



## Clinical trial results:

**Multicenter, open label study to evaluate the predictability of early response to certolizumab pegol (in combination with methotrexate) as confirmed at week 52 in subjects with moderate-severe rheumatoid arthritis (RA)**

### Summary

|                          |                |
|--------------------------|----------------|
| EudraCT number           | 2011-000385-35 |
| Trial protocol           | IT             |
| Global end of trial date | 12 May 2015    |

### Results information

|                                |                  |
|--------------------------------|------------------|
| Result version number          | v1 (current)     |
| This version publication date  | 05 February 2016 |
| First version publication date | 05 February 2016 |

### Trial information

#### Trial identification

|                       |        |
|-----------------------|--------|
| Sponsor protocol code | RA0069 |
|-----------------------|--------|

#### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT01443364 |
| WHO universal trial number (UTN)   | -           |

Notes:

### Sponsors

|                              |   |
|------------------------------|---|
| Sponsor organisation name    | UCB Pharma S.p.a.   |
| Sponsor organisation address | Via Gadames 57, Milano, Italy, 20151  |
| Public contact               | Clinical Trial Registries and Results Disclosure, UCB BIOSCIENCES GmbH, +49 2173 48 15 15, clinicaltrials@ucb.com |
| Scientific contact           | Clinical Trial Registries and Results Disclosure, UCB BIOSCIENCES GmbH, +49 2173 48 15 15, clinicaltrials@ucb.com |

Notes:

### Paediatric regulatory details

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

Notes:

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**Results analysis stage**

|  |              |
|--|--------------|
| Analysis stage                                       | Final        |
| Date of interim/final analysis                       | 09 July 2015 |
| Is this the analysis of the primary completion data? | No           |
| Global end of trial reached?                         | Yes          |
| Global end of trial date                             | 12 May 2015  |
| Was the trial ended prematurely?                     | No           |

Notes:

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**General information about the trial**

Main objective of the trial:

To detect the time-point of clinical response with the highest predictive value of long term efficacy (at Week 52).

Protection of trial subjects:

Not applicable

Background therapy:

Not applicable

Evidence for comparator:

Not applicable

|   |                  |
|---|------------------|
| Actual start date of recruitment                          | 05 December 2011 |
| Long term follow-up planned                               | No               |
| Independent data monitoring committee (IDMC) involvement? | No               |

Notes:

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**Population of trial subjects**

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**Subjects enrolled per country**

|                                      |            |
|--------------------------------------|------------|
| Country: Number of subjects enrolled | Italy: 132 |
| Worldwide total number of subjects   | 132        |
| EEA total number of subjects         | 132        |

Notes:

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**Subjects enrolled per age group**

|   |    |
|---|----|
| In utero                                  | 0  |
| Preterm newborn - gestational age < 37 wk | 0  |
| Newborns (0-27 days)                      | 0  |
| Infants and toddlers (28 days-23 months)  | 0  |
| Children (2-11 years)                     | 0  |
| Adolescents (12-17 years)                 | 0  |
| Adults (18-64 years)                      | 94 |
| From 65 to 84 years                       | 38 |
| 85 years and over                         | 0  |

## Subject disposition

### Recruitment

Recruitment details:

This study started to enroll patients in December 2011 and concluded in May 2015.

### Pre-assignment

Screening details:

Participant Flow refers to all subjects randomized who have received at least one dose of study medication.

### Period 1

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

### Arms

|                  |                    |
|------------------|--------------------|
| <b>Arm title</b> | Certolizumab pegol |
|------------------|--------------------|

Arm description:

Subjects will be treated for 52 weeks with Certolizumab Pegol (CZP) (administration every two weeks) in combination with Methotrexate (MTX) (administration weekly). Dosing regimen of CZP consists of 3 administrations of 400 mg at Weeks 0, 2 and 4 followed by 200 mg every other week up to and including Week 50.

|  |   |
|--|---|
| Arm type                               | Experimental                                |
| Investigational medicinal product name | Certolizumab pegol                          |
| Investigational medicinal product code | Cimzia                                      |
| Other name                             |   |
| Pharmaceutical forms                   | Solution for infusion in pre-filled syringe |
| Routes of administration               | Subcutaneous use                            |

Dosage and administration details:

Pre-filled syringe with 1 ml of liquid at CZP dosage of 200 mg/ml

| Number of subjects in period 1           | Certolizumab pegol |
|--|--------------------|
| Started                                  | 132                |
| Completed                                | 91                 |
| Not completed                            | 41                 |
| Consent withdrawn by subject             | 5                  |
| Other Reason                             | 4                  |
| AE, non-serious non-fatal                | 8                  |
| SAE, non-fatal+AE, non-serious non-fatal | 1                  |
| Lost to follow-up                        | 3                  |
| SAE, non-fatal                           | 6                  |
| Lack of efficacy                         | 14                 |



## Baseline characteristics

### Reporting groups

|                       |                    |
|-----------------------|--------------------|
| Reporting group title | Certolizumab pegol |
|-----------------------|--------------------|

Reporting group description:

Subjects will be treated for 52 weeks with Certolizumab Pegol (CZP) (administration every two weeks) in combination with Methotrexate (MTX) (administration weekly). Dosing regimen of CZP consists of 3 administrations of 400 mg at Weeks 0, 2 and 4 followed by 200 mg every other week up to and including Week 50.

| Reporting group values  | Certolizumab pegol | Total |  |
|-------------------------|--------------------|-------|--|
| Number of subjects      | 132                | 132   |  |
| Age Categorical         |                    |       |  |
| Units: Subjects         |                    |       |  |
| <=18 years              | 0                  | 0     |  |
| Between 18 and 65 years | 94                 | 94    |  |
| >=65 years              | 38                 | 38    |  |
| Age Continuous          |                    |       |  |
| Units: years            |                    |       |  |
| arithmetic mean         | 54.8               |       |  |
| standard deviation      | ± 13.2             | -     |  |
| Gender Categorical      |                    |       |  |
| Units: Subjects         |                    |       |  |
| Female                  | 108                | 108   |  |
| Male                    | 24                 | 24    |  |
| Ethnicity (NIH/OMB)     |                    |       |  |
| Units: Subjects         |                    |       |  |
| Hispanic or Latino      | 35                 | 35    |  |
| Not Hispanic or Latino  | 97                 | 97    |  |
| Weight                  |                    |       |  |
| Units: kilogram         |                    |       |  |
| arithmetic mean         | 69.33              |       |  |
| standard deviation      | ± 14.1             | -     |  |
| BMI                     |                    |       |  |
| Units: kg/m^2           |                    |       |  |
| arithmetic mean         | 25.66              |       |  |
| standard deviation      | ± 4.52             | -     |  |
| Height                  |                    |       |  |
| Units: centimeter       |                    |       |  |
| arithmetic mean         | 164.16             |       |  |
| standard deviation      | ± 8.48             | -     |  |

## End points

### End points reporting groups

|  |                          |
|--|--------------------------|
| Reporting group title  | Certolizumab pegol       |
| Reporting group description:<br>Subjects will be treated for 52 weeks with Certolizumab Pegol (CZP) (administration every two weeks) in combination with Methotrexate (MTX) (administration weekly). Dosing regimen of CZP consists of 3 administrations of 400 mg at Weeks 0, 2 and 4 followed by 200 mg every other week up to and including Week 50.      |                          |
| Subject analysis set title   | Certolizumab pegol (FAS) |
| Subject analysis set type  | Full analysis            |
| Subject analysis set description:<br>Subjects will be treated for 52 weeks with Certolizumab Pegol (CZP) (administration every two weeks) in combination with Methotrexate (MTX) (administration weekly). Dosing regimen of CZP consists of 3 administrations of 400 mg at Weeks 0, 2 and 4 followed by 200 mg every other week up to and including Week 50. |                          |

### Primary: The percentage of subjects with clinical response at Week 12 who also had clinical response at Week 52

|   |   |
|---|---|
| End point title   | The percentage of subjects with clinical response at Week 12 who also had clinical response at Week 52 <sup>[1]</sup> |
| End point description:<br>Clinical response is defined as a reduction from Baseline (Week 0) of more than 1.2 scores in the Disease Activity Score <sub>28</sub> [Erythrocyte Sedimentation Rate] (DAS <sub>28</sub> -ESR) scoring system |   |
| End point type  | Primary   |
| End point timeframe:<br>From Baseline to Week 12 and Week 52  |   |

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No formal statistical hypothesis testing was planned for this study. Results were summarized in tables as descriptive statistics only.

| End point values                 | Certolizumab pegol (FAS) |  |  |  |
|----------------------------------|--------------------------|--|--|--|
| Subject group type               | Subject analysis set     |  |  |  |
| Number of subjects analysed      | 131                      |  |  |  |
| Units: percentage of subjects    |                          |  |  |  |
| number (confidence interval 95%) |                          |  |  |  |
| percentage of subjects           | 69.1 (58.78 to 78.27)    |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Primary: The percentage of subjects with clinical response at Week 8 who also had clinical response at Week 52

|   |  |
|---|--|
| End point title   | The percentage of subjects with clinical response at Week 8 who also had clinical response at Week 52 <sup>[2]</sup> |
| End point description:<br>Clinical response is defined as a reduction from Baseline (Week 0) of more than 1.2 scores in the Disease Activity Score <sub>28</sub> [Erythrocyte Sedimentation Rate] (DAS <sub>28</sub> -ESR) scoring system |  |

|   |         |
|---|---------|
| End point type  | Primary |
| End point timeframe:  |         |
| From Baseline to Week 8 and Week 52   |         |
| Notes:  |         |
| [2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. |         |
| Justification: No formal statistical hypothesis testing was planned for this study. Results were summarized in tables as descriptive statistics only.               |         |

|                                  |                          |  |  |  |
|----------------------------------|--------------------------|--|--|--|
| <b>End point values</b>          | Certolizumab pegol (FAS) |  |  |  |
| Subject group type               | Subject analysis set     |  |  |  |
| Number of subjects analysed      | 131                      |  |  |  |
| Units: percentage of subjects    |                          |  |  |  |
| number (confidence interval 95%) |                          |  |  |  |
| percentage of subjects           | 69.8 (59.57 to 78.75)    |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: The percentage of subjects with clinical response at Week 6 who also had clinical response at Week 52

|   |  |
|---|--|
| End point title   | The percentage of subjects with clinical response at Week 6 who also had clinical response at Week 52 <sup>[3]</sup> |
| End point description:  |  |
| Clinical response is defined as a reduction from Baseline (Week 0) of more than 1.2 scores in the Disease Activity Score <sub>28</sub> [Erythrocyte Sedimentation Rate] (DAS <sub>28</sub> -ESR) scoring system |  |
| End point type  | Primary  |
| End point timeframe:  |  |
| From Baseline to Week 6 and Week 52   |  |
| Notes:  |  |
| [3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.   |  |
| Justification: No formal statistical hypothesis testing was planned for this study. Results were summarized in tables as descriptive statistics only.   |  |

|                                  |                          |  |  |  |
|----------------------------------|--------------------------|--|--|--|
| <b>End point values</b>          | Certolizumab pegol (FAS) |  |  |  |
| Subject group type               | Subject analysis set     |  |  |  |
| Number of subjects analysed      | 131                      |  |  |  |
| Units: percentage of subjects    |                          |  |  |  |
| number (confidence interval 95%) |                          |  |  |  |
| percentage of subjects           | 65.2 (54.33 to 74.96)    |  |  |  |

## Statistical analyses

No statistical analyses for this end point

**Primary: The percentage of subjects with clinical response at Week 4 who also had clinical response at Week 52**

|                 |  |
|-----------------|--|
| End point title | The percentage of subjects with clinical response at Week 4 who also had clinical response at Week 52 <sup>[4]</sup> |
|-----------------|--|

End point description:

Clinical response is defined as a reduction from Baseline (Week 0) of more than 1.2 scores in the Disease Activity Score<sub>28</sub> [Erythrocyte Sedimentation Rate] (DAS<sub>28</sub>-ESR) scoring system

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

End point timeframe:

From Baseline to Week 4 and Week 52

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No formal statistical hypothesis testing was planned for this study. Results were summarized in tables as descriptive statistics only.

|                                  |                          |  |  |  |
|----------------------------------|--------------------------|--|--|--|
| <b>End point values</b>          | Certolizumab pegol (FAS) |  |  |  |
| Subject group type               | Subject analysis set     |  |  |  |
| Number of subjects analysed      | 131                      |  |  |  |
| Units: percentage of subjects    |                          |  |  |  |
| number (confidence interval 95%) |                          |  |  |  |
| percentage of subjects           | 66.7 (56.13 to 76.11)    |  |  |  |

**Statistical analyses**

No statistical analyses for this end point

**Primary: The percentage of subjects with clinical response at Week 2 who also had clinical response at Week 52**

|                 |  |
|-----------------|--|
| End point title | The percentage of subjects with clinical response at Week 2 who also had clinical response at Week 52 <sup>[5]</sup> |
|-----------------|--|

End point description:

Clinical response is defined as a reduction from Baseline (Week 0) of more than 1.2 scores in the Disease Activity Score<sub>28</sub> [Erythrocyte Sedimentation Rate] (DAS<sub>28</sub>-ESR) scoring system

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

End point timeframe:

From Baseline to Week 2 and Week 52

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No formal statistical hypothesis testing was planned for this study. Results were summarized in tables as descriptive statistics only.

|                                  |                          |  |  |  |
|----------------------------------|--------------------------|--|--|--|
| <b>End point values</b>          | Certolizumab pegol (FAS) |  |  |  |
| Subject group type               | Subject analysis set     |  |  |  |
| Number of subjects analysed      | 131                      |  |  |  |
| Units: percentage of subjects    |                          |  |  |  |
| number (confidence interval 95%) |                          |  |  |  |
| percentage of subjects           | 64.9 (52.89 to 75.61)    |  |  |  |



## Statistical analyses

No statistical analyses for this end point

### Primary: The percentage of subjects with clinical response at Week 1 who also had clinical response at Week 52

|                 |  |
|-----------------|--|
| End point title | The percentage of subjects with clinical response at Week 1 who also had clinical response at Week 52 <sup>[6]</sup> |
|-----------------|--|

End point description:

Clinical response is defined as a reduction from Baseline (Week 0) of more than 1.2 scores in the Disease Activity Score<sub>28</sub> [Erythrocyte Sedimentation Rate] (DAS<sub>28</sub>-ESR) scoring system

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

End point timeframe:

From Baseline to Week 1 and Week 52

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No formal statistical hypothesis testing was planned for this study. Results were summarized in tables as descriptive statistics only.

|                                  |                          |  |  |  |
|----------------------------------|--------------------------|--|--|--|
| <b>End point values</b>          | Certolizumab pegol (FAS) |  |  |  |
| Subject group type               | Subject analysis set     |  |  |  |
| Number of subjects analysed      | 131                      |  |  |  |
| Units: percentage of subjects    |                          |  |  |  |
| number (confidence interval 95%) |                          |  |  |  |
| percentage of subjects           | 55.8 (39.88 to 70.92)    |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the synovial fluid and proliferation at Week 52

|                 |   |
|-----------------|---|
| End point title | Change from Baseline in the synovial fluid and proliferation at Week 52 |
|-----------------|---|

End point description:

The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

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

End point timeframe:

From Baseline to Week 52

|                               |                          |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| <b>End point values</b>       | Certolizumab pegol (FAS) |  |  |  |
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 59                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -1 (-9 to 4)             |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the synovial fluid and proliferation at Week 36

|   |   |
|---|---|
| End point title   | Change from Baseline in the synovial fluid and proliferation at Week 36 |
| End point description:<br>The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity. |   |
| End point type  | Secondary   |
| End point timeframe:<br>From Baseline to Week 36  |   |

|                               |                          |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| <b>End point values</b>       | Certolizumab pegol (FAS) |  |  |  |
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 59                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -1 (-9 to 4)             |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the synovial fluid and proliferation at Week 24

|   |   |
|---|---|
| End point title   | Change from Baseline in the synovial fluid and proliferation at Week 24 |
| End point description:<br>The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity. |   |
| End point type  | Secondary   |
| End point timeframe:<br>From Baseline to Week 24  |   |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 58                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -1 (-9 to 4)             |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the synovial fluid and proliferation at Week 12

|   |   |
|---|---|
| End point title   | Change from Baseline in the synovial fluid and proliferation at Week 12 |
| End point description:<br>The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity. |   |
| End point type  | Secondary   |
| End point timeframe:<br>From Baseline to Week 12  |   |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 58                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -1 (-12 to 5)            |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the synovial fluid and proliferation at Week 8

|   |  |
|---|--|
| End point title   | Change from Baseline in the synovial fluid and proliferation at Week 8 |
| End point description:<br>The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity. |  |
| End point type  | Secondary  |

End point timeframe:  
From Baseline to Week 8

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 58                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -1 (-12 to 2)            |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the synovial fluid and proliferation at Week 6

|                 |  |
|-----------------|--|
| End point title | Change from Baseline in the synovial fluid and proliferation at Week 6 |
|-----------------|--|

End point description:

The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

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

End point timeframe:

From Baseline to Week 6

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 58                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -1 (-10 to 2)            |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the synovial fluid and proliferation at Week 4

|                 |  |
|-----------------|--|
| End point title | Change from Baseline in the synovial fluid and proliferation at Week 4 |
|-----------------|--|

End point description:

The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

|                         |           |
|-------------------------|-----------|
| End point type          | Secondary |
| End point timeframe:    |           |
| From Baseline to Week 4 |           |

|                               |                          |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| <b>End point values</b>       | Certolizumab pegol (FAS) |  |  |  |
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 58                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -1 (-8 to 4)             |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the synovial fluid and proliferation at Week 2

|   |  |
|---|--|
| End point title   | Change from Baseline in the synovial fluid and proliferation at Week 2 |
| End point description:  |  |
| The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity. |  |
| End point type  | Secondary  |
| End point timeframe:  |  |
| From Baseline to Week 2   |  |

|                               |                          |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| <b>End point values</b>       | Certolizumab pegol (FAS) |  |  |  |
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 57                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -1 (-5 to 4)             |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the synovial fluid and proliferation at Week 1

|                 |  |
|-----------------|--|
| End point title | Change from Baseline in the synovial fluid and proliferation at Week 1 |
|-----------------|--|

End point description:

The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score

indicates greater disease activity.

|                         |           |
|-------------------------|-----------|
| End point type          | Secondary |
| End point timeframe:    |           |
| From Baseline to Week 1 |           |

|                               |                          |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| <b>End point values</b>       | Certolizumab pegol (FAS) |  |  |  |
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 53                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 0 (-5 to 3)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the Doppler signal and blood flow at Week 52

|                 |  |
|-----------------|--|
| End point title | Change from Baseline in the Doppler signal and blood flow at Week 52 |
|-----------------|--|

End point description:

The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

|                          |           |
|--------------------------|-----------|
| End point type           | Secondary |
| End point timeframe:     |           |
| From Baseline to Week 52 |           |

|                               |                          |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| <b>End point values</b>       | Certolizumab pegol (FAS) |  |  |  |
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 59                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -1 (-12 to 4)            |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the Doppler signal and blood flow at Week 36

|                 |  |
|-----------------|--|
| End point title | Change from Baseline in the Doppler signal and blood flow at Week 36 |
|-----------------|--|

End point description:

The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

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

End point timeframe:

From Baseline to Week 36

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 59                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -1 (-11 to 4)            |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the Doppler signal and blood flow at Week 24

|                 |  |
|-----------------|--|
| End point title | Change from Baseline in the Doppler signal and blood flow at Week 24 |
|-----------------|--|

End point description:

The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

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

End point timeframe:

From Baseline to Week 24

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 58                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -1 (-11 to 6)            |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the Doppler signal and blood flow at Week 12

|                 |  |
|-----------------|--|
| End point title | Change from Baseline in the Doppler signal and blood flow at |
|-----------------|--|

End point description:

The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type Secondary

End point timeframe:

From Baseline to Week 12

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 58                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -1 (-12 to 9)            |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the Doppler signal and blood flow at Week 8

End point title Change from Baseline in the Doppler signal and blood flow at Week 8

End point description:

The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

End point type Secondary

End point timeframe:

From Baseline to Week 8

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 58                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -1 (-12 to 2)            |  |  |  |

### Statistical analyses

No statistical analyses for this end point



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**Secondary: Change from Baseline in the Doppler signal and blood flow at Week 6**

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|                 |   |
|-----------------|---|
| End point title | Change from Baseline in the Doppler signal and blood flow at Week 6 |
|-----------------|---|

End point description:

The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

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

End point timeframe:

From Baseline to Week 6

---

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 58                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -1 (-12 to 2)            |  |  |  |

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**Statistical analyses**

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No statistical analyses for this end point

---

**Secondary: Change from Baseline in the Doppler signal and blood flow at Week 4**

---

|                 |   |
|-----------------|---|
| End point title | Change from Baseline in the Doppler signal and blood flow at Week 4 |
|-----------------|---|

End point description:

The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

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

End point timeframe:

From Baseline to Week 4

---

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 58                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -0.5 (-10 to 2)          |  |  |  |

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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 the Doppler signal and blood flow at Week 2**

---

|                 |   |
|-----------------|---|
| End point title | Change from Baseline in the Doppler signal and blood flow at Week 2 |
|-----------------|---|

End point description:

The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

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

End point timeframe:

From Baseline to Week 2

---

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 57                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 0 (-10 to 3)             |  |  |  |

---

**Statistical analyses**

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No statistical analyses for this end point

---

**Secondary: Change from Baseline in the Doppler signal and blood flow at Week 1**

---

|                 |   |
|-----------------|---|
| End point title | Change from Baseline in the Doppler signal and blood flow at Week 1 |
|-----------------|---|

End point description:

The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity.

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

End point timeframe:

From Baseline to Week 1

---

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 53                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 0 (-10 to 3)             |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the Cartilage damage at Week 52

|                 |   |
|-----------------|---|
| End point title | Change from Baseline in the Cartilage damage at Week 52 |
|-----------------|---|

End point description:

The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

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

End point timeframe:

From Baseline to Week 52

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 55                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 0 (-11 to 8)             |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the Cartilage damage at Week 36

|                 |   |
|-----------------|---|
| End point title | Change from Baseline in the Cartilage damage at Week 36 |
|-----------------|---|

End point description:

The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

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

End point timeframe:

From Baseline to Week 36

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 55                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 0 (-12 to 16)            |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the Cartilage damage at Week 24

|                 |   |
|-----------------|---|
| End point title | Change from Baseline in the Cartilage damage at Week 24 |
|-----------------|---|

End point description:

The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

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

End point timeframe:

From Baseline to Week 24

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 54                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 0 (-13 to 11)            |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the Cartilage damage at Week 12

|                 |   |
|-----------------|---|
| End point title | Change from Baseline in the Cartilage damage at Week 12 |
|-----------------|---|

End point description:

The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

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

End point timeframe:

From Baseline to Week 12

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 54                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 0 (-11 to 11)            |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the Cartilage damage at Week 8

|                 |  |
|-----------------|--|
| End point title | Change from Baseline in the Cartilage damage at Week 8 |
|-----------------|--|

End point description:

The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

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

End point timeframe:

From Baseline to Week 8

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 54                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 0 (-11 to 9)             |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the Cartilage damage at Week 6

|                 |  |
|-----------------|--|
| End point title | Change from Baseline in the Cartilage damage at Week 6 |
|-----------------|--|

End point description:

The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

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

End point timeframe:

From Baseline to Week 6

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 54                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 0 (-11 to 7)             |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the Cartilage damage at Week 4

|                 |  |
|-----------------|--|
| End point title | Change from Baseline in the Cartilage damage at Week 4 |
|-----------------|--|

End point description:

The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

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

End point timeframe:

From Baseline to Week 4

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 54                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 0 (-11 to 4)             |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the Cartilage damage at Week 2

|                 |  |
|-----------------|--|
| End point title | Change from Baseline in the Cartilage damage at Week 2 |
|-----------------|--|

End point description:

The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

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

End point timeframe:

From Baseline to Week 2

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 53                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 0 (-11 to 9)             |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the Cartilage damage at Week 1

|                 |  |
|-----------------|--|
| End point title | Change from Baseline in the Cartilage damage at Week 1 |
|-----------------|--|

End point description:

The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

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

End point timeframe:

From Baseline to Week 1

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 50                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 0 (-8 to 4)              |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the bone erosion at Week 52

|                 |   |
|-----------------|---|
| End point title | Change from Baseline in the bone erosion at Week 52 |
|-----------------|---|

End point description:

The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

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

End point timeframe:

From Baseline to Week 52

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 59                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 0 (-5 to 3)              |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the bone erosion at Week 36

|   |   |
|---|---|
| End point title   | Change from Baseline in the bone erosion at Week 36 |
| End point description:<br>The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity. |   |
| End point type  | Secondary   |
| End point timeframe:<br>From Baseline to Week 36  |   |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 59                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 0 (-5 to 4)              |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the bone erosion at Week 24

|   |   |
|---|---|
| End point title   | Change from Baseline in the bone erosion at Week 24 |
| End point description:<br>The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity. |   |
| End point type  | Secondary   |
| End point timeframe:<br>From Baseline to Week 24  |   |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 58                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 0 (-5 to 10)             |  |  |  |



## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the bone erosion at Week 12

|   |   |
|---|---|
| End point title   | Change from Baseline in the bone erosion at Week 12 |
| End point description:<br>The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity. |   |
| End point type  | Secondary   |
| End point timeframe:<br>From Baseline to Week 12  |   |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 58                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 0 (-5 to 3)              |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the bone erosion at Week 8

|   |  |
|---|--|
| End point title   | Change from Baseline in the bone erosion at Week 8 |
| End point description:<br>The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity. |  |
| End point type  | Secondary  |
| End point timeframe:<br>From Baseline to Week 8   |  |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 58                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 0 (-5 to 5)              |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the bone erosion at Week 6

|                 |  |
|-----------------|--|
| End point title | Change from Baseline in the bone erosion at Week 6 |
|-----------------|--|

End point description:

The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

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

End point timeframe:

From Baseline to Week 6

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 58                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 0 (-5 to 3)              |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the bone erosion at Week 4

|                 |  |
|-----------------|--|
| End point title | Change from Baseline in the bone erosion at Week 4 |
|-----------------|--|

End point description:

The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

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

End point timeframe:

From Baseline to Week 4

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 58                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 0 (-5 to 3)              |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the bone erosion at Week 2

|                 |  |
|-----------------|--|
| End point title | Change from Baseline in the bone erosion at Week 2 |
|-----------------|--|

End point description:

The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

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

End point timeframe:

From Baseline to Week 2

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 57                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 0 (-4 to 2)              |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the bone erosion at Week 1

|                 |  |
|-----------------|--|
| End point title | Change from Baseline in the bone erosion at Week 1 |
|-----------------|--|

End point description:

The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity.

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

End point timeframe:

From Baseline to Week 1

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 53                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 0 (-4 to 2)              |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 52

|                 |  |
|-----------------|--|
| End point title | Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 52 |
|-----------------|--|

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

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

End point timeframe:

From Baseline to Week 52

|                               |                          |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| <b>End point values</b>       | Certolizumab pegol (FAS) |  |  |  |
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 59                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -3 (-20 to 5)            |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 36

|                 |  |
|-----------------|--|
| End point title | Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 36 |
|-----------------|--|

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

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

End point timeframe:

From Baseline to Week 36

|                               |                          |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| <b>End point values</b>       | Certolizumab pegol (FAS) |  |  |  |
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 59                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -3 (-20 to 6)            |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 24

|                        |   |
|------------------------|---|
| End point title        | Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 24  |
| End point description: | The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity. |
| End point type         | Secondary   |
| End point timeframe:   | From Baseline to Week 24  |

|                               |                          |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| <b>End point values</b>       | Certolizumab pegol (FAS) |  |  |  |
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 58                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -3 (-20 to 10)           |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 12

|                        |   |
|------------------------|---|
| End point title        | Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 12  |
| End point description: | The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity. |
| End point type         | Secondary   |
| End point timeframe:   | From Baseline to Week 12  |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 58                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -3 (-23 to 14)           |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 8

|                 |   |
|-----------------|---|
| End point title | Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 8 |
|-----------------|---|

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

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

End point timeframe:

From Baseline to Week 8

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 58                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -3 (-23 to 3)            |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 6

|                 |   |
|-----------------|---|
| End point title | Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 6 |
|-----------------|---|

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

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

End point timeframe:

From Baseline to Week 6

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 58                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -2.5 (-20 to 3)          |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 4

|                 |   |
|-----------------|---|
| End point title | Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 4 |
|-----------------|---|

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

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

End point timeframe:

From Baseline to Week 4

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 58                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -2.5 (-17 to 4)          |  |  |  |

### Statistical analyses

No statistical analyses for this end point

**Secondary: Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 2**

|                 |   |
|-----------------|---|
| End point title | Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 2 |
|-----------------|---|

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

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

End point timeframe:

From Baseline to Week 2

|                               |                          |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| <b>End point values</b>       | Certolizumab pegol (FAS) |  |  |  |
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 57                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -2 (-13 to 4)            |  |  |  |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 1**

|                 |   |
|-----------------|---|
| End point title | Change from Baseline in Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 1 |
|-----------------|---|

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

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

End point timeframe:

From Baseline to Week 1

|                               |                          |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| <b>End point values</b>       | Certolizumab pegol (FAS) |  |  |  |
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 53                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -1 (-13 to 3)            |  |  |  |



## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 52

|                 |  |
|-----------------|--|
| End point title | Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 52 |
|-----------------|--|

End point description:

The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity.

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

End point timeframe:

From Baseline to Week 52

|                               |                          |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| End point values              | Certolizumab pegol (FAS) |  |  |  |
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 55                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -2 (-15 to 9)            |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 36

|                 |  |
|-----------------|--|
| End point title | Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 36 |
|-----------------|--|

End point description:

The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity.

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

End point timeframe:

From Baseline to Week 36

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 55                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -2 (-15 to 17)           |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 24

|                        |  |
|------------------------|--|
| End point title        | Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 24   |
| End point description: | The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity. |
| End point type         | Secondary  |
| End point timeframe:   | From Baseline to Week 24   |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 54                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -1.5 (-15 to 10)         |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 12

|                 |  |
|-----------------|--|
| End point title | Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 12 |
|-----------------|--|

End point description:

The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity.

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

End point timeframe:

From Baseline to Week 12

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 54                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -2 (-15 to 11)           |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 8

|                 |   |
|-----------------|---|
| End point title | Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 8 |
|-----------------|---|

End point description:

The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity.

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

End point timeframe:

From Baseline to Week 8

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 54                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -2 (-13 to 11)           |  |  |  |

### Statistical analyses

No statistical analyses for this end point

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**Secondary: Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 6**

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|                 |   |
|-----------------|---|
| End point title | Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 6 |
|-----------------|---|

End point description:

The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity.

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

End point timeframe:

From Baseline to Week 6

---

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 54                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -2 (-15 to 5)            |  |  |  |

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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 the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 4**

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|                 |   |
|-----------------|---|
| End point title | Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 4 |
|-----------------|---|

End point description:

The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity.

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

End point timeframe:

From Baseline to Week 4

---

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 54                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -1 (-15 to 4)            |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 2

|  |   |
|--|---|
| End point title  | Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 2 |
| End point description:<br>The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity. |   |
| End point type   | Secondary   |
| End point timeframe:<br>From Baseline to Week 2  |   |

|                               |                          |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| End point values              | Certolizumab pegol (FAS) |  |  |  |
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 53                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -1 (-15 to 9)            |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 1

|  |   |
|--|---|
| End point title  | Change from Baseline in the sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 1 |
| End point description:<br>The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity. |   |
| End point type   | Secondary   |
| End point timeframe:<br>From Baseline to Week 1  |   |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 50                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | -1 (-10 to 4)            |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Synovial fluid and proliferation at Week 52

|   |   |
|---|---|
| End point title   | Synovial fluid and proliferation at Week 52 |
| End point description:<br>The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity. |   |
| End point type  | Secondary                                   |
| End point timeframe:<br>Week 52   |   |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 65                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 5 (0 to 16)              |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Synovial fluid and proliferation at Week 36

|   |   |
|---|---|
| End point title   | Synovial fluid and proliferation at Week 36 |
| End point description:<br>The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity. |   |
| End point type  | Secondary                                   |
| End point timeframe:<br>Week 36   |   |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 65                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 5 (0 to 16)              |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Synovial fluid and proliferation at Week 24

|   |   |
|---|---|
| End point title   | Synovial fluid and proliferation at Week 24 |
| End point description:  |   |
| The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity. |   |
| End point type  | Secondary                                   |
| End point timeframe:  |   |
| Week 24   |   |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 64                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 5 (0 to 16)              |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Synovial fluid and proliferation at Week 12

|   |   |
|---|---|
| End point title   | Synovial fluid and proliferation at Week 12 |
| End point description:  |   |
| The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity. |   |
| End point type  | Secondary                                   |
| End point timeframe:  |   |
| Week 12   |   |

|                               |                          |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| <b>End point values</b>       | Certolizumab pegol (FAS) |  |  |  |
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 64                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 5 (0 to 13)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Synovial fluid and proliferation at Week 8

|   |  |
|---|--|
| End point title   | Synovial fluid and proliferation at Week 8 |
| End point description:  |  |
| The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity. |  |
| End point type  | Secondary                                  |
| End point timeframe:  |  |
| Week 8  |  |

|                               |                          |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| <b>End point values</b>       | Certolizumab pegol (FAS) |  |  |  |
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 64                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 5 (0 to 14)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Synovial fluid and proliferation at Week 6

|   |  |
|---|--|
| End point title   | Synovial fluid and proliferation at Week 6 |
| End point description:  |  |
| The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity. |  |
| End point type  | Secondary                                  |
| End point timeframe:  |  |
| Week 6  |  |



| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 64                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 6 (0 to 12)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Synovial fluid and proliferation at Week 4

|   |  |
|---|--|
| End point title   | Synovial fluid and proliferation at Week 4 |
| End point description:  |  |
| The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity. |  |
| End point type  | Secondary                                  |
| End point timeframe:  |  |
| Week 4  |  |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 64                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 6 (0 to 13)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Synovial fluid and proliferation at Week 2

|   |  |
|---|--|
| End point title   | Synovial fluid and proliferation at Week 2 |
| End point description:  |  |
| The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity. |  |
| End point type  | Secondary                                  |
| End point timeframe:  |  |
| Week 2  |  |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 63                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 7 (0 to 12)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Synovial fluid and proliferation at Week 1

|   |  |
|---|--|
| End point title   | Synovial fluid and proliferation at Week 1 |
| End point description:  |  |
| The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity. |  |
| End point type  | Secondary                                  |
| End point timeframe:  |  |
| Week 1  |  |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 59                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 7 (1 to 13)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Synovial fluid and proliferation at Week 0

|   |  |
|---|--|
| End point title   | Synovial fluid and proliferation at Week 0 |
| End point description:  |  |
| The synovial fluid and proliferation is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity. |  |
| End point type  | Secondary                                  |
| End point timeframe:  |  |
| Week 0 (Baseline)   |  |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 59                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 8 (0 to 15)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Doppler signal and blood flow at Week 52

|  |  |
|--|--|
| End point title  | Doppler signal and blood flow at Week 52 |
| End point description:<br>The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity. |  |
| End point type   | Secondary                                |
| End point timeframe:<br>Week 52  |  |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 65                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 0 (0 to 10)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Doppler signal and blood flow at Week 36

|  |  |
|--|--|
| End point title  | Doppler signal and blood flow at Week 36 |
| End point description:<br>The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity. |  |
| End point type   | Secondary                                |
| End point timeframe:<br>Week 36  |  |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 65                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 0 (0 to 10)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Doppler signal and blood flow at Week 24

|  |  |
|--|--|
| End point title  | Doppler signal and blood flow at Week 24 |
| End point description:<br>The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity. |  |
| End point type   | Secondary                                |
| End point timeframe:<br>Week 24  |  |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 64                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 0 (0 to 10)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Doppler signal and blood flow at Week 12

|  |  |
|--|--|
| End point title  | Doppler signal and blood flow at Week 12 |
| End point description:<br>The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity. |  |
| End point type   | Secondary                                |
| End point timeframe:<br>Week 12  |  |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 64                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 0 (0 to 12)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Doppler signal and blood flow at Week 8

|  |   |
|--|---|
| End point title  | Doppler signal and blood flow at Week 8 |
| End point description:<br>The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity. |   |
| End point type   | Secondary                               |
| End point timeframe:<br>Week 8   |   |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 64                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 0 (0 to 7)               |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Doppler signal and blood flow at Week 6

|  |   |
|--|---|
| End point title  | Doppler signal and blood flow at Week 6 |
| End point description:<br>The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity. |   |
| End point type   | Secondary                               |
| End point timeframe:<br>Week 6   |   |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 64                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 0.5 (0 to 7)             |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Doppler signal and blood flow at Week 4

|  |   |
|--|---|
| End point title  | Doppler signal and blood flow at Week 4 |
| End point description:<br>The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity. |   |
| End point type   | Secondary                               |
| End point timeframe:<br>Week 4   |   |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 64                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 2 (0 to 9)               |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Doppler signal and blood flow at Week 2

|  |   |
|--|---|
| End point title  | Doppler signal and blood flow at Week 2 |
| End point description:<br>The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity. |   |
| End point type   | Secondary                               |
| End point timeframe:<br>Week 2   |   |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 63                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 1 (0 to 11)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Doppler signal and blood flow at Week 1

|  |   |
|--|---|
| End point title  | Doppler signal and blood flow at Week 1 |
| End point description:<br>The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity. |   |
| End point type   | Secondary                               |
| End point timeframe:<br>Week 1   |   |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 59                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 1 (0 to 11)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Doppler signal and blood flow at Week 0

|  |   |
|--|---|
| End point title  | Doppler signal and blood flow at Week 0 |
| End point description:<br>The Doppler signal and blood flow is a semiquantitative score (0-3 on each of 6 joints). A greater score indicates greater disease activity. |   |
| End point type   | Secondary                               |
| End point timeframe:<br>Week 0 (Baseline)  |   |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 59                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 2 (0 to 12)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Cartilage damage at Week 52

|   |                             |
|---|-----------------------------|
| End point title   | Cartilage damage at Week 52 |
| End point description:<br>The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity. |                             |
| End point type  | Secondary                   |
| End point timeframe:<br>Week 52   |                             |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 65                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 4 (0 to 20)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Cartilage damage at Week 36

|   |                             |
|---|-----------------------------|
| End point title   | Cartilage damage at Week 36 |
| End point description:<br>The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity. |                             |
| End point type  | Secondary                   |
| End point timeframe:<br>Week 36   |                             |



| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 65                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 5 (0 to 24)              |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cartilage damage at Week 24

|   |                             |
|---|-----------------------------|
| End point title   | Cartilage damage at Week 24 |
| End point description:<br>The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity. |                             |
| End point type  | Secondary                   |
| End point timeframe:<br>Week 24   |                             |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 64                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 4.5 (0 to 19)            |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cartilage damage at Week 12

|   |                             |
|---|-----------------------------|
| End point title   | Cartilage damage at Week 12 |
| End point description:<br>The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity. |                             |
| End point type  | Secondary                   |
| End point timeframe:<br>Week 12   |                             |

|                               |                          |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| <b>End point values</b>       | Certolizumab pegol (FAS) |  |  |  |
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 64                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 5 (0 to 20)              |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cartilage damage at Week 8

|   |                            |
|---|----------------------------|
| End point title   | Cartilage damage at Week 8 |
| End point description:<br>The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity. |                            |
| End point type  | Secondary                  |
| End point timeframe:<br>Week 8  |                            |

|                               |                          |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| <b>End point values</b>       | Certolizumab pegol (FAS) |  |  |  |
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 64                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 4.5 (0 to 20)            |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cartilage damage at Week 6

|   |                            |
|---|----------------------------|
| End point title   | Cartilage damage at Week 6 |
| End point description:<br>The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity. |                            |
| End point type  | Secondary                  |
| End point timeframe:<br>Week 6  |                            |

|                               |                          |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| <b>End point values</b>       | Certolizumab pegol (FAS) |  |  |  |
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 63                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 4 (0 to 20)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Cartilage damage at Week 4

|   |                            |
|---|----------------------------|
| End point title   | Cartilage damage at Week 4 |
| End point description:<br>The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity. |                            |
| End point type  | Secondary                  |
| End point timeframe:<br>Week 4  |                            |

|                               |                          |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| <b>End point values</b>       | Certolizumab pegol (FAS) |  |  |  |
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 63                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 4 (0 to 20)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Cartilage damage at Week 2

|   |                            |
|---|----------------------------|
| End point title   | Cartilage damage at Week 2 |
| End point description:<br>The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity. |                            |
| End point type  | Secondary                  |
| End point timeframe:<br>Week 2  |                            |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 61                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 4 (0 to 21)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Cartilage damage at Week 1

|   |                            |
|---|----------------------------|
| End point title   | Cartilage damage at Week 1 |
| End point description:<br>The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity. |                            |
| End point type  | Secondary                  |
| End point timeframe:<br>Week 1  |                            |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 57                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 5 (0 to 21)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Cartilage damage at Week 0

|   |                            |
|---|----------------------------|
| End point title   | Cartilage damage at Week 0 |
| End point description:<br>The Cartilage damage is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity. |                            |
| End point type  | Secondary                  |
| End point timeframe:<br>Week 0 (Baseline)   |                            |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 56                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 6 (0 to 21)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Bone erosion at Week 52

|   |                         |
|---|-------------------------|
| End point title   | Bone erosion at Week 52 |
| End point description:<br>The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity. |                         |
| End point type  | Secondary               |
| End point timeframe:<br>Week 52   |                         |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 65                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 2 (0 to 10)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Bone erosion at Week 36

|   |                         |
|---|-------------------------|
| End point title   | Bone erosion at Week 36 |
| End point description:<br>The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity. |                         |
| End point type  | Secondary               |
| End point timeframe:<br>Week 36   |                         |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 65                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 2 (0 to 11)              |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Bone erosion at Week 24

|   |                         |
|---|-------------------------|
| End point title   | Bone erosion at Week 24 |
| End point description:<br>The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity. |                         |
| End point type  | Secondary               |
| End point timeframe:<br>Week 24   |                         |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 64                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 2 (0 to 11)              |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Bone erosion at Week 12

|   |                         |
|---|-------------------------|
| End point title   | Bone erosion at Week 12 |
| End point description:<br>The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity. |                         |
| End point type  | Secondary               |
| End point timeframe:<br>Week 12   |                         |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 64                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 2 (0 to 10)              |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Bone erosion at Week 8

|   |                        |
|---|------------------------|
| End point title   | Bone erosion at Week 8 |
| End point description:<br>The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity. |                        |
| End point type  | Secondary              |
| End point timeframe:<br>Week 8  |                        |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 64                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 2 (0 to 10)              |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Bone erosion at Week 6

|   |                        |
|---|------------------------|
| End point title   | Bone erosion at Week 6 |
| End point description:<br>The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity. |                        |
| End point type  | Secondary              |
| End point timeframe:<br>Week 6  |                        |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 64                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 2 (0 to 10)              |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Bone erosion at Week 4

|   |                        |
|---|------------------------|
| End point title   | Bone erosion at Week 4 |
| End point description:<br>The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity. |                        |
| End point type  | Secondary              |
| End point timeframe:<br>Week 4  |                        |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 64                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 2 (0 to 10)              |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Bone erosion at Week 2

|   |                        |
|---|------------------------|
| End point title   | Bone erosion at Week 2 |
| End point description:<br>The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity. |                        |
| End point type  | Secondary              |
| End point timeframe:<br>Week 2  |                        |



| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 63                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 2 (0 to 15)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Bone erosion at Week 1

|   |                        |
|---|------------------------|
| End point title   | Bone erosion at Week 1 |
| End point description:<br>The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity. |                        |
| End point type  | Secondary              |
| End point timeframe:<br>Week 1  |                        |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 59                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 2 (0 to 15)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Bone erosion at Week 0

|   |                        |
|---|------------------------|
| End point title   | Bone erosion at Week 0 |
| End point description:<br>The bone erosion is a semiquantitative score (0-4 on each of 6 joints). A greater score indicates greater disease severity. |                        |
| End point type  | Secondary              |
| End point timeframe:<br>Week 0 (Baseline)   |                        |

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 60                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 2 (0 to 15)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 52

|                 |  |
|-----------------|--|
| End point title | Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 52 |
|-----------------|--|

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

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

End point timeframe:

Week 52

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 65                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 5 (0 to 26)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 36

|                 |  |
|-----------------|--|
| End point title | Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 36 |
|-----------------|--|

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Week 36              |           |

|                               |                          |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| <b>End point values</b>       | Certolizumab pegol (FAS) |  |  |  |
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 65                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 6 (0 to 26)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 24

|   |  |
|---|--|
| End point title   | Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 24 |
| End point description:  |  |
| The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity. |  |
| End point type  | Secondary  |
| End point timeframe:  |  |
| Week 24   |  |

|                               |                          |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| <b>End point values</b>       | Certolizumab pegol (FAS) |  |  |  |
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 64                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 6.5 (0 to 26)            |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 12

|                 |  |
|-----------------|--|
| End point title | Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 12 |
|-----------------|--|

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

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

End point timeframe:

Week 12

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 64                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 7 (0 to 22)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 8

|                 |   |
|-----------------|---|
| End point title | Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 8 |
|-----------------|---|

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

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

End point timeframe:

Week 8

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 64                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 6 (0 to 16)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Sum of the Synovial Fluid and Synovial Proliferation, and Doppler

## Signal/Blood Flow at Week 6

|   |   |
|---|---|
| End point title   | Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 6 |
| End point description:<br>The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity. |   |
| End point type  | Secondary   |
| End point timeframe:<br>Week 6  |   |

|                               |                          |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| <b>End point values</b>       | Certolizumab pegol (FAS) |  |  |  |
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 64                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 7 (0 to 16)              |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 4

|   |   |
|---|---|
| End point title   | Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 4 |
| End point description:<br>The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity. |   |
| End point type  | Secondary   |
| End point timeframe:<br>Week 4  |   |

|                               |                          |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| <b>End point values</b>       | Certolizumab pegol (FAS) |  |  |  |
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 64                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 8 (0 to 18)              |  |  |  |

## Statistical analyses

No statistical analyses for this end point

---

**Secondary: Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 2**

---

|                 |   |
|-----------------|---|
| End point title | Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 2 |
|-----------------|---|

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

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

End point timeframe:

Week 2

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 63                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 8 (0 to 23)              |  |  |  |

---

**Statistical analyses**

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No statistical analyses for this end point

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**Secondary: Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 1**

---

|                 |   |
|-----------------|---|
| End point title | Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 1 |
|-----------------|---|

End point description:

The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity.

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

End point timeframe:

Week 1

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 59                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 8 (1 to 23)              |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 0

|   |   |
|---|---|
| End point title   | Sum of the Synovial Fluid and Synovial Proliferation, and Doppler Signal/Blood Flow at Week 0 |
| End point description:<br>The sum of the synovial fluid volume, synovial proliferation, Doppler Signal and Blood Flow is a score (0-6) on each of 6 joints. A greater score indicates greater disease activity. |   |
| End point type  | Secondary   |
| End point timeframe:<br>Week 0 (Baseline)   |   |

|                               |                          |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| End point values              | Certolizumab pegol (FAS) |  |  |  |
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 59                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 10 (1 to 24)             |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 52

|  |  |
|--|--|
| End point title  | Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 52 |
| End point description:<br>The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity. |  |
| End point type   | Secondary  |
| End point timeframe:<br>Week 52  |  |

|                               |                          |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| <b>End point values</b>       | Certolizumab pegol (FAS) |  |  |  |
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 65                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 7 (0 to 38)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 36

|  |  |
|--|--|
| End point title  | Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 36 |
| End point description:<br>The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity. |  |
| End point type   | Secondary  |
| End point timeframe:<br>Week 36  |  |

|                               |                          |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| <b>End point values</b>       | Certolizumab pegol (FAS) |  |  |  |
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 65                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 8 (0 to 38)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 24

|  |  |
|--|--|
| End point title  | Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 24 |
| End point description:<br>The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity. |  |
| End point type   | Secondary  |
| End point timeframe:<br>Week 24  |  |



| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 64                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 10 (0 to 38)             |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 12

|                 |  |
|-----------------|--|
| End point title | Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 12 |
|-----------------|--|

End point description:

The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity.

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

End point timeframe:

Week 12

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 64                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 9 (0 to 38)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 8

|                 |   |
|-----------------|---|
| End point title | Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 8 |
|-----------------|---|

End point description:

The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Week 8               |           |

|                               |                          |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| <b>End point values</b>       | Certolizumab pegol (FAS) |  |  |  |
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 64                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 9 (0 to 34)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 6

|  |   |
|--|---|
| End point title  | Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 6 |
| End point description:   |   |
| The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity. |   |
| End point type   | Secondary   |
| End point timeframe:   |   |
| Week 6   |   |

|                               |                          |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| <b>End point values</b>       | Certolizumab pegol (FAS) |  |  |  |
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 63                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 8 (0 to 33)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 4

|                 |   |
|-----------------|---|
| End point title | Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 4 |
|-----------------|---|

End point description:

The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity.

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

End point timeframe:

Week 4

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 63                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 8 (0 to 34)              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 2

|                 |   |
|-----------------|---|
| End point title | Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 2 |
|-----------------|---|

End point description:

The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity.

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

End point timeframe:

Week 2

| End point values              | Certolizumab pegol (FAS) |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 61                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 10 (0 to 43)             |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Sum of the progression in the Doppler signal, cartilage damage and

**bone erosion score at Week 1**

|                 |   |
|-----------------|---|
| End point title | Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 1 |
|-----------------|---|

End point description:

The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity.

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

End point timeframe:

Week 1

|                               |                          |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| <b>End point values</b>       | Certolizumab pegol (FAS) |  |  |  |
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 57                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| median (full range)           | 10 (0 to 47)             |  |  |  |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 0**

|                 |   |
|-----------------|---|
| End point title | Sum of the progression in the Doppler signal, cartilage damage and bone erosion score at Week 0 |
|-----------------|---|

End point description:

The sum of the progression in the Doppler signal, cartilage damage and bone erosion score is a score (0-11 on each of 6 joints). A greater score indicates greater disease severity.

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

End point timeframe:

Week 0 (Baseline)

|                               |                          |  |  |  |
|-------------------------------|--------------------------|--|--|--|
| <b>End point values</b>       | Certolizumab pegol (FAS) |  |  |  |
| Subject group type            | Subject analysis set     |  |  |  |
| Number of subjects analysed   | 55                       |  |  |  |
| Units: units on a scale       |                          |  |  |  |
| median (full range (min-max)) |                          |  |  |  |
| mean (standard deviation)     | 12 (0 to 47)             |  |  |  |

**Statistical analyses**



## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Treatment Emergent Adverse Events were reported from Baseline (Week 0) up to the Safety Follow-up Visit (Week 60).

Adverse event reporting additional description:

Adverse Events refer to the Safety Set (SS) which consists of all subjects who received at least one dose of study medication.

|                 |                |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

### Dictionary used

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

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

### Reporting groups

|                       |                    |
|-----------------------|--------------------|
| Reporting group title | Certolizumab pegol |
|-----------------------|--------------------|

Reporting group description:

Subjects will be treated for 52 weeks with Certolizumab Pegol (CZP) (administration every two weeks) in combination with Methotrexate (MTX) (administration weekly). Dosing regimen of CZP consists of 3 administrations of 400 mg at Weeks 0, 2 and 4 followed by 200 mg every other week up to and including Week 50.

| Serious adverse events  | Certolizumab pegol |  |  |
|---|--------------------|--|--|
| Total subjects affected by serious adverse events                   |                    |  |  |
| subjects affected / exposed   | 16 / 132 (12.12%)  |  |  |
| number of deaths (all causes)                                       | 0                  |  |  |
| number of deaths resulting from adverse events                      | 0                  |  |  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                    |  |  |
| Lobular breast carcinoma in situ                                    |                    |  |  |
| subjects affected / exposed   | 1 / 132 (0.76%)    |  |  |
| occurrences causally related to treatment / all                     | 1 / 1              |  |  |
| deaths causally related to treatment / all                          | 0 / 0              |  |  |
| Malignant melanoma in situ  |                    |  |  |
| subjects affected / exposed   | 1 / 132 (0.76%)    |  |  |
| occurrences causally related to treatment / all                     | 1 / 1              |  |  |
| deaths causally related to treatment / all                          | 0 / 0              |  |  |
| Non-Hodgkin's lymphoma  |                    |  |  |
| subjects affected / exposed   | 1 / 132 (0.76%)    |  |  |
| occurrences causally related to treatment / all                     | 1 / 1              |  |  |
| deaths causally related to treatment / all                          | 0 / 0              |  |  |
| Vascular disorders  |                    |  |  |

|   |                 |  |  |
|---|-----------------|--|--|
| Flushing  |                 |  |  |
| subjects affected / exposed                     | 1 / 132 (0.76%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Hypertension                                    |                 |  |  |
| subjects affected / exposed                     | 1 / 132 (0.76%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Pregnancy, puerperium and perinatal conditions  |                 |  |  |
| Abortion spontaneous                            |                 |  |  |
| subjects affected / exposed                     | 1 / 132 (0.76%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Reproductive system and breast disorders        |                 |  |  |
| Genital prolapse                                |                 |  |  |
| subjects affected / exposed                     | 1 / 132 (0.76%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Respiratory, thoracic and mediastinal disorders |                 |  |  |
| Dyspnoea  |                 |  |  |
| subjects affected / exposed                     | 1 / 132 (0.76%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Sinus disorder                                  |                 |  |  |
| subjects affected / exposed                     | 1 / 132 (0.76%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Cardiac disorders                               |                 |  |  |
| Atrial fibrillation                             |                 |  |  |
| subjects affected / exposed                     | 1 / 132 (0.76%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Nervous system disorders                        |                 |  |  |

|   |                 |  |  |
|---|-----------------|--|--|
| Anosmia   |                 |  |  |
| subjects affected / exposed                     | 1 / 132 (0.76%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Headache  |                 |  |  |
| subjects affected / exposed                     | 1 / 132 (0.76%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Tremor  |                 |  |  |
| subjects affected / exposed                     | 1 / 132 (0.76%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Blood and lymphatic system disorders            |                 |  |  |
| Retroperitoneal lymphadenopathy                 |                 |  |  |
| subjects affected / exposed                     | 1 / 132 (0.76%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Eye disorders                                   |                 |  |  |
| Periorbital oedema                              |                 |  |  |
| subjects affected / exposed                     | 1 / 132 (0.76%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Gastrointestinal disorders                      |                 |  |  |
| Abdominal pain upper                            |                 |  |  |
| subjects affected / exposed                     | 1 / 132 (0.76%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Skin and subcutaneous tissue disorders          |                 |  |  |
| Rash  |                 |  |  |
| subjects affected / exposed                     | 1 / 132 (0.76%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Urticaria                                       |                 |  |  |



|   |                 |  |  |
|---|-----------------|--|--|
| subjects affected / exposed                     | 1 / 132 (0.76%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Renal and urinary disorders                     |                 |  |  |
| Bladder prolapse                                |                 |  |  |
| subjects affected / exposed                     | 1 / 132 (0.76%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Bladder mass                                    |                 |  |  |
| subjects affected / exposed                     | 1 / 132 (0.76%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Haematuria                                      |                 |  |  |
| subjects affected / exposed                     | 1 / 132 (0.76%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Infections and infestations                     |                 |  |  |
| Abdominal abscess                               |                 |  |  |
| subjects affected / exposed                     | 1 / 132 (0.76%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Bronchopneumonia                                |                 |  |  |
| subjects affected / exposed                     | 1 / 132 (0.76%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Paratyphoid fever                               |                 |  |  |
| subjects affected / exposed                     | 1 / 132 (0.76%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Endophthalmitis                                 |                 |  |  |
| subjects affected / exposed                     | 1 / 132 (0.76%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |

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

| <b>Non-serious adverse events</b>                     | Certolizumab pegol |  |  |
|---|--------------------|--|--|
| Total subjects affected by non-serious adverse events |                    |  |  |
| subjects affected / exposed                           | 31 / 132 (23.48%)  |  |  |
| General disorders and administration site conditions  |                    |  |  |
| Pyrexia   |                    |  |  |
| subjects affected / exposed                           | 7 / 132 (5.30%)    |  |  |
| occurrences (all)                                     | 7                  |  |  |
| Musculoskeletal and connective tissue disorders       |                    |  |  |
| Arthralgia  |                    |  |  |
| subjects affected / exposed                           | 9 / 132 (6.82%)    |  |  |
| occurrences (all)                                     | 18                 |  |  |
| Infections and infestations                           |                    |  |  |
| Influenza   |                    |  |  |
| subjects affected / exposed                           | 15 / 132 (11.36%)  |  |  |
| occurrences (all)                                     | 16                 |  |  |
| Bronchitis  |                    |  |  |
| subjects affected / exposed                           | 7 / 132 (5.30%)    |  |  |
| occurrences (all)                                     | 7                  |  |  |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date            | Amendment  |
|-----------------|--|
| 07 July 2011    | <p>Protocol Amendment 1, dated 07 Jul 2011, was implemented after the central ethics committee review of the initial protocol, when changes were deemed necessary for conduct of this study in Italy. This amendment occurred prior to inclusion of subjects.</p> <p>The following changes were made throughout the protocol:</p> <ul style="list-style-type: none"><li>• Quality of Life assessments were altered (eg, removal of PRISM test, Euro QoL-5D changed to EQ-5D-3L).</li><li>• Evaluation of healthcare use' was added as an exploratory objective (and accordingly was added in list of other efficacy variables and concomitant procedures).</li><li>• Laboratory assessments were centralized, except for ESR, TB and urine pregnancy testing.</li></ul>  |
| 07 July 2011    | <ul style="list-style-type: none"><li>• Safety reporting was updated, with extension of the follow up period from 30 days to 10 weeks, and clarification that a serious AE (SAE) or an AE leading to premature discontinuation from the study had to be followed up until it had resolved, stabilized or the Investigator no longer felt it was clinically significant; TB and ischemic cardiac events were added to AEs of interest list; the anticipated AE list was removed.</li><li>• Biomarkers assessments were updated (Week 0 assessment changed to Week -2).</li><li>• Immunological assessments were updated (Week -2 assessment deleted, and Weeks 0, 2, 6, 12, and 36 assessments added to text).</li><li>• For pregnancy testing and x-ray assessment, previously missing text was added (to correspond with schedule).</li><li>• An explanation was added that EQ-5D-3L dimensions scores, VAS actual scores, and healthcare resource utilization scores would be summarized using descriptive statistics.</li><li>• Previously termed 'anticipated AEs' in Appendices were renamed 'predicted AEs,' and those for CZP added.</li><li>• Inclusion criterion number 9 was changed from 'Subject is naïve or has received up to 1 prior anti-TNF therapy, which was not discontinued due to primary failure' to 'Subject is naïve to RA related biologics (eg, anti-TNF therapy).</li><li>• Exclusion criteria numbers 13 to 17 regarding prior treatments were replaced with 'Subject has received previous RA related biologics therapy (eg, anti-TNF)'.</li></ul> |
| 24 October 2011 | <p>Protocol Amendment 2, dated 24 Oct 2011, was implemented after the Sponsor discussed the subgroup analysis with other experts. It was decided to remove the MRI assessments: although the use of gadolinium would have resulted in better data, this invasive method could have been a limiting factor and restrict recruitment. Lack of interest in MRI assessments at investigational sites also contributed to this decision. It was agreed that remaining methods would still provide sufficient data to monitor the response of joint synovitis and to investigate the predictability of an early sonography response for long-term response. The MRI Assessment was therefore removed from all applicable sections.</p> <p>In addition, clarification was added that methotrexate should be taken throughout the study without discontinuation, and that no dose adjustment was allowed except for documented intolerance or toxicity.</p> <p>This amendment was approved after one subject had been screened.</p>  |

|               |  |
|---------------|--|
| 06 March 2013 | <p>Protocol Amendment 3, dated 06 Mar 2013, was implemented after to clarify objectives and endpoints of the study, to add a second reading of US images for the purpose of assessing interreader variability, to align the protocol with UCB standards in terms of definitions, naming conventions, and procedures, and to streamline the planned data analysis in alignment with the objectives.</p> <p>Specifically:</p> <ul style="list-style-type: none"> <li>• The secondary objective was modified to allow for more general conclusions on the results of US assessments; assessment of the changes in CRP and ESR were replaced with assessment of the relationship between US response and clinical response over time.</li> <li>• Endpoints were shifted in the appropriate sections in alignment with the objectives; in particular, CRP and ESR were moved to the Other Efficacy section.</li> <li>• The procedure of the analysis of US images was amended to allow for an assessment of interobserver reliability.</li> <li>• Clarifications and definitions were added to specify the study conduct and procedures.</li> </ul>   |
| 06 March 2013 | <ul style="list-style-type: none"> <li>• Definitions were updated to be consistent with UCB standards (eg, specifications of tuberculosis [TB] assessments and the TEAE definition).</li> <li>• Study timelines were amended according to new forecasts.</li> <li>• Rescreening of subjects was allowed for screen-failed subjects.</li> </ul> <p>The following additional changes were made throughout the protocol:</p> <ul style="list-style-type: none"> <li>• The upper limit of the category Low Disease Activity was changed from &lt;3.2 to ≤3.2.</li> <li>• The definition of clinical response based on DAS28-ESR was changed from a reduction of &gt;1.2 scores in the DAS28-ESR to a reduction of ≥1.2 scores in the DAS28-ESR.</li> <li>• The Health assessment questionnaire (HAQ) was renamed Health Assessment Questionnaire Disability Index (HAQ-DI).</li> <li>• The term Investigator's Assessment of Disease Activity (IGA) was changed to Physician's Assessment of Disease Activity (PhGADA).</li> <li>• The abbreviation of Patient's Assessment of Disease Activity (PGA) was changed to PtGADA.</li> <li>• The word parameter was replaced by the word variable.</li> <li>• HBV DNA requirements were clarified.</li> </ul> |

Notes:

## Interruptions (globally)

Were there any global interruptions to the trial? No

## Limitations and caveats

None reported