

The CDAI is a tool for measurement of disease activity in RA that does not require a laboratory component and was scored by the investigative site. It integrates TJC28, SJC28, Patient's Global Assessment of Disease Activity using visual analog scale (cm), and Physician's Global Assessment of Disease Activity using visual analog scale (cm). The CDAI is calculated by summing the values of the 4 components. Lower scores indicated less disease activity.

Analysis Population Description: All randomized participants who received at least 1 dose of the study drug, with a baseline value and at least 1 post-baseline value. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using modified last observation carried forward (mLOCF) .

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

End point timeframe:

Baseline, Week 24

| End point values                     | Placebo          | Baricitinib 2 mg | Baricitinib 4 mg |  |
|--------------------------------------|------------------|------------------|------------------|--|
| Subject group type                   | Reporting group  | Reporting group  | Reporting group  |  |
| Number of subjects analysed          | 218              | 224              | 219              |  |
| Units: units on a scale              |                  |                  |                  |  |
| arithmetic mean (standard deviation) | -14.29 (± 16.04) | -20.99 (± 14.48) | -23.18 (± 13.47) |  |

## Statistical analyses

No statistical analyses for this end point

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**Secondary: Change from Baseline in Measures of Simplified Disease Activity Index (SDAI) Score**

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|                 |  |
|-----------------|--|
| End point title | Change from Baseline in Measures of Simplified Disease Activity Index (SDAI) Score |
|-----------------|--|

End point description:

The SDAI is a tool for measurement of disease activity in RA that integrates TJC28, SJC28, acute phase response using C-reactive protein (milligrams per liter), Patient's Global Assessment of Disease Activity using visual analog scale (cm), and Physician's Global Assessment of Disease Activity using visual analog scale (cm). The SDAI is calculated by summing the values of the 5 components. Lower scores indicated less disease activity.

Analysis Population Description: All randomized participants who received at least 1 dose of the study drug, with a baseline value and at least 1 post-baseline value. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using mLOCF.

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

End point timeframe:

Baseline, Week 24

---

| End point values                     | Placebo          | Baricitinib 2 mg | Baricitinib 4 mg |  |
|--------------------------------------|------------------|------------------|------------------|--|
| Subject group type                   | Reporting group  | Reporting group  | Reporting group  |  |
| Number of subjects analysed          | 218              | 224              | 219              |  |
| Units: units on a scale              |                  |                  |                  |  |
| arithmetic mean (standard deviation) | -14.55 (± 16.37) | -21.87 (± 14.99) | -23.78 (± 13.94) |  |

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**Statistical analyses**

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No statistical analyses for this end point

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**Secondary: Change from Baseline in DAS28-Erythrocyte Sedimentation Rate (DAS28-ESR)**

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|                 |  |
|-----------------|--|
| End point title | Change from Baseline in DAS28-Erythrocyte Sedimentation Rate (DAS28-ESR) |
|-----------------|--|

End point description:

DAS28 consisted of composite score of following variables: tender joint count (TJC28), swollen joint count (SJC28), Erythrocyte Sedimentation Rate (ESR) (millimeters per hour), and Patient's Global Assessment of Disease Activity. DAS28 was calculated using following formula:  $\text{DAS28-ESR} = 0.56 \times \sqrt{\text{TJC28}} + 0.28 \times \sqrt{\text{SJC28}} + 0.70 \times \ln(\text{ESR}) + 0.014 \times \text{Patient's Global VAS}$ . Scores ranged 1.0-9.4, where lower scores indicated less disease activity.

Analysis Population Description: All randomized participants who received at least 1 dose of the study drug. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using mLOCF.

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

End point timeframe:

Baseline, Week 12

---

| End point values                     | Placebo         | Baricitinib 2 mg | Baricitinib 4 mg |  |
|--------------------------------------|-----------------|------------------|------------------|--|
| Subject group type                   | Reporting group | Reporting group  | Reporting group  |  |
| Number of subjects analysed          | 220             | 226              | 221              |  |
| Units: units on a scale              |                 |                  |                  |  |
| arithmetic mean (standard deviation) | -1.16 (± 1.27)  | -1.89 (± 1.23)   | -1.97 (± 1.16)   |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants Achieving American College of Rheumatology European League Against Rheumatism (ACR/EULAR) Remission – Boolean Remission

|                 |  |
|-----------------|--|
| End point title | Percentage of Participants Achieving American College of Rheumatology European League Against Rheumatism (ACR/EULAR) Remission – Boolean Remission |
|-----------------|--|

End point description:

The ACR/EULAR definition of RA remission include a Boolean-based definition. The Boolean-based definition of remission occurs when all 4 of the following criteria are met at the same visit: TJC28 ≤1, SJC28 ≤1, acute phase response using C-reactive protein (milligrams per deciliter) ≤1, Patient's Global Assessment of Disease Activity using VAS (cm) ≤1.

Analysis Population Description: All randomized participants who received at least 1 dose of the study drug. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using NRI.

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

End point timeframe:

Week 12

| End point values                  | Placebo         | Baricitinib 2 mg | Baricitinib 4 mg |  |
|-----------------------------------|-----------------|------------------|------------------|--|
| Subject group type                | Reporting group | Reporting group  | Reporting group  |  |
| Number of subjects analysed       | 228             | 229              | 227              |  |
| Units: percentage of participants |                 |                  |                  |  |
| number (not applicable)           | 0.4             | 7                | 6.6              |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) Scores.

|                 |  |
|-----------------|--|
| End point title | Change from Baseline in Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) Scores. |
|-----------------|--|

End point description:

The Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) Scale is a brief 13-item, symptom-specific questionnaire that specifically assesses the participant's self-reported severity of

fatigue and its impact upon daily activities and functioning. The FACIT-F uses a numeric rating scale of 0 ("Not at all") to 4 ("Very much") for each item to assess fatigue and its impact in the past 7 days. Total scores range from 0 to 52, with higher scores indicating less fatigue.

Analysis Population Description: All randomized participants who received at least 1 dose of the study drug, with a baseline value and at least 1 post-baseline value. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using mLOCF.

|                                     |           |
|-------------------------------------|-----------|
| End point type                      | Secondary |
| End point timeframe:                |           |
| Baseline, Week 12; Baseline Week 24 |           |

| End point values                     | Placebo         | Baricitinib 2 mg | Baricitinib 4 mg |  |
|--------------------------------------|-----------------|------------------|------------------|--|
| Subject group type                   | Reporting group | Reporting group  | Reporting group  |  |
| Number of subjects analysed          | 216             | 227              | 216              |  |
| Units: units on a scale              |                 |                  |                  |  |
| arithmetic mean (standard deviation) |                 |                  |                  |  |
| Week 12                              | 7.6 (± 10.3)    | 8.7 (± 11.1)     | 8.8 (± 10.6)     |  |
| Week 24                              | 7.8 (± 11)      | 9.2 (± 10.7)     | 9.7 (± 10.8)     |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in Mental Component Score (MCS), Physical Component Score (PCS) of the Medical Outcomes Study 36-Item Short Form Health Survey Version 2 Acute (SF-36v2 Acute)

|                 |   |
|-----------------|---|
| End point title | Change from Baseline in Mental Component Score (MCS), Physical Component Score (PCS) of the Medical Outcomes Study 36-Item Short Form Health Survey Version 2 Acute (SF-36v2 Acute) |
|-----------------|---|

End point description:

The SF-36 is a health-related survey that assesses participant's quality of life and consists of 36 questions covering 8 health domains: physical functioning, bodily pain, role limitations due to physical problems and emotional problems, general health, mental health, social functioning, vitality, as well as 2 component scores (mental [MCS] and physical [PCS]). MCS consisted of social functioning, vitality, mental health, and role-emotional scales. PCS consisted of physical functioning, bodily pain, role-physical, and general health scales. Each domain is scored by summing the individual items and transforming the scores into a 0 to 100 scale with higher scores indicating better health status or functioning.

Analysis Population Description: All randomized participants who received at least 1 dose of the study drug, with a baseline value and at least 1 post-baseline value. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using mLOCF.

|                                      |           |
|--------------------------------------|-----------|
| End point type                       | Secondary |
| End point timeframe:                 |           |
| Baseline, Week 12; Baseline, Week 24 |           |

| End point values                     | Placebo         | Baricitinib 2 mg | Baricitinib 4 mg |  |
|--------------------------------------|-----------------|------------------|------------------|--|
| Subject group type                   | Reporting group | Reporting group  | Reporting group  |  |
| Number of subjects analysed          | 218             | 229              | 219              |  |
| Units: units on a scale              |                 |                  |                  |  |
| arithmetic mean (standard deviation) |                 |                  |                  |  |
| Week 12, MCS                         | 3.3 (± 10.6)    | 3.6 (± 10.5)     | 3.3 (± 11)       |  |
| Week 24, MCS                         | 2.7 (± 11.5)    | 3 (± 10.4)       | 3.3 (± 11.3)     |  |
| Week 12, PCS                         | 4.1 (± 7.3)     | 7.7 (± 8.5)      | 7 (± 8.3)        |  |
| Week 24, PCS                         | 4.9 (± 8)       | 8.5 (± 9)        | 8.6 (± 9)        |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in European Quality of Life-5 Dimensions-5 Level (EQ-5D-5L) Scores

|                 |   |
|-----------------|---|
| End point title | Change from Baseline in European Quality of Life-5 Dimensions-5 Level (EQ-5D-5L) Scores |
|-----------------|---|

End point description:

European Quality of Life-5 Dimensions-5 Level (EQ-5D-5L) is a standardized measure of health status of the participant. One component consists of a descriptive system of the respondent's health comprised of the following 5 participant-reported dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems, and extreme problems. The responses are used to derive the health state index scores using the United Kingdom (UK) algorithm, with scores ranging from -0.594 to 1, and the United States (US) algorithm, with scores ranging from -0.109 to 1. A higher score indicates better health state.

Analysis Population Description: All randomized participants who received at least 1 dose of the study drug , with a baseline value and at least 1 post-baseline value. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using mLOCF.

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

End point timeframe:

Baseline Week 12; Baseline Week 24

| End point values                     | Placebo         | Baricitinib 2 mg | Baricitinib 4 mg |  |
|--------------------------------------|-----------------|------------------|------------------|--|
| Subject group type                   | Reporting group | Reporting group  | Reporting group  |  |
| Number of subjects analysed          | 216             | 227              | 216              |  |
| Units: units on a scale              |                 |                  |                  |  |
| arithmetic mean (standard deviation) |                 |                  |                  |  |
| Index Score (US Algorithm) Week 12   | 0.054 (± 0.155) | 0.117 (± 0.151)  | 0.109 (± 0.165)  |  |
| Index Score (US Algorithm) Week 24   | 0.051 (± 0.149) | 0.113 (± 0.172)  | 0.129 (± 0.173)  |  |
| Index Score (UK Algorithm) Week 12   | 0.074 (± 0.23)  | 0.167 (± 0.221)  | 0.159 (± 0.237)  |  |
| Index Score (UK Algorithm) Week 24   | 0.075 (± 0.218) | 0.162 (± 0.254)  | 0.185 (± 0.25)   |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change From Baseline in European Quality of Life-5 Dimensions-5 Level (EQ-5D-5L) Scores (Self-Perceived Health)

|                 |   |
|-----------------|---|
| End point title | Change From Baseline in European Quality of Life-5 Dimensions-5 Level (EQ-5D-5L) Scores (Self-Perceived Health) |
|-----------------|---|

End point description:

A second component of the EQ-5D-5L is a self-perceived health score which is assessed using a VAS that ranges from 0 to 100 millimeter (mm), where 0 indicates the worst health you can imagine and 100 indicates the best health you can imagine.

Analysis Population Description: All randomized participants who received at least 1 dose of the study drug, with a baseline value and at least 1 post-baseline value. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using mLOCF.

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

End point timeframe:

Baseline Week 12; Baseline Week 24

| End point values                     | Placebo         | Baricitinib 2 mg | Baricitinib 4 mg |  |
|--------------------------------------|-----------------|------------------|------------------|--|
| Subject group type                   | Reporting group | Reporting group  | Reporting group  |  |
| Number of subjects analysed          | 216             | 227              | 216              |  |
| Units: mm                            |                 |                  |                  |  |
| arithmetic mean (standard deviation) |                 |                  |                  |  |
| Self-Perceived Health, Week 12       | 5.7 (± 23.8)    | 13.4 (± 21.8)    | 11.5 (± 25.2)    |  |
| Self-Perceived Health, Week 24       | 8.4 (± 25.1)    | 13.1 (± 25.8)    | 10.4 (± 28.9)    |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in Work Productivity and Activity Impairment-Rheumatoid Arthritis (WPAI-RA) Scores

|                 |   |
|-----------------|---|
| End point title | Change from Baseline in Work Productivity and Activity Impairment-Rheumatoid Arthritis (WPAI-RA) Scores |
|-----------------|---|

End point description:

The Work Productivity and Activity Impairment-Rheumatoid Arthritis (WPAI-RA) questionnaire was developed to measure the effect of general health and symptom severity on work productivity and regular activities in the 7 days prior to the visit. It contains 6 items covering overall work productivity (health), overall work productivity (symptom), impairment of regular activities (health), and impairment of regular activities (symptom). Scores are calculated as impairment percentages. The WPAI-RA yields

four types of scores: Absenteeism (work time missed), Presenteeism (impairment at work), Work productivity loss (overall work impairment), and Activity impairment.

Analysis Population Description: All randomized participants who received at least 1 dose of the study drug. Change from baseline includes participants with a baseline value and an observed value at the time point being summarized.

|                                      |           |
|--------------------------------------|-----------|
| End point type                       | Secondary |
| End point timeframe:                 |           |
| Baseline, Week 12; Baseline, Week 24 |           |

| End point values                             | Placebo         | Baricitinib 2 mg | Baricitinib 4 mg |  |
|--|-----------------|------------------|------------------|--|
| Subject group type                           | Reporting group | Reporting group  | Reporting group  |  |
| Number of subjects analysed                  | 228             | 229              | 227              |  |
| Units: percentage of impairment              |                 |                  |                  |  |
| arithmetic mean (standard deviation)         |                 |                  |                  |  |
| Absenteeism Week 12 (n= 73,72,69)            | 2.6 (± 23.5)    | -6.3 (± 26.5)    | 2.5 (± 24.7)     |  |
| Absenteeism Week 24 (n= 44,62,56)            | -2.1 (± 13.9)   | -3.8 (± 28.2)    | 4 (± 27.2)       |  |
| Presenteeism Week 12 (n= 71, 69, 66)         | -8 (± 26)       | -17 (± 25)       | -15 (± 27)       |  |
| Presenteeism Week 24 (n= 44,61,53)           | -17 (± 26)      | -20 (± 23)       | -17 (± 21)       |  |
| Work Productivity Loss Week 12 (n= 71,69,66) | -4.2 (± 27.7)   | -17.6 (± 30.4)   | -9.9 (± 23.7)    |  |
| Work Productivity Loss Week 24 (n= 44,61,53) | -15.9 (± 26.1)  | -19.6 (± 25)     | -14.3 (± 23)     |  |
| Activity Impairment Week 12(n=206, 222, 213) | -13 (± 25)      | -19 (± 27)       | -19 (± 25)       |  |
| Activity Impairment Week 24 (n= 141,187,187) | -18 (± 27)      | -23 (± 28)       | -21 (± 27)       |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Population Pharmacokinetics (PK): Maximum Concentration at Steady State of Dosing (C<sub>max,ss</sub>) of LY3009104

|   |   |
|---|---|
| End point title   | Population Pharmacokinetics (PK): Maximum Concentration at Steady State of Dosing (C <sub>max,ss</sub> ) of LY3009104 |
| End point description:  |   |
| End point type  | Secondary   |
| End point timeframe:  |   |
| Week 0: 30 and 90 minutes postdose; Week 8: 1 hour postdose; Week 12, Week 20 and Week 24:predose |   |



| End point values                                    | PK population<br>2 mg<br>Baricitinib | PK Population 4<br>mg Baricitinib |  |  |
|---|--------------------------------------|-----------------------------------|--|--|
| Subject group type                                  | Subject analysis set                 | Subject analysis set              |  |  |
| Number of subjects analysed                         | 246                                  | 245                               |  |  |
| Units: nanogram per milliliter (ng/mL)              |                                      |                                   |  |  |
| geometric mean (geometric coefficient of variation) | 70.2 ( $\pm$ 26.2)                   | 138 ( $\pm$ 25.7)                 |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Population PK: Maximum Concentration at Steady State of Dosing (AUC<sub>ss</sub>) of LY3009104

|                 |  |
|-----------------|--|
| End point title | Population PK: Maximum Concentration at Steady State of Dosing (AUC <sub>ss</sub> ) of LY3009104 |
|-----------------|--|

End point description:

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

End point timeframe:

Week 0: 30 and 90 minutes postdose; Week 8: 1 hour postdose; Week 12, Week 20 and Week 24; predose

| End point values                                    | PK population<br>2 mg<br>Baricitinib | PK Population 4<br>mg Baricitinib |  |  |
|---|--------------------------------------|-----------------------------------|--|--|
| Subject group type                                  | Subject analysis set                 | Subject analysis set              |  |  |
| Number of subjects analysed                         | 246                                  | 245                               |  |  |
| Units: nanograms per mL per hour (ng/mL*h)          |                                      |                                   |  |  |
| geometric mean (geometric coefficient of variation) | 637 ( $\pm$ 44.5)                    | 1210 ( $\pm$ 47)                  |  |  |

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Entire Study

Adverse event reporting additional description:

I4V-MC-JADX

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

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 17.1 |
|--------------------|------|

### Reporting groups

|                       |         |
|-----------------------|---------|
| Reporting group title | PLACEBO |
|-----------------------|---------|

Reporting group description: -

|                       |                  |
|-----------------------|------------------|
| Reporting group title | Baricitinib 2 mg |
|-----------------------|------------------|

Reporting group description: -

|                       |                  |
|-----------------------|------------------|
| Reporting group title | Baricitinib 4 mg |
|-----------------------|------------------|

Reporting group description: -

|                       |        |
|-----------------------|--------|
| Reporting group title | Rescue |
|-----------------------|--------|

Reporting group description: -

|                       |                    |
|-----------------------|--------------------|
| Reporting group title | Placebo- Follow Up |
|-----------------------|--------------------|

Reporting group description: -

|                       |                              |
|-----------------------|------------------------------|
| Reporting group title | Baricitinib 2 mg – Follow Up |
|-----------------------|------------------------------|

Reporting group description: -

|                       |                              |
|-----------------------|------------------------------|
| Reporting group title | Baricitinib 4 mg – Follow Up |
|-----------------------|------------------------------|

Reporting group description: -

| Serious adverse events                            | PLACEBO          | Baricitinib 2 mg | Baricitinib 4 mg |
|---|------------------|------------------|------------------|
| Total subjects affected by serious adverse events |                  |                  |                  |
| subjects affected / exposed                       | 13 / 228 (5.70%) | 6 / 229 (2.62%)  | 12 / 227 (5.29%) |
| number of deaths (all causes)                     | 0                | 0                | 0                |
| number of deaths resulting from adverse events    | 0                | 0                | 0                |
| Injury, poisoning and procedural complications    |                  |                  |                  |
| animal bite                                       |                  |                  |                  |
| alternative dictionary used: MedDRA 17.1          |                  |                  |                  |
| subjects affected / exposed                       | 0 / 228 (0.00%)  | 0 / 229 (0.00%)  | 1 / 227 (0.44%)  |
| occurrences causally related to treatment / all   | 0 / 0            | 0 / 0            | 0 / 1            |
| deaths causally related to treatment / all        | 0 / 0            | 0 / 0            | 0 / 0            |
| fall  |                  |                  |                  |
| alternative dictionary used: MedDRA 17.1          |                  |                  |                  |

|  |                 |                 |                 |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed  | 2 / 228 (0.88%) | 0 / 229 (0.00%) | 0 / 227 (0.00%) |
| occurrences causally related to treatment / all                      | 0 / 2           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all                           | 0 / 0           | 0 / 0           | 0 / 0           |
| patella fracture<br>alternative dictionary used:<br>MedDRA 17.1      |                 |                 |                 |
| subjects affected / exposed  | 1 / 228 (0.44%) | 0 / 229 (0.00%) | 0 / 227 (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           |
| tibia fracture<br>alternative dictionary used:<br>MedDRA 17.1        |                 |                 |                 |
| subjects affected / exposed  | 0 / 228 (0.00%) | 0 / 229 (0.00%) | 1 / 227 (0.44%) |
| occurrences causally related to treatment / all                      | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all                           | 0 / 0           | 0 / 0           | 0 / 0           |
| upper limb fracture<br>alternative dictionary used:<br>MedDRA 17.1   |                 |                 |                 |
| subjects affected / exposed  | 1 / 228 (0.44%) | 0 / 229 (0.00%) | 0 / 227 (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           |
| Cardiac disorders  |                 |                 |                 |
| angina pectoris<br>alternative dictionary used:<br>MedDRA 17.1       |                 |                 |                 |
| subjects affected / exposed  | 0 / 228 (0.00%) | 0 / 229 (0.00%) | 1 / 227 (0.44%) |
| occurrences causally related to treatment / all                      | 0 / 0           | 0 / 0           | 1 / 1           |
| deaths causally related to treatment / all                           | 0 / 0           | 0 / 0           | 0 / 0           |
| atrial fibrillation<br>alternative dictionary used:<br>MedDRA 17.1   |                 |                 |                 |
| subjects affected / exposed  | 0 / 228 (0.00%) | 1 / 229 (0.44%) | 0 / 227 (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           |
| myocardial infarction<br>alternative dictionary used:<br>MedDRA 17.1 |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed   | 1 / 228 (0.44%) | 0 / 229 (0.00%) | 0 / 227 (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           |
| ventricular tachycardia<br>alternative dictionary used:<br>MedDRA 17.1  |                 |                 |                 |
| subjects affected / exposed   | 1 / 228 (0.44%) | 0 / 229 (0.00%) | 0 / 227 (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           |
| Nervous system disorders  |                 |                 |                 |
| migraine<br>alternative dictionary used:<br>MedDRA 17.1                 |                 |                 |                 |
| subjects affected / exposed   | 0 / 228 (0.00%) | 1 / 229 (0.44%) | 0 / 227 (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           |
| subarachnoid haemorrhage<br>alternative dictionary used:<br>MedDRA 17.1 |                 |                 |                 |
| subjects affected / exposed   | 1 / 228 (0.44%) | 0 / 229 (0.00%) | 0 / 227 (0.00%) |
| occurrences causally related to treatment / all                         | 1 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all                              | 1 / 1           | 0 / 0           | 0 / 0           |
| Blood and lymphatic system disorders                                    |                 |                 |                 |
| anaemia<br>alternative dictionary used:<br>MedDRA 17.1                  |                 |                 |                 |
| subjects affected / exposed   | 1 / 228 (0.44%) | 0 / 229 (0.00%) | 0 / 227 (0.00%) |
| occurrences causally related to treatment / all                         | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all                              | 0 / 0           | 0 / 0           | 0 / 0           |
| Gastrointestinal disorders  |                 |                 |                 |
| diverticulum intestinal<br>alternative dictionary used:<br>MedDRA 17.1  |                 |                 |                 |
| subjects affected / exposed   | 1 / 228 (0.44%) | 0 / 229 (0.00%) | 0 / 227 (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           |
| dyspepsia<br>alternative dictionary used:<br>MedDRA 17.1                |                 |                 |                 |

|  |                 |                 |                 |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed  | 0 / 228 (0.00%) | 0 / 229 (0.00%) | 1 / 227 (0.44%) |
| occurrences causally related to treatment / all                                    | 0 / 0           | 0 / 0           | 1 / 1           |
| deaths causally related to treatment / all   | 0 / 0           | 0 / 0           | 0 / 0           |
| gastrointestinal haemorrhage<br>alternative dictionary used:<br>MedDRA 17.1        |                 |                 |                 |
| subjects affected / exposed  | 1 / 228 (0.44%) | 0 / 229 (0.00%) | 0 / 227 (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           |
| Respiratory, thoracic and mediastinal disorders                                    |                 |                 |                 |
| acute respiratory distress syndrome<br>alternative dictionary used:<br>MedDRA 17.1 |                 |                 |                 |
| subjects affected / exposed  | 0 / 228 (0.00%) | 1 / 229 (0.44%) | 0 / 227 (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           |
| acute respiratory failure<br>alternative dictionary used:<br>MedDRA 17.1           |                 |                 |                 |
| subjects affected / exposed  | 0 / 228 (0.00%) | 1 / 229 (0.44%) | 0 / 227 (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           |
| allergic bronchitis<br>alternative dictionary used:<br>MedDRA 17.1                 |                 |                 |                 |
| subjects affected / exposed  | 0 / 228 (0.00%) | 0 / 229 (0.00%) | 1 / 227 (0.44%) |
| occurrences causally related to treatment / all                                    | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all   | 0 / 0           | 0 / 0           | 0 / 0           |
| interstitial lung disease<br>alternative dictionary used:<br>MedDRA 17.1           |                 |                 |                 |
| subjects affected / exposed  | 0 / 228 (0.00%) | 0 / 229 (0.00%) | 1 / 227 (0.44%) |
| occurrences causally related to treatment / all                                    | 0 / 0           | 0 / 0           | 1 / 1           |
| deaths causally related to treatment / all   | 0 / 0           | 0 / 0           | 0 / 0           |
| pleural effusion<br>alternative dictionary used:<br>MedDRA 17.1                    |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 228 (0.00%) | 0 / 229 (0.00%) | 1 / 227 (0.44%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 1 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| pulmonary embolism                              |                 |                 |                 |
| alternative dictionary used: MedDRA 17.1        |                 |                 |                 |
| subjects affected / exposed                     | 0 / 228 (0.00%) | 0 / 229 (0.00%) | 1 / 227 (0.44%) |
| 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                         |                 |                 |                 |
| cholecystitis acute                             |                 |                 |                 |
| alternative dictionary used: MedDRA 17.1        |                 |                 |                 |
| subjects affected / exposed                     | 0 / 228 (0.00%) | 0 / 229 (0.00%) | 1 / 227 (0.44%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Skin and subcutaneous tissue disorders          |                 |                 |                 |
| psoriasis                                       |                 |                 |                 |
| alternative dictionary used: MedDRA 17.1        |                 |                 |                 |
| subjects affected / exposed                     | 0 / 228 (0.00%) | 1 / 229 (0.44%) | 0 / 227 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 1 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| rash pruritic                                   |                 |                 |                 |
| alternative dictionary used: MedDRA 17.1        |                 |                 |                 |
| subjects affected / exposed                     | 0 / 228 (0.00%) | 0 / 229 (0.00%) | 1 / 227 (0.44%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 1 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| subcutaneous emphysema                          |                 |                 |                 |
| alternative dictionary used: MedDRA 17.1        |                 |                 |                 |
| subjects affected / exposed                     | 1 / 228 (0.44%) | 0 / 229 (0.00%) | 0 / 227 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Psychiatric disorders                           |                 |                 |                 |
| depression                                      |                 |                 |                 |
| alternative dictionary used: MedDRA 17.1        |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed   | 1 / 228 (0.44%) | 0 / 229 (0.00%) | 0 / 227 (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           |
| post-traumatic stress disorder<br>alternative dictionary used:<br>MedDRA 17.1 |                 |                 |                 |
| subjects affected / exposed   | 0 / 228 (0.00%) | 1 / 229 (0.44%) | 0 / 227 (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           |
| suicidal ideation<br>alternative dictionary used:<br>MedDRA 17.1              |                 |                 |                 |
| subjects affected / exposed   | 1 / 228 (0.44%) | 0 / 229 (0.00%) | 0 / 227 (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           |
| Renal and urinary disorders   |                 |                 |                 |
| renal failure<br>alternative dictionary used:<br>MedDRA 17.1                  |                 |                 |                 |
| subjects affected / exposed   | 1 / 228 (0.44%) | 0 / 229 (0.00%) | 0 / 227 (0.00%) |
| occurrences causally related to treatment / all                               | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all                                    | 0 / 1           | 0 / 0           | 0 / 0           |
| Musculoskeletal and connective tissue disorders                               |                 |                 |                 |
| back pain<br>alternative dictionary used:<br>MedDRA 17.1                      |                 |                 |                 |
| subjects affected / exposed   | 1 / 228 (0.44%) | 0 / 229 (0.00%) | 0 / 227 (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           |
| muscular weakness<br>alternative dictionary used:<br>MedDRA 17.1              |                 |                 |                 |
| subjects affected / exposed   | 0 / 228 (0.00%) | 0 / 229 (0.00%) | 1 / 227 (0.44%) |
| occurrences causally related to treatment / all                               | 0 / 0           | 0 / 0           | 1 / 1           |
| deaths causally related to treatment / all                                    | 0 / 0           | 0 / 0           | 0 / 0           |
| myalgia<br>alternative dictionary used:<br>MedDRA 17.1                        |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 228 (0.00%) | 0 / 229 (0.00%) | 1 / 227 (0.44%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 1 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| myositis  |                 |                 |                 |
| alternative dictionary used: MedDRA 17.1        |                 |                 |                 |
| subjects affected / exposed                     | 0 / 228 (0.00%) | 0 / 229 (0.00%) | 1 / 227 (0.44%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 1 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| polymyositis                                    |                 |                 |                 |
| alternative dictionary used: MedDRA 17.1        |                 |                 |                 |
| subjects affected / exposed                     | 0 / 228 (0.00%) | 0 / 229 (0.00%) | 0 / 227 (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           |
| rheumatoid arthritis                            |                 |                 |                 |
| alternative dictionary used: MedDRA 17.1        |                 |                 |                 |
| subjects affected / exposed                     | 1 / 228 (0.44%) | 0 / 229 (0.00%) | 0 / 227 (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           |
| spinal pain                                     |                 |                 |                 |
| alternative dictionary used: MedDRA 17.1        |                 |                 |                 |
| subjects affected / exposed                     | 0 / 228 (0.00%) | 0 / 229 (0.00%) | 1 / 227 (0.44%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| synovial cyst                                   |                 |                 |                 |
| alternative dictionary used: MedDRA 17.1        |                 |                 |                 |
| subjects affected / exposed                     | 1 / 228 (0.44%) | 0 / 229 (0.00%) | 0 / 227 (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           |
| Infections and infestations                     |                 |                 |                 |
| appendicitis                                    |                 |                 |                 |
| alternative dictionary used: MedDRA 17.1        |                 |                 |                 |



|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 228 (0.00%) | 0 / 229 (0.00%) | 0 / 227 (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           |
| bacterial infection                             |                 |                 |                 |
| alternative dictionary used: MedDRA 17.1        |                 |                 |                 |
| subjects affected / exposed                     | 0 / 228 (0.00%) | 0 / 229 (0.00%) | 1 / 227 (0.44%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 1 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| bronchitis                                      |                 |                 |                 |
| alternative dictionary used: MedDRA 17.1        |                 |                 |                 |
| subjects affected / exposed                     | 1 / 228 (0.44%) | 0 / 229 (0.00%) | 0 / 227 (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           |
| cellulitis                                      |                 |                 |                 |
| alternative dictionary used: MedDRA 17.1        |                 |                 |                 |
| subjects affected / exposed                     | 0 / 228 (0.00%) | 0 / 229 (0.00%) | 0 / 227 (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           |
| disseminated tuberculosis                       |                 |                 |                 |
| alternative dictionary used: MedDRA 17.1        |                 |                 |                 |
| subjects affected / exposed                     | 0 / 228 (0.00%) | 0 / 229 (0.00%) | 1 / 227 (0.44%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 1 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| gastroenteritis                                 |                 |                 |                 |
| alternative dictionary used: MedDRA 17.1        |                 |                 |                 |
| subjects affected / exposed                     | 0 / 228 (0.00%) | 1 / 229 (0.44%) | 0 / 227 (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           |
| lower respiratory tract infection               |                 |                 |                 |
| alternative dictionary used: MedDRA 17.1        |                 |                 |                 |
| subjects affected / exposed                     | 0 / 228 (0.00%) | 0 / 229 (0.00%) | 1 / 227 (0.44%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 1 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |

|  |                 |                 |                 |
|--|-----------------|-----------------|-----------------|
| pelvic abscess                                     |                 |                 |                 |
| alternative dictionary used:<br>MedDRA 17.1        |                 |                 |                 |
| subjects affected / exposed                        | 0 / 228 (0.00%) | 0 / 229 (0.00%) | 0 / 227 (0.00%) |
| occurrences causally related to<br>treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| pneumonia  |                 |                 |                 |
| alternative dictionary used:<br>MedDRA 17.1        |                 |                 |                 |
| subjects affected / exposed                        | 2 / 228 (0.88%) | 1 / 229 (0.44%) | 1 / 227 (0.44%) |
| occurrences causally related to<br>treatment / all | 0 / 2           | 0 / 1           | 1 / 1           |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| sepsis   |                 |                 |                 |
| alternative dictionary used:<br>MedDRA 17.1        |                 |                 |                 |
| subjects affected / exposed                        | 0 / 228 (0.00%) | 0 / 229 (0.00%) | 1 / 227 (0.44%) |
| occurrences causally related to<br>treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| urinary tract infection                            |                 |                 |                 |
| alternative dictionary used:<br>MedDRA 17.1        |                 |                 |                 |
| subjects affected / exposed                        | 1 / 228 (0.44%) | 0 / 229 (0.00%) | 0 / 227 (0.00%) |
| occurrences causally related to<br>treatment / all | 1 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| viral infection                                    |                 |                 |                 |
| alternative dictionary used:<br>MedDRA 17.1        |                 |                 |                 |
| subjects affected / exposed                        | 0 / 228 (0.00%) | 0 / 229 (0.00%) | 1 / 227 (0.44%) |
| occurrences causally related to<br>treatment / all | 0 / 0           | 0 / 0           | 1 / 1           |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| wound infection staphylococcal                     |                 |                 |                 |
| alternative dictionary used:<br>MedDRA 17.1        |                 |                 |                 |
| subjects affected / exposed                        | 1 / 228 (0.44%) | 0 / 229 (0.00%) | 0 / 227 (0.00%) |
| occurrences causally related to<br>treatment / all | 1 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to<br>treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |

| <b>Serious adverse events</b>                        | Rescue | Placebo- Follow Up | Baricitinib 2 mg –<br>Follow Up |
|--|--------|--------------------|---------------------------------|
| Total subjects affected by serious<br>adverse events |        |                    |                                 |

|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed                     | 1 / 91 (1.10%) | 1 / 17 (5.88%) | 0 / 19 (0.00%) |
| number of deaths (all causes)                   | 0              | 0              | 0              |
| number of deaths resulting from adverse events  | 0              | 0              | 0              |
| Injury, poisoning and procedural complications  |                |                |                |
| animal bite                                     |                |                |                |
| alternative dictionary used: MedDRA 17.1        |                |                |                |
| subjects affected / exposed                     | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| fall  |                |                |                |
| alternative dictionary used: MedDRA 17.1        |                |                |                |
| subjects affected / exposed                     | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| patella fracture                                |                |                |                |
| alternative dictionary used: MedDRA 17.1        |                |                |                |
| subjects affected / exposed                     | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| tibia fracture                                  |                |                |                |
| alternative dictionary used: MedDRA 17.1        |                |                |                |
| subjects affected / exposed                     | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| upper limb fracture                             |                |                |                |
| alternative dictionary used: MedDRA 17.1        |                |                |                |
| subjects affected / exposed                     | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| Cardiac disorders                               |                |                |                |
| angina pectoris                                 |                |                |                |
| alternative dictionary used: MedDRA 17.1        |                |                |                |

|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| atrial fibrillation                             |                |                |                |
| alternative dictionary used: MedDRA 17.1        |                |                |                |
| subjects affected / exposed                     | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| myocardial infarction                           |                |                |                |
| alternative dictionary used: MedDRA 17.1        |                |                |                |
| subjects affected / exposed                     | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| ventricular tachycardia                         |                |                |                |
| alternative dictionary used: MedDRA 17.1        |                |                |                |
| subjects affected / exposed                     | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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  |                |                |                |
| alternative dictionary used: MedDRA 17.1        |                |                |                |
| subjects affected / exposed                     | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| subarachnoid haemorrhage                        |                |                |                |
| alternative dictionary used: MedDRA 17.1        |                |                |                |
| subjects affected / exposed                     | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| Blood and lymphatic system disorders            |                |                |                |
| anaemia   |                |                |                |
| alternative dictionary used: MedDRA 17.1        |                |                |                |

|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| Gastrointestinal disorders                      |                |                |                |
| diverticulum intestinal                         |                |                |                |
| alternative dictionary used: MedDRA 17.1        |                |                |                |
| subjects affected / exposed                     | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| dyspepsia                                       |                |                |                |
| alternative dictionary used: MedDRA 17.1        |                |                |                |
| subjects affected / exposed                     | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| gastrointestinal haemorrhage                    |                |                |                |
| alternative dictionary used: MedDRA 17.1        |                |                |                |
| subjects affected / exposed                     | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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 |                |                |                |
| acute respiratory distress syndrome             |                |                |                |
| alternative dictionary used: MedDRA 17.1        |                |                |                |
| subjects affected / exposed                     | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| acute respiratory failure                       |                |                |                |
| alternative dictionary used: MedDRA 17.1        |                |                |                |
| subjects affected / exposed                     | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| allergic bronchitis                             |                |                |                |
| alternative dictionary used: MedDRA 17.1        |                |                |                |

|  |                |                |                |
|--|----------------|----------------|----------------|
| subjects affected / exposed  | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| interstitial lung disease<br>alternative dictionary used:<br>MedDRA 17.1 |                |                |                |
| subjects affected / exposed  | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| pleural effusion<br>alternative dictionary used:<br>MedDRA 17.1          |                |                |                |
| subjects affected / exposed  | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| pulmonary embolism<br>alternative dictionary used:<br>MedDRA 17.1        |                |                |                |
| subjects affected / exposed  | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| Hepatobiliary disorders  |                |                |                |
| cholecystitis acute<br>alternative dictionary used:<br>MedDRA 17.1       |                |                |                |
| subjects affected / exposed  | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| Skin and subcutaneous tissue disorders                                   |                |                |                |
| psoriasis<br>alternative dictionary used:<br>MedDRA 17.1                 |                |                |                |
| subjects affected / exposed  | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| rash pruritic<br>alternative dictionary used:<br>MedDRA 17.1             |                |                |                |

|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed   | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| subcutaneous emphysema<br>alternative dictionary used:<br>MedDRA 17.1         |                |                |                |
| subjects affected / exposed   | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| Psychiatric disorders   |                |                |                |
| depression<br>alternative dictionary used:<br>MedDRA 17.1                     |                |                |                |
| subjects affected / exposed   | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| post-traumatic stress disorder<br>alternative dictionary used:<br>MedDRA 17.1 |                |                |                |
| subjects affected / exposed   | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| suicidal ideation<br>alternative dictionary used:<br>MedDRA 17.1              |                |                |                |
| subjects affected / exposed   | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| Renal and urinary disorders   |                |                |                |
| renal failure<br>alternative dictionary used:<br>MedDRA 17.1                  |                |                |                |
| subjects affected / exposed   | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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                               |                |                |                |
| back pain<br>alternative dictionary used:<br>MedDRA 17.1                      |                |                |                |

|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| muscular weakness                               |                |                |                |
| alternative dictionary used: MedDRA 17.1        |                |                |                |
| subjects affected / exposed                     | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| myalgia   |                |                |                |
| alternative dictionary used: MedDRA 17.1        |                |                |                |
| subjects affected / exposed                     | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| myositis  |                |                |                |
| alternative dictionary used: MedDRA 17.1        |                |                |                |
| subjects affected / exposed                     | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| polymyositis                                    |                |                |                |
| alternative dictionary used: MedDRA 17.1        |                |                |                |
| subjects affected / exposed                     | 0 / 91 (0.00%) | 1 / 17 (5.88%) | 0 / 19 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 1 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| rheumatoid arthritis                            |                |                |                |
| alternative dictionary used: MedDRA 17.1        |                |                |                |
| subjects affected / exposed                     | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| spinal pain                                     |                |                |                |
| alternative dictionary used: MedDRA 17.1        |                |                |                |
| subjects affected / exposed                     | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |



|  |  |  |  |
|--|--|--|--|
| synovial cyst<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences causally related to<br>treatment / all<br>deaths causally related to<br>treatment / all             | <br><br><br>0 / 91 (0.00%)<br><br>0 / 0<br><br>0 / 0 | <br><br><br>0 / 17 (0.00%)<br><br>0 / 0<br><br>0 / 0 | <br><br><br>0 / 19 (0.00%)<br><br>0 / 0<br><br>0 / 0 |
| Infections and infestations  |  |  |  |
| appendicitis<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences causally related to<br>treatment / all<br>deaths causally related to<br>treatment / all              | <br><br><br>0 / 91 (0.00%)<br><br>0 / 0<br><br>0 / 0 | <br><br><br>1 / 17 (5.88%)<br><br>0 / 1<br><br>0 / 0 | <br><br><br>0 / 19 (0.00%)<br><br>0 / 0<br><br>0 / 0 |
| bacterial infection<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences causally related to<br>treatment / all<br>deaths causally related to<br>treatment / all       | <br><br><br>0 / 91 (0.00%)<br><br>0 / 0<br><br>0 / 0 | <br><br><br>0 / 17 (0.00%)<br><br>0 / 0<br><br>0 / 0 | <br><br><br>0 / 19 (0.00%)<br><br>0 / 0<br><br>0 / 0 |
| bronchitis<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences causally related to<br>treatment / all<br>deaths causally related to<br>treatment / all                | <br><br><br>0 / 91 (0.00%)<br><br>0 / 0<br><br>0 / 0 | <br><br><br>0 / 17 (0.00%)<br><br>0 / 0<br><br>0 / 0 | <br><br><br>0 / 19 (0.00%)<br><br>0 / 0<br><br>0 / 0 |
| cellulitis<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences causally related to<br>treatment / all<br>deaths causally related to<br>treatment / all                | <br><br><br>1 / 91 (1.10%)<br><br>1 / 1<br><br>0 / 0 | <br><br><br>0 / 17 (0.00%)<br><br>0 / 0<br><br>0 / 0 | <br><br><br>0 / 19 (0.00%)<br><br>0 / 0<br><br>0 / 0 |
| disseminated tuberculosis<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences causally related to<br>treatment / all<br>deaths causally related to<br>treatment / all | <br><br><br>0 / 91 (0.00%)<br><br>0 / 0<br><br>0 / 0 | <br><br><br>0 / 17 (0.00%)<br><br>0 / 0<br><br>0 / 0 | <br><br><br>0 / 19 (0.00%)<br><br>0 / 0<br><br>0 / 0 |
| gastroenteritis<br>alternative dictionary used:<br>MedDRA 17.1   |  |  |  |

|  |                |                |                |
|--|----------------|----------------|----------------|
| subjects affected / exposed  | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| lower respiratory tract infection<br>alternative dictionary used:<br>MedDRA 17.1 |                |                |                |
| subjects affected / exposed  | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| pelvic abscess<br>alternative dictionary used:<br>MedDRA 17.1                    |                |                |                |
| subjects affected / exposed  | 0 / 91 (0.00%) | 1 / 17 (5.88%) | 0 / 19 (0.00%) |
| occurrences causally related to treatment / all                                  | 0 / 0          | 1 / 1          | 0 / 0          |
| deaths causally related to treatment / all                                       | 0 / 0          | 0 / 0          | 0 / 0          |
| pneumonia<br>alternative dictionary used:<br>MedDRA 17.1                         |                |                |                |
| subjects affected / exposed  | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| sepsis<br>alternative dictionary used:<br>MedDRA 17.1                            |                |                |                |
| subjects affected / exposed  | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| urinary tract infection<br>alternative dictionary used:<br>MedDRA 17.1           |                |                |                |
| subjects affected / exposed  | 1 / 91 (1.10%) | 0 / 17 (0.00%) | 0 / 19 (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          |
| viral infection<br>alternative dictionary used:<br>MedDRA 17.1                   |                |                |                |
| subjects affected / exposed  | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (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          |

|   |                |                |                |
|---|----------------|----------------|----------------|
| wound infection staphylococcal<br>alternative dictionary used:<br>MedDRA 17.1 |                |                |                |
| subjects affected / exposed   | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (0.00%) |
| occurrences causally related to<br>treatment / all                            | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to<br>treatment / all                                 | 0 / 0          | 0 / 0          | 0 / 0          |

| <b>Serious adverse events</b>                        | Baricitinib 4 mg –<br>Follow Up |  |  |
|--|---------------------------------|--|--|
| Total subjects affected by serious<br>adverse events |                                 |  |  |
| subjects affected / exposed                          | 1 / 22 (4.55%)                  |  |  |
| number of deaths (all causes)                        | 0                               |  |  |
| number of deaths resulting from<br>adverse events    | 0                               |  |  |
| Injury, poisoning and procedural<br>complications    |                                 |  |  |
| animal bite  |                                 |  |  |
| alternative dictionary used:<br>MedDRA 17.1          |                                 |  |  |
| subjects affected / exposed                          | 0 / 22 (0.00%)                  |  |  |
| occurrences causally related to<br>treatment / all   | 0 / 0                           |  |  |
| deaths causally related to<br>treatment / all        | 0 / 0                           |  |  |
| fall   |                                 |  |  |
| alternative dictionary used:<br>MedDRA 17.1          |                                 |  |  |
| subjects affected / exposed                          | 0 / 22 (0.00%)                  |  |  |
| occurrences causally related to<br>treatment / all   | 0 / 0                           |  |  |
| deaths causally related to<br>treatment / all        | 0 / 0                           |  |  |
| patella fracture                                     |                                 |  |  |
| alternative dictionary used:<br>MedDRA 17.1          |                                 |  |  |
| subjects affected / exposed                          | 0 / 22 (0.00%)                  |  |  |
| occurrences causally related to<br>treatment / all   | 0 / 0                           |  |  |
| deaths causally related to<br>treatment / all        | 0 / 0                           |  |  |
| tibia fracture                                       |                                 |  |  |
| alternative dictionary used:<br>MedDRA 17.1          |                                 |  |  |
| subjects affected / exposed                          | 0 / 22 (0.00%)                  |  |  |
| occurrences causally related to<br>treatment / all   | 0 / 0                           |  |  |
| deaths causally related to<br>treatment / all        | 0 / 0                           |  |  |
| upper limb fracture                                  |                                 |  |  |
| alternative dictionary used:<br>MedDRA 17.1          |                                 |  |  |

|   |                |  |  |
|---|----------------|--|--|
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Cardiac disorders                               |                |  |  |
| angina pectoris                                 |                |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| atrial fibrillation                             |                |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| myocardial infarction                           |                |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| ventricular tachycardia                         |                |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Nervous system disorders                        |                |  |  |
| migraine  |                |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| subarachnoid haemorrhage                        |                |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |

|   |                |  |  |
|---|----------------|--|--|
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Blood and lymphatic system disorders            |                |  |  |
| anaemia   |                |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Gastrointestinal disorders                      |                |  |  |
| diverticulum intestinal                         |                |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| dyspepsia                                       |                |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| gastrointestinal haemorrhage                    |                |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Respiratory, thoracic and mediastinal disorders |                |  |  |
| acute respiratory distress syndrome             |                |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| acute respiratory failure                       |                |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |

|   |                |  |  |
|---|----------------|--|--|
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| allergic bronchitis                             |                |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| interstitial lung disease                       |                |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| pleural effusion                                |                |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| pulmonary embolism                              |                |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |
| subjects affected / exposed                     | 1 / 22 (4.55%) |  |  |
| occurrences causally related to treatment / all | 0 / 1          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Hepatobiliary disorders                         |                |  |  |
| cholecystitis acute                             |                |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Skin and subcutaneous tissue disorders          |                |  |  |
| psoriasis                                       |                |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |

|   |                |  |  |
|---|----------------|--|--|
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| rash pruritic                                   |                |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| subcutaneous emphysema                          |                |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Psychiatric disorders                           |                |  |  |
| depression                                      |                |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| post-traumatic stress disorder                  |                |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| suicidal ideation                               |                |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Renal and urinary disorders                     |                |  |  |
| renal failure                                   |                |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |

|   |                |  |  |
|---|----------------|--|--|
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Musculoskeletal and connective tissue disorders |                |  |  |
| back pain                                       |                |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| muscular weakness                               |                |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| myalgia   |                |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| myositis  |                |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| polymyositis                                    |                |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| rheumatoid arthritis                            |                |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |



|   |                |  |  |  |
|---|----------------|--|--|--|
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |  |
| spinal pain                                     |                |  |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |  |
| synovial cyst                                   |                |  |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |  |
| Infections and infestations                     |                |  |  |  |
| appendicitis                                    |                |  |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |  |
| bacterial infection                             |                |  |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |  |
| bronchitis                                      |                |  |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |  |
| cellulitis                                      |                |  |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |  |

|   |                |  |  |  |
|---|----------------|--|--|--|
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |  |
| disseminated tuberculosis                       |                |  |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |  |
| gastroenteritis                                 |                |  |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |  |
| lower respiratory tract infection               |                |  |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |  |
| pelvic abscess                                  |                |  |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |  |
| pneumonia                                       |                |  |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |  |
| sepsis  |                |  |  |  |
| alternative dictionary used: MedDRA 17.1        |                |  |  |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |  |

|   |                                  |  |  |  |
|---|----------------------------------|--|--|--|
| urinary tract infection<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences causally related to<br>treatment / all<br>deaths causally related to<br>treatment / all        | 0 / 22 (0.00%)<br>0 / 0<br>0 / 0 |  |  |  |
| viral infection<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences causally related to<br>treatment / all<br>deaths causally related to<br>treatment / all                | 0 / 22 (0.00%)<br>0 / 0<br>0 / 0 |  |  |  |
| wound infection staphylococcal<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences causally related to<br>treatment / all<br>deaths causally related to<br>treatment / all | 0 / 22 (0.00%)<br>0 / 0<br>0 / 0 |  |  |  |

Frequency threshold for reporting non-serious adverse events: 2 %

| <b>Non-serious adverse events</b>  | PLACEBO              | Baricitinib 2 mg       | Baricitinib 4 mg     |
|--|----------------------|------------------------|----------------------|
| Total subjects affected by non-serious adverse events<br>subjects affected / exposed   | 105 / 228 (46.05%)   | 108 / 229 (47.16%)     | 127 / 227 (55.95%)   |
| Vascular disorders<br>hypertension<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)  | 2 / 228 (0.88%)<br>2 | 10 / 229 (4.37%)<br>10 | 6 / 227 (2.64%)<br>6 |
| General disorders and administration site conditions<br>fatigue<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)<br><br>oedema peripheral<br>alternative dictionary used:<br>MedDRA 17.1 | 5 / 228 (2.19%)<br>5 | 2 / 229 (0.87%)<br>3   | 5 / 227 (2.20%)<br>5 |

|   |   |  |  |
|---|---|--|--|
| <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>pyrexia</p> <p>alternative dictionary used:<br/>MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>  | <p>6 / 228 (2.63%)</p> <p>6</p> <p>2 / 228 (0.88%)</p> <p>2</p>                                 | <p>3 / 229 (1.31%)</p> <p>3</p> <p>1 / 229 (0.44%)</p> <p>1</p>                                  | <p>3 / 227 (1.32%)</p> <p>3</p> <p>5 / 227 (2.20%)</p> <p>7</p>                                  |
| <p>Reproductive system and breast disorders</p> <p>erectile dysfunction</p> <p>alternative dictionary used:<br/>MedDRA 17.1</p> <p>subjects affected / exposed<sup>[1]</sup></p> <p>occurrences (all)</p> <p>vulvovaginal pruritus</p> <p>alternative dictionary used:<br/>MedDRA 17.1</p> <p>subjects affected / exposed<sup>[2]</sup></p> <p>occurrences (all)</p>  | <p>0 / 39 (0.00%)</p> <p>0</p> <p>0 / 189 (0.00%)</p> <p>0</p>                                  | <p>0 / 45 (0.00%)</p> <p>0</p> <p>0 / 184 (0.00%)</p> <p>0</p>                                   | <p>1 / 40 (2.50%)</p> <p>1</p> <p>0 / 187 (0.00%)</p> <p>0</p>                                   |
| <p>Respiratory, thoracic and mediastinal disorders</p> <p>cough</p> <p>alternative dictionary used:<br/>MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>dyspnoea</p> <p>alternative dictionary used:<br/>MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>oropharyngeal pain</p> <p>alternative dictionary used:<br/>MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>3 / 228 (1.32%)</p> <p>4</p> <p>0 / 228 (0.00%)</p> <p>0</p> <p>2 / 228 (0.88%)</p> <p>2</p> | <p>9 / 229 (3.93%)</p> <p>11</p> <p>0 / 229 (0.00%)</p> <p>0</p> <p>4 / 229 (1.75%)</p> <p>4</p> | <p>9 / 227 (3.96%)</p> <p>10</p> <p>0 / 227 (0.00%)</p> <p>0</p> <p>9 / 227 (3.96%)</p> <p>9</p> |
| <p>Psychiatric disorders</p> <p>depression</p> <p>alternative dictionary used:<br/>MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>  | <p>7 / 228 (3.07%)</p> <p>7</p>   | <p>0 / 229 (0.00%)</p> <p>0</p>  | <p>1 / 227 (0.44%)</p> <p>1</p>  |
| Investigations  |   |  |  |

|   |   |  |   |
|---|---|--|---|
| alanine aminotransferase increased<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)   | 2 / 228 (0.88%)<br>3                              | 5 / 229 (2.18%)<br>6                               | 5 / 227 (2.20%)<br>6                              |
| aspartate aminotransferase increased<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)   | 1 / 228 (0.44%)<br>2                              | 3 / 229 (1.31%)<br>3                               | 6 / 227 (2.64%)<br>7                              |
| blood creatine phosphokinase increased<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)   | 0 / 228 (0.00%)<br>0                              | 8 / 229 (3.49%)<br>8                               | 15 / 227 (6.61%)<br>17                            |
| Cardiac disorders<br>sinus bradycardia<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)   | 0 / 228 (0.00%)<br>0                              | 0 / 229 (0.00%)<br>0                               | 0 / 227 (0.00%)<br>0                              |
| Nervous system disorders<br>dizziness<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)<br><br>headache<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all) | 4 / 228 (1.75%)<br>4<br><br>8 / 228 (3.51%)<br>10 | 3 / 229 (1.31%)<br>3<br><br>15 / 229 (6.55%)<br>17 | 7 / 227 (3.08%)<br>9<br><br>9 / 227 (3.96%)<br>10 |
| Blood and lymphatic system disorders<br>anaemia<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)  | 6 / 228 (2.63%)<br>6                              | 6 / 229 (2.62%)<br>6                               | 4 / 227 (1.76%)<br>4                              |
| Gastrointestinal disorders<br>abdominal pain<br>alternative dictionary used:<br>MedDRA 17.1   |   |  |   |

|   |                  |                  |                 |
|---|------------------|------------------|-----------------|
| subjects affected / exposed                 | 0 / 228 (0.00%)  | 5 / 229 (2.18%)  | 3 / 227 (1.32%) |
| occurrences (all)                           | 0                | 5                | 3               |
| abdominal pain upper                        |                  |                  |                 |
| alternative dictionary used:<br>MedDRA 17.1 |                  |                  |                 |
| subjects affected / exposed                 | 1 / 228 (0.44%)  | 5 / 229 (2.18%)  | 4 / 227 (1.76%) |
| occurrences (all)                           | 1                | 5                | 4               |
| constipation                                |                  |                  |                 |
| alternative dictionary used:<br>MedDRA 17.1 |                  |                  |                 |
| subjects affected / exposed                 | 3 / 228 (1.32%)  | 7 / 229 (3.06%)  | 5 / 227 (2.20%) |
| occurrences (all)                           | 4                | 7                | 5               |
| diarrhoea                                   |                  |                  |                 |
| alternative dictionary used:<br>MedDRA 17.1 |                  |                  |                 |
| subjects affected / exposed                 | 10 / 228 (4.39%) | 10 / 229 (4.37%) | 4 / 227 (1.76%) |
| occurrences (all)                           | 11               | 11               | 5               |
| dyspepsia                                   |                  |                  |                 |
| alternative dictionary used:<br>MedDRA 17.1 |                  |                  |                 |
| subjects affected / exposed                 | 2 / 228 (0.88%)  | 1 / 229 (0.44%)  | 5 / 227 (2.20%) |
| occurrences (all)                           | 2                | 1                | 5               |
| gastritis                                   |                  |                  |                 |
| alternative dictionary used:<br>MedDRA 17.1 |                  |                  |                 |
| subjects affected / exposed                 | 0 / 228 (0.00%)  | 0 / 229 (0.00%)  | 0 / 227 (0.00%) |
| occurrences (all)                           | 0                | 0                | 0               |
| gastrooesophageal reflux disease            |                  |                  |                 |
| alternative dictionary used:<br>MedDRA 17.1 |                  |                  |                 |
| subjects affected / exposed                 | 5 / 228 (2.19%)  | 2 / 229 (0.87%)  | 1 / 227 (0.44%) |
| occurrences (all)                           | 5                | 2                | 1               |
| lip disorder                                |                  |                  |                 |
| alternative dictionary used:<br>MedDRA 17.1 |                  |                  |                 |
| subjects affected / exposed                 | 0 / 228 (0.00%)  | 0 / 229 (0.00%)  | 0 / 227 (0.00%) |
| occurrences (all)                           | 0                | 0                | 0               |
| mouth ulceration                            |                  |                  |                 |
| alternative dictionary used:<br>MedDRA 17.1 |                  |                  |                 |
| subjects affected / exposed                 | 0 / 228 (0.00%)  | 5 / 229 (2.18%)  | 3 / 227 (1.32%) |
| occurrences (all)                           | 0                | 6                | 3               |

|  |                        |                      |                      |
|--|------------------------|----------------------|----------------------|
| nausea<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)  | 8 / 228 (3.51%)<br>9   | 7 / 229 (3.06%)<br>7 | 5 / 227 (2.20%)<br>5 |
| vomiting<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)  | 4 / 228 (1.75%)<br>5   | 7 / 229 (3.06%)<br>7 | 4 / 227 (1.76%)<br>4 |
| Skin and subcutaneous tissue disorders<br>acne<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)                | 0 / 228 (0.00%)<br>0   | 0 / 229 (0.00%)<br>0 | 0 / 227 (0.00%)<br>0 |
| alopecia<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)  | 4 / 228 (1.75%)<br>4   | 1 / 229 (0.44%)<br>1 | 6 / 227 (2.64%)<br>6 |
| dermatitis bullous<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)  | 0 / 228 (0.00%)<br>0   | 0 / 229 (0.00%)<br>0 | 0 / 227 (0.00%)<br>0 |
| Musculoskeletal and connective tissue disorders<br>arthralgia<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all) | 3 / 228 (1.32%)<br>3   | 6 / 229 (2.62%)<br>8 | 6 / 227 (2.64%)<br>6 |
| back pain<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)   | 10 / 228 (4.39%)<br>10 | 9 / 229 (3.93%)<br>9 | 5 / 227 (2.20%)<br>5 |
| Infections and infestations<br>bronchitis<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)                     | 11 / 228 (4.82%)<br>12 | 6 / 229 (2.62%)<br>7 | 7 / 227 (3.08%)<br>8 |

|  |                        |                        |                         |
|--|------------------------|------------------------|-------------------------|
| gastroenteritis<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)   | 1 / 228 (0.44%)<br>1   | 4 / 229 (1.75%)<br>4   | 9 / 227 (3.96%)<br>9    |
| nasopharyngitis<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)   | 18 / 228 (7.89%)<br>19 | 10 / 229 (4.37%)<br>10 | 18 / 227 (7.93%)<br>22  |
| pharyngitis<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)   | 3 / 228 (1.32%)<br>3   | 6 / 229 (2.62%)<br>6   | 8 / 227 (3.52%)<br>8    |
| rash pustular<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)   | 0 / 228 (0.00%)<br>0   | 0 / 229 (0.00%)<br>0   | 0 / 227 (0.00%)<br>0    |
| sinusitis<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)   | 6 / 228 (2.63%)<br>6   | 3 / 229 (1.31%)<br>3   | 4 / 227 (1.76%)<br>4    |
| upper respiratory tract infection<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)                           | 18 / 228 (7.89%)<br>19 | 14 / 229 (6.11%)<br>16 | 24 / 227 (10.57%)<br>26 |
| urinary tract infection<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)                                     | 4 / 228 (1.75%)<br>5   | 12 / 229 (5.24%)<br>13 | 9 / 227 (3.96%)<br>9    |
| Metabolism and nutrition disorders<br>hypercholesterolaemia<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all) | 2 / 228 (0.88%)<br>2   | 5 / 229 (2.18%)<br>5   | 9 / 227 (3.96%)<br>9    |
| hyperlipidaemia<br>alternative dictionary used:<br>MedDRA 17.1   |                        |                        |                         |



|                             |                 |                 |                 |
|-----------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 2 / 228 (0.88%) | 2 / 229 (0.87%) | 6 / 227 (2.64%) |
| occurrences (all)           | 2               | 2               | 6               |

| <b>Non-serious adverse events</b>                     | Rescue           | Placebo- Follow Up | Baricitinib 2 mg – Follow Up |
|---|------------------|--------------------|------------------------------|
| Total subjects affected by non-serious adverse events |                  |                    |                              |
| subjects affected / exposed                           | 21 / 91 (23.08%) | 2 / 17 (11.76%)    | 0 / 19 (0.00%)               |
| Vascular disorders                                    |                  |                    |                              |
| hypertension  |                  |                    |                              |
| alternative dictionary used: MedDRA 17.1              |                  |                    |                              |
| subjects affected / exposed                           | 0 / 91 (0.00%)   | 0 / 17 (0.00%)     | 0 / 19 (0.00%)               |
| occurrences (all)                                     | 0                | 0                  | 0                            |
| General disorders and administration site conditions  |                  |                    |                              |
| fatigue   |                  |                    |                              |
| alternative dictionary used: MedDRA 17.1              |                  |                    |                              |
| subjects affected / exposed                           | 0 / 91 (0.00%)   | 0 / 17 (0.00%)     | 0 / 19 (0.00%)               |
| occurrences (all)                                     | 0                | 0                  | 0                            |
| oedema peripheral                                     |                  |                    |                              |
| alternative dictionary used: MedDRA 17.1              |                  |                    |                              |
| subjects affected / exposed                           | 0 / 91 (0.00%)   | 0 / 17 (0.00%)     | 0 / 19 (0.00%)               |
| occurrences (all)                                     | 0                | 0                  | 0                            |
| pyrexia   |                  |                    |                              |
| alternative dictionary used: MedDRA 17.1              |                  |                    |                              |
| subjects affected / exposed                           | 0 / 91 (0.00%)   | 1 / 17 (5.88%)     | 0 / 19 (0.00%)               |
| occurrences (all)                                     | 0                | 1                  | 0                            |
| Reproductive system and breast disorders              |                  |                    |                              |
| erectile dysfunction                                  |                  |                    |                              |
| alternative dictionary used: MedDRA 17.1              |                  |                    |                              |
| subjects affected / exposed <sup>[1]</sup>            | 0 / 13 (0.00%)   | 0 / 6 (0.00%)      | 0 / 4 (0.00%)                |
| occurrences (all)                                     | 0                | 0                  | 0                            |
| vulvovaginal pruritus                                 |                  |                    |                              |
| alternative dictionary used: MedDRA 17.1              |                  |                    |                              |
| subjects affected / exposed <sup>[2]</sup>            | 0 / 78 (0.00%)   | 1 / 11 (9.09%)     | 0 / 15 (0.00%)               |
| occurrences (all)                                     | 0                | 1                  | 0                            |
| Respiratory, thoracic and mediastinal disorders       |                  |                    |                              |

|   |                     |                     |                     |
|---|---------------------|---------------------|---------------------|
| cough<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)  | 0 / 91 (0.00%)<br>0 | 0 / 17 (0.00%)<br>0 | 0 / 19 (0.00%)<br>0 |
| dyspnoea<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)   | 0 / 91 (0.00%)<br>0 | 0 / 17 (0.00%)<br>0 | 0 / 19 (0.00%)<br>0 |
| oropharyngeal pain<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)                                   | 3 / 91 (3.30%)<br>3 | 0 / 17 (0.00%)<br>0 | 0 / 19 (0.00%)<br>0 |
| Psychiatric disorders<br>depression<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)                  | 0 / 91 (0.00%)<br>0 | 0 / 17 (0.00%)<br>0 | 0 / 19 (0.00%)<br>0 |
| Investigations<br>alanine aminotransferase increased<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all) | 0 / 91 (0.00%)<br>0 | 0 / 17 (0.00%)<br>0 | 0 / 19 (0.00%)<br>0 |
| aspartate aminotransferase increased<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)                 | 0 / 91 (0.00%)<br>0 | 0 / 17 (0.00%)<br>0 | 0 / 19 (0.00%)<br>0 |
| blood creatine phosphokinase increased<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)               | 0 / 91 (0.00%)<br>0 | 1 / 17 (5.88%)<br>1 | 0 / 19 (0.00%)<br>0 |
| Cardiac disorders<br>sinus bradycardia<br>alternative dictionary used:<br>MedDRA 17.1   |                     |                     |                     |

|  |                     |                     |                     |
|--|---------------------|---------------------|---------------------|
| subjects affected / exposed<br>occurrences (all)   | 0 / 91 (0.00%)<br>0 | 0 / 17 (0.00%)<br>0 | 0 / 19 (0.00%)<br>0 |
| Nervous system disorders<br>dizziness<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)           | 0 / 91 (0.00%)<br>0 | 0 / 17 (0.00%)<br>0 | 0 / 19 (0.00%)<br>0 |
| headache<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)  | 3 / 91 (3.30%)<br>3 | 0 / 17 (0.00%)<br>0 | 0 / 19 (0.00%)<br>0 |
| Blood and lymphatic system disorders<br>anaemia<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all) | 0 / 91 (0.00%)<br>0 | 0 / 17 (0.00%)<br>0 | 0 / 19 (0.00%)<br>0 |
| Gastrointestinal disorders<br>abdominal pain<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)    | 0 / 91 (0.00%)<br>0 | 0 / 17 (0.00%)<br>0 | 0 / 19 (0.00%)<br>0 |
| abdominal pain upper<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)                            | 0 / 91 (0.00%)<br>0 | 0 / 17 (0.00%)<br>0 | 0 / 19 (0.00%)<br>0 |
| constipation<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)                                    | 0 / 91 (0.00%)<br>0 | 0 / 17 (0.00%)<br>0 | 0 / 19 (0.00%)<br>0 |
| diarrhoea<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)                                       | 2 / 91 (2.20%)<br>2 | 1 / 17 (5.88%)<br>1 | 0 / 19 (0.00%)<br>0 |
| dyspepsia<br>alternative dictionary used:<br>MedDRA 17.1   |                     |                     |                     |

|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed                 | 2 / 91 (2.20%) | 0 / 17 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)                           | 2              | 0              | 0              |
| gastritis                                   |                |                |                |
| alternative dictionary used:<br>MedDRA 17.1 |                |                |                |
| subjects affected / exposed                 | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)                           | 0              | 0              | 0              |
| gastrooesophageal reflux disease            |                |                |                |
| alternative dictionary used:<br>MedDRA 17.1 |                |                |                |
| subjects affected / exposed                 | 2 / 91 (2.20%) | 0 / 17 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)                           | 2              | 0              | 0              |
| lip disorder                                |                |                |                |
| alternative dictionary used:<br>MedDRA 17.1 |                |                |                |
| subjects affected / exposed                 | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)                           | 0              | 0              | 0              |
| mouth ulceration                            |                |                |                |
| alternative dictionary used:<br>MedDRA 17.1 |                |                |                |
| subjects affected / exposed                 | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)                           | 0              | 0              | 0              |
| nausea                                      |                |                |                |
| alternative dictionary used:<br>MedDRA 17.1 |                |                |                |
| subjects affected / exposed                 | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)                           | 0              | 0              | 0              |
| vomiting                                    |                |                |                |
| alternative dictionary used:<br>MedDRA 17.1 |                |                |                |
| subjects affected / exposed                 | 2 / 91 (2.20%) | 0 / 17 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)                           | 2              | 0              | 0              |
| Skin and subcutaneous tissue disorders      |                |                |                |
| acne  |                |                |                |
| alternative dictionary used:<br>MedDRA 17.1 |                |                |                |
| subjects affected / exposed                 | 2 / 91 (2.20%) | 0 / 17 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)                           | 2              | 0              | 0              |
| alopecia                                    |                |                |                |
| alternative dictionary used:<br>MedDRA 17.1 |                |                |                |

|  |  |   |   |
|--|--|---|---|
| <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>dermatitis bullous</p> <p>alternative dictionary used:<br/>MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>  | <p>0 / 91 (0.00%)</p> <p>0</p> <p>0 / 91 (0.00%)</p> <p>0</p>  | <p>0 / 17 (0.00%)</p> <p>0</p> <p>1 / 17 (5.88%)</p> <p>1</p>   | <p>0 / 19 (0.00%)</p> <p>0</p> <p>0 / 19 (0.00%)</p> <p>0</p>   |
| <p>Musculoskeletal and connective tissue disorders</p> <p>arthralgia</p> <p>alternative dictionary used:<br/>MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>back pain</p> <p>alternative dictionary used:<br/>MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>  | <p>0 / 91 (0.00%)</p> <p>0</p> <p>0 / 91 (0.00%)</p> <p>0</p>  | <p>0 / 17 (0.00%)</p> <p>0</p> <p>0 / 17 (0.00%)</p> <p>0</p>   | <p>0 / 19 (0.00%)</p> <p>0</p> <p>0 / 19 (0.00%)</p> <p>0</p>   |
| <p>Infections and infestations</p> <p>bronchitis</p> <p>alternative dictionary used:<br/>MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>gastroenteritis</p> <p>alternative dictionary used:<br/>MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>nasopharyngitis</p> <p>alternative dictionary used:<br/>MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>pharyngitis</p> <p>alternative dictionary used:<br/>MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>rash pustular</p> <p>alternative dictionary used:<br/>MedDRA 17.1</p> | <p>2 / 91 (2.20%)</p> <p>2</p> <p>0 / 91 (0.00%)</p> <p>0</p> <p>0 / 91 (0.00%)</p> <p>0</p> <p>0 / 91 (0.00%)</p> <p>0</p> <p>0 / 91 (0.00%)</p> <p>0</p> | <p>0 / 17 (0.00%)</p> <p>0</p> <p>0 / 17 (0.00%)</p> <p>0</p> <p>0 / 17 (0.00%)</p> <p>0</p> <p>0 / 17 (0.00%)</p> <p>0</p> | <p>0 / 19 (0.00%)</p> <p>0</p> <p>0 / 19 (0.00%)</p> <p>0</p> <p>0 / 19 (0.00%)</p> <p>0</p> <p>0 / 19 (0.00%)</p> <p>0</p> |

|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed                 | 0 / 91 (0.00%) | 1 / 17 (5.88%) | 0 / 19 (0.00%) |
| occurrences (all)                           | 0              | 1              | 0              |
| sinusitis                                   |                |                |                |
| alternative dictionary used:<br>MedDRA 17.1 |                |                |                |
| subjects affected / exposed                 | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)                           | 0              | 0              | 0              |
| upper respiratory tract infection           |                |                |                |
| alternative dictionary used:<br>MedDRA 17.1 |                |                |                |
| subjects affected / exposed                 | 2 / 91 (2.20%) | 0 / 17 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)                           | 2              | 0              | 0              |
| urinary tract infection                     |                |                |                |
| alternative dictionary used:<br>MedDRA 17.1 |                |                |                |
| subjects affected / exposed                 | 3 / 91 (3.30%) | 0 / 17 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)                           | 3              | 0              | 0              |
| Metabolism and nutrition disorders          |                |                |                |
| hypercholesterolaemia                       |                |                |                |
| alternative dictionary used:<br>MedDRA 17.1 |                |                |                |
| subjects affected / exposed                 | 4 / 91 (4.40%) | 0 / 17 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)                           | 4              | 0              | 0              |
| hyperlipidaemia                             |                |                |                |
| alternative dictionary used:<br>MedDRA 17.1 |                |                |                |
| subjects affected / exposed                 | 0 / 91 (0.00%) | 0 / 17 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all)                           | 0              | 0              | 0              |

|  |                                 |  |  |
|--|---------------------------------|--|--|
| <b>Non-serious adverse events</b>                        | Baricitinib 4 mg –<br>Follow Up |  |  |
| Total subjects affected by non-serious<br>adverse events |                                 |  |  |
| subjects affected / exposed                              | 4 / 22 (18.18%)                 |  |  |
| Vascular disorders                                       |                                 |  |  |
| hypertension   |                                 |  |  |
| alternative dictionary used:<br>MedDRA 17.1              |                                 |  |  |
| subjects affected / exposed                              | 0 / 22 (0.00%)                  |  |  |
| occurrences (all)  | 0                               |  |  |
| General disorders and administration<br>site conditions  |                                 |  |  |
| fatigue  |                                 |  |  |
| alternative dictionary used:<br>MedDRA 17.1              |                                 |  |  |

|  |  |  |  |
|--|--|--|--|
| <p>subjects affected / exposed</p> <p>0 / 22 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>oedema peripheral</p> <p>alternative dictionary used:<br/>MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>0 / 22 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>pyrexia</p> <p>alternative dictionary used:<br/>MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>0 / 22 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>   |  |  |  |
| <p>Reproductive system and breast disorders</p> <p>erectile dysfunction</p> <p>alternative dictionary used:<br/>MedDRA 17.1</p> <p>subjects affected / exposed<sup>[1]</sup></p> <p>0 / 3 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>vulvovaginal pruritus</p> <p>alternative dictionary used:<br/>MedDRA 17.1</p> <p>subjects affected / exposed<sup>[2]</sup></p> <p>0 / 19 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>  |  |  |  |
| <p>Respiratory, thoracic and mediastinal disorders</p> <p>cough</p> <p>alternative dictionary used:<br/>MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>1 / 22 (4.55%)</p> <p>occurrences (all)</p> <p>1</p> <p>dyspnoea</p> <p>alternative dictionary used:<br/>MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>1 / 22 (4.55%)</p> <p>occurrences (all)</p> <p>1</p> <p>oropharyngeal pain</p> <p>alternative dictionary used:<br/>MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>0 / 22 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> |  |  |  |
| Psychiatric disorders  |  |  |  |

|   |   |  |  |
|---|---|--|--|
| depression<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)   | 0 / 22 (0.00%)<br>0   |  |  |
| Investigations<br>alanine aminotransferase increased<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)<br><br>aspartate aminotransferase increased<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)<br><br>blood creatine phosphokinase increased<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all) | 0 / 22 (0.00%)<br>0<br><br>0 / 22 (0.00%)<br>0<br><br>0 / 22 (0.00%)<br>0 |  |  |
| Cardiac disorders<br>sinus bradycardia<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)   | 1 / 22 (4.55%)<br>1   |  |  |
| Nervous system disorders<br>dizziness<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)<br><br>headache<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)   | 0 / 22 (0.00%)<br>0<br><br>0 / 22 (0.00%)<br>0                            |  |  |
| Blood and lymphatic system disorders<br>anaemia<br>alternative dictionary used:<br>MedDRA 17.1  |   |  |  |



|   |                |  |  |
|---|----------------|--|--|
| subjects affected / exposed                 | 0 / 22 (0.00%) |  |  |
| occurrences (all)                           | 0              |  |  |
| Gastrointestinal disorders                  |                |  |  |
| abdominal pain                              |                |  |  |
| alternative dictionary used:<br>MedDRA 17.1 |                |  |  |
| subjects affected / exposed                 | 0 / 22 (0.00%) |  |  |
| occurrences (all)                           | 0              |  |  |
| abdominal pain upper                        |                |  |  |
| alternative dictionary used:<br>MedDRA 17.1 |                |  |  |
| subjects affected / exposed                 | 0 / 22 (0.00%) |  |  |
| occurrences (all)                           | 0              |  |  |
| constipation                                |                |  |  |
| alternative dictionary used:<br>MedDRA 17.1 |                |  |  |
| subjects affected / exposed                 | 0 / 22 (0.00%) |  |  |
| occurrences (all)                           | 0              |  |  |
| diarrhoea                                   |                |  |  |
| alternative dictionary used:<br>MedDRA 17.1 |                |  |  |
| subjects affected / exposed                 | 0 / 22 (0.00%) |  |  |
| occurrences (all)                           | 0              |  |  |
| dyspepsia                                   |                |  |  |
| alternative dictionary used:<br>MedDRA 17.1 |                |  |  |
| subjects affected / exposed                 | 0 / 22 (0.00%) |  |  |
| occurrences (all)                           | 0              |  |  |
| gastritis                                   |                |  |  |
| alternative dictionary used:<br>MedDRA 17.1 |                |  |  |
| subjects affected / exposed                 | 1 / 22 (4.55%) |  |  |
| occurrences (all)                           | 1              |  |  |
| gastrooesophageal reflux disease            |                |  |  |
| alternative dictionary used:<br>MedDRA 17.1 |                |  |  |
| subjects affected / exposed                 | 0 / 22 (0.00%) |  |  |
| occurrences (all)                           | 0              |  |  |
| lip disorder                                |                |  |  |
| alternative dictionary used:<br>MedDRA 17.1 |                |  |  |

|  |  |  |  |
|--|--|--|--|
| <p>subjects affected / exposed</p> <p>1 / 22 (4.55%)</p> <p>occurrences (all)</p> <p>1</p>   |  |  |  |
| <p>mouth ulceration</p> <p>alternative dictionary used:<br/>MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>0 / 22 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>   |  |  |  |
| <p>nausea</p> <p>alternative dictionary used:<br/>MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>0 / 22 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>   |  |  |  |
| <p>vomiting</p> <p>alternative dictionary used:<br/>MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>0 / 22 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>   |  |  |  |
| <p>Skin and subcutaneous tissue disorders</p> <p>acne</p> <p>alternative dictionary used:<br/>MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>0 / 22 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>alopecia</p> <p>alternative dictionary used:<br/>MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>0 / 22 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>dermatitis bullous</p> <p>alternative dictionary used:<br/>MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>0 / 22 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> |  |  |  |
| <p>Musculoskeletal and connective tissue disorders</p> <p>arthralgia</p> <p>alternative dictionary used:<br/>MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>0 / 22 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>back pain</p> <p>alternative dictionary used:<br/>MedDRA 17.1</p>   |  |  |  |

|  |                     |  |  |
|--|---------------------|--|--|
| subjects affected / exposed  | 0 / 22 (0.00%)      |  |  |
| occurrences (all)  | 0                   |  |  |
| Infections and infestations<br>bronchitis<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all) | 0 / 22 (0.00%)<br>0 |  |  |
| gastroenteritis<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)                           | 0 / 22 (0.00%)<br>0 |  |  |
| nasopharyngitis<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)                           | 0 / 22 (0.00%)<br>0 |  |  |
| pharyngitis<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)                               | 0 / 22 (0.00%)<br>0 |  |  |
| rash pustular<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)                             | 0 / 22 (0.00%)<br>0 |  |  |
| sinusitis<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)                                 | 0 / 22 (0.00%)<br>0 |  |  |
| upper respiratory tract infection<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)         | 0 / 22 (0.00%)<br>0 |  |  |
| urinary tract infection<br>alternative dictionary used:<br>MedDRA 17.1   |                     |  |  |

|  |                     |  |  |
|--|---------------------|--|--|
| subjects affected / exposed<br>occurrences (all)   | 0 / 22 (0.00%)<br>0 |  |  |
| Metabolism and nutrition disorders<br>hypercholesterolaemia<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all) | 0 / 22 (0.00%)<br>0 |  |  |
| hyperlipidaemia<br>alternative dictionary used:<br>MedDRA 17.1<br>subjects affected / exposed<br>occurrences (all)   | 0 / 22 (0.00%)<br>0 |  |  |

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

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

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|---------------|
| None reported |
|---------------|

Notes: