# EU Clinical Trials Register

## Clinical trial results:
## Phase 2, Multicenter, Open-Label Extension (OLE) Study with ABT-122 in Rheumatoid Arthritis Subjects Who Have Completed the Preceding M12-963 Phase 2 Randomized Controlled Trial (RCT)

### Summary

| EudraCT number | 2014-001471-31 |
|---|---|
| Trial protocol | HU CZ DE BG RO |
| Global end of trial date | 23 May 2016 |

### Results information

| Result version number | v1 (current) |
|---|---|
| This version publication date | 04 June 2017 |
| First version publication date | 04 June 2017 |

### Trial information

### Trial identification

| Sponsor protocol code | M12-965 |
|---|---|

### Additional study identifiers

| ISRCTN number | - |
|---|---|
| ClinicalTrials.gov id (NCT number) | NCT02433340 |
| WHO universal trial number (UTN) | - |

Notes:

### Sponsors

| Sponsor organisation name | Abbvie Deutschland GmbH & Co.KG |
|---|---|
| Sponsor organisation address | AbbVie House, Vanwall Business Park, Vanwall Road , Maidenhead, Berkshire , United Kingdom, SL6-4UB |
| Public contact | Lawrence McNamee, Clinical Lead, AbbVie, Lawrence.McNamee@abbvie.com |
| Scientific contact | Paul Peloso, Medical Director, AbbVie, heikki.mansikka@abbvie.com |

Notes:

### Paediatric regulatory details

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

Notes:

## Results analysis stage

| | |
|---|---|
| Analysis stage | Final |
| Date of interim/final analysis | 23 May 2016 |
| Is this the analysis of the primary completion data? | No |

| | |
|---|---|
| Global end of trial reached? | Yes |
| Global end of trial date | 23 May 2016 |
| Was the trial ended prematurely? | Yes |

Notes:

## General information about the trial

Main objective of the trial:

This is a Phase 2, multicenter, 24-week OLE study to assess the safety and tolerability of ABT-122 in participants with rheumatoid arthritis (RA) who had had an inadequate response to methotrexate (MTX) therapy and who completed the preceding Study M12-963 randomized controlled trial, in which participants had been randomized to receive 1 of 3 doses of ABT-122 (60 mg every other week [EOW], 120 mg EOW, or 120 mg every week [EW]) or adalimumab 40 mg EOW given on background methotrexate.

Protection of trial subjects:

Participant and/or legal guardian read and understood the information provided about the study and gave written permission.

Background therapy: -

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 20 April 2015 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

## Population of trial subjects

### Subjects enrolled per country

| | |
|---|---|
| Country: Number of subjects enrolled | Czech Republic: 17 |
| Country: Number of subjects enrolled | Bulgaria: 15 |
| Country: Number of subjects enrolled | Germany: 1 |
| Country: Number of subjects enrolled | Hungary: 11 |
| Country: Number of subjects enrolled | New Zealand: 8 |
| Country: Number of subjects enrolled | Poland: 100 |
| Country: Number of subjects enrolled | Romania: 6 |
| Worldwide total number of subjects | 158 |
| EEA total number of subjects | 150 |

Notes:

### Subjects enrolled per age group

| | |
|---|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |

| | |
|---|---|
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 120 |
| From 65 to 84 years | 38 |
| 85 years and over | 0 |

# Subject disposition

## Recruitment

Recruitment details: -

## Pre-assignment

Screening details:

A total of 158 subjects (98% of those eligible) diagnosed with active rheumatoid arthritis (RA) on background methotrexate who had participated in the randomized controlled trial M12-963 (2014-001471-31) enrolled in this open-label extension. Results include analyses of data for these subjects from time points during M12-963, per protocol.

## Period 1

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

### Arms

| Are arms mutually exclusive? | Yes |
|---|---|
| **Arm title** | ADA 40 mg EOW / ABT-122 120 mg EOW |

Arm description:

Double-blind Adalimumab (ADA) 40 mg every other week (EOW) for 11 weeks. Open-label ABT-122 120 mg EOW.

| Arm type | Experimental |
|---|---|
| Investigational medicinal product name | ABT-122 |
| Investigational medicinal product code | ABT-122 |
| Other name | Remtolumab |
| Pharmaceutical forms | Powder for injection, Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

ABT-122 was provided as a lyophilized powder for reconstitution prior to injection; however, once the PFS became available, ABT-122 was provided as a solution for injection in a pre-filled syringe. All subjects received ABT-122 120 mg EOW in an open-label fashion with the possibility of an extra 120 mg dose based upon the loss of ACR20 response.

| **Arm title** | ABT-122 60 mg EOW / 120 mg EOW |
|---|---|

Arm description:

Double-blind ABT-122 60 mg EOW for 11 weeks. Open-label ABT-122 120 mg EOW.

| Arm type | Experimental |
|---|---|
| Investigational medicinal product name | ABT-122 |
| Investigational medicinal product code | ABT-122 |
| Other name | Remtolumab |
| Pharmaceutical forms | Powder for injection, Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

ABT-122 was provided as a lyophilized powder for reconstitution prior to injection; however, once the PFS became available, ABT-122 was provided as a solution for injection in a pre-filled syringe. All subjects received ABT-122 120 mg EOW in an open-label fashion with the possibility of an extra 120 mg dose based upon the loss of ACR20 response.

| **Arm title** | ABT-122 120 mg EOW / 120 mg EOW |
|---|---|

Arm description:

Double-blind ABT-122 120 mg EOW for 11 weeks. Open-label ABT-122 120 mg EOW.

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

| Investigational medicinal product name | ABT-122 |
|---|---|
| Investigational medicinal product code | ABT-122 |
| Other name | Remtolumab |
| Pharmaceutical forms | Powder for injection, Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

ABT-122 was provided as a lyophilized powder for reconstitution prior to injection; however, once the PFS became available, ABT-122 was provided as a solution for injection in a pre-filled syringe. All subjects received ABT-122 120 mg EOW in an open-label fashion with the possibility of an extra 120 mg dose based upon the loss of ACR20 response.

| **Arm title** | ABT-122 120 mg EW / 120 mg EOW |
|---|---|

Arm description:

Double-blind ABT-122 120 mg every week (EW) for 11 weeks. Open-label ABT-122 120 mg EOW.

| Arm type | Experimental |
|---|---|
| Investigational medicinal product name | ABT-122 |
| Investigational medicinal product code | ABT-122 |
| Other name | Remtolumab |
| Pharmaceutical forms | Powder for injection, Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

ABT-122 was provided as a lyophilized powder for reconstitution prior to injection; however, once the PFS became available, ABT-122 was provided as a solution for injection in a pre-filled syringe. All subjects received ABT-122 120 mg EOW in an open-label fashion with the possibility of an extra 120 mg dose based upon the loss of ACR20 response.

| **Number of subjects in period 1** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW |
|---|---|---|---|
| Started | 42 | 37 | 39 |
| Completed | 40 | 35 | 37 |
| Not completed | 2 | 2 | 2 |
|    Consent withdrawn by subject | 1 | - | 1 |
|    Adverse event, non-fatal | - | - | 1 |
|    Not Specified | - | 1 | - |
|    Required Alternative/Prohibited Therapy | 1 | - | - |
|    Lost to follow-up | - | 1 | - |

| **Number of subjects in period 1** | ABT-122 120 mg EW / 120 mg EOW |
|---|---|
| Started | 40 |
| Completed | 38 |
| Not completed | 2 |
|    Consent withdrawn by subject | 2 |
|    Adverse event, non-fatal | - |
|    Not Specified | - |
|    Required Alternative/Prohibited Therapy | - |
|    Lost to follow-up | - |

## Baseline characteristics

### Reporting groups

| | |
|---|---|
| Reporting group title | ADA 40 mg EOW / ABT-122 120 mg EOW |
| Reporting group description: | |
| Double-blind Adalimumab (ADA) 40 mg every other week (EOW) for 11 weeks. Open-label ABT-122 120 mg EOW. | |
| Reporting group title | ABT-122 60 mg EOW / 120 mg EOW |
| Reporting group description: | |
| Double-blind ABT-122 60 mg EOW for 11 weeks. Open-label ABT-122 120 mg EOW. | |
| Reporting group title | ABT-122 120 mg EOW / 120 mg EOW |
| Reporting group description: | |
| Double-blind ABT-122 120 mg EOW for 11 weeks. Open-label ABT-122 120 mg EOW. | |
| Reporting group title | ABT-122 120 mg EW / 120 mg EOW |
| Reporting group description: | |
| Double-blind ABT-122 120 mg every week (EW) for 11 weeks. Open-label ABT-122 120 mg EOW. | |

| Reporting group values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW |
|---|---|---|---|
| Number of subjects | 42 | 37 | 39 |
| Age, Customized | | | |
| Units: Participants | | | |
| < 40 years | 4 | 5 | 7 |
| 40 to < 65 years | 27 | 24 | 22 |
| >= 65 years | 11 | 8 | 10 |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 30 | 29 | 33 |
| Male | 12 | 8 | 6 |

| Reporting group values | ABT-122 120 mg EW / 120 mg EOW | Total | |
|---|---|---|---|
| Number of subjects | 40 | 158 | |
| Age, Customized | | | |
| Units: Participants | | | |
| < 40 years | 5 | 21 | |
| 40 to < 65 years | 26 | 99 | |
| >= 65 years | 9 | 38 | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 32 | 124 | |
| Male | 8 | 34 | |

## End points

### End points reporting groups

| | |
|---|---|
| Reporting group title | ADA 40 mg EOW / ABT-122 120 mg EOW |
| Reporting group description: | |
| Double-blind Adalimumab (ADA) 40 mg every other week (EOW) for 11 weeks. Open-label ABT-122 120 mg EOW. | |
| Reporting group title | ABT-122 60 mg EOW / 120 mg EOW |
| Reporting group description: | |
| Double-blind ABT-122 60 mg EOW for 11 weeks. Open-label ABT-122 120 mg EOW. | |
| Reporting group title | ABT-122 120 mg EOW / 120 mg EOW |
| Reporting group description: | |
| Double-blind ABT-122 120 mg EOW for 11 weeks. Open-label ABT-122 120 mg EOW. | |
| Reporting group title | ABT-122 120 mg EW / 120 mg EOW |
| Reporting group description: | |
| Double-blind ABT-122 120 mg every week (EW) for 11 weeks. Open-label ABT-122 120 mg EOW. | |
| Subject analysis set title | All ABT-122 120 mg EOW |
| Subject analysis set type | Full analysis |
| Subject analysis set description: | |
| Open-label ABT-122 120 mg EOW. | |
| Subject analysis set title | All ABT-122 120 mg EOW |
| Subject analysis set type | Full analysis |
| Subject analysis set description: | |
| Open-label ABT-122 120 mg EOW. | |
| Subject analysis set title | All ABT-122 120 mg EOW |
| Subject analysis set type | Full analysis |
| Subject analysis set description: | |
| Open-label ABT-122 120 mg EOW. | |
| Subject analysis set title | All ABT-122 120 mg EOW |
| Subject analysis set type | Full analysis |
| Subject analysis set description: | |
| Open-label ABT-122 120 mg EOW. | |
| Subject analysis set title | All ABT-122 120 mg EOW |
| Subject analysis set type | Full analysis |
| Subject analysis set description: | |
| Open-label ABT-122 120 mg EOW. | |
| Subject analysis set title | All ABT-122 120 mg EOW |
| Subject analysis set type | Full analysis |
| Subject analysis set description: | |
| Open-label ABT-122 120 mg EOW. | |
| Subject analysis set title | All ABT-122 120 mg EOW |
| Subject analysis set type | Full analysis |
| Subject analysis set description: | |
| Open-label ABT-122 120 mg EOW. | |
| Subject analysis set title | All ABT-122 120 mg EOW |
| Subject analysis set type | Full analysis |
| Subject analysis set description: | |
| Open-label ABT-122 120 mg EOW. | |
| Subject analysis set title | All ABT-122 120 mg EOW |
| Subject analysis set type | Full analysis |

Subject analysis set description:

Open-label ABT-122 120 mg EOW.

| Subject analysis set title | All ABT-122 120 mg EOW |
|---|---|
| Subject analysis set type | Full analysis |

Subject analysis set description:

Open-label ABT-122 120 mg EOW.

## Primary: American College of Rheumatology (ACR) 20 Response Rate at Week 2

| End point title | American College of Rheumatology (ACR) 20 Response Rate at Week 2[1] |
|---|---|

End point description:

Percentage of subjects with an ACR20 response, defined as at least 20% reduction (improvement) compared with baseline in tender joint count (TJC68), swollen joint count (SJC66), and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, patient's global assessment of disease activity (PtGA); physician's global assessment of disease activity (PGA), Health Assessment Questionnaire - Disability Index (HAQ-DI), and high-sensitivity C-reactive protein (hsCRP). Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. Last observation carried forward (LOCF) was used for missing data.

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

End point timeframe:

Week 2 of Study M12-963

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: Descriptive statistics are presented, per protocol.

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 40 | 37 | 39 | 38 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 45 (30.7 to 60.2) | 43.2 (28.7 to 59.1) | 46.2 (31.6 to 61.4) | 47.4 (32.5 to 62.7) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 154 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 45.5 (37.8 to 53.3) | | | |

## Statistical analyses

No statistical analyses for this end point

### Primary: ACR20 Response Rate at Week 4

| End point title | ACR20 Response Rate at Week 4[2] |
|---|---|

End point description:

Percentage of subjects with an ACR20 response, defined as at least 20% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 4 of Study M12-963

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: Descriptive statistics are presented, per protocol.

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 39 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 50 (35.5 to 64.5) | 64.9 (48.7 to 78.2) | 46.2 (31.6 to 61.4) | 74.4 (58.8 to 85.6) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 58.6 (50.8 to 66) | | | |

### Statistical analyses

No statistical analyses for this end point

### Primary: ACR20 Response Rate at Week 6

| End point title | ACR20 Response Rate at Week 6[3] |
|---|---|

End point description:

Percentage of subjects with an ACR20 response, defined as at least 20% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 6 of Study M12-963

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: Descriptive statistics are presented, per protocol.

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 39 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 66.7 (51.5 to 79.1) | 70.3 (54.1 to 82.6) | 66.7 (50.9 to 79.4) | 79.5 (64.2 to 89.5) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 70.7 (63.1 to 77.3) | | | |

### Statistical analyses

No statistical analyses for this end point

### Primary: ACR20 Response Rate at Week 8

| End point title | ACR20 Response Rate at Week 8[4] |
|---|---|

End point description:

Percentage of subjects with an ACR20 response, defined as at least 20% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 8 of Study M12-963

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: Descriptive statistics are presented, per protocol.

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 76.2 (61.3 to 86.7) | 75.7 (59.7 to 86.8) | 69.2 (53.5 to 81.5) | 80 (65 to 89.8) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 158 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 75.3 (68 to 81.4) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: ACR20 Response Rate at Week 12

| End point title | ACR20 Response Rate at Week 12[5] |
|---|---|

End point description:

Percentage of subjects with an ACR20 response, defined as at least 20% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 12 of Study M12-963 (considered Week 0 of Study M12-965)

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: Descriptive statistics are presented, per protocol.

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 78.6 (63.8 to 88.5) | 70.3 (54.1 to 82.6) | 84.6 (69.9 to 93.1) | 82.5 (67.7 to 91.6) |

| End point values | All ABT-122 120 mg EOW | | | |
| --- | --- | --- | --- | --- |
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 158 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 79.1 (72.1 to 84.8) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: ACR20 Response Rate at Week 16

| End point title | ACR20 Response Rate at Week 16[6] |
| --- | --- |

End point description:

Percentage of subjects with an ACR20 response, defined as at least 20% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 16 (Week 4 of Study M12-965)

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: Descriptive statistics are presented, per protocol.

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
| --- | --- | --- | --- | --- |
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 41 | 36 | 37 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 85.4 (71.2 to 93.5) | 77.8 (61.7 to 88.5) | 86.5 (71.5 to 94.6) | 77.5 (62.3 to 87.9) |

| End point values | All ABT-122 120 mg EOW | | | |
| --- | --- | --- | --- | --- |
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 154 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 81.8 (74.9 to 87.2) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: ACR20 Response Rate at Week 20

| End point title | ACR20 Response Rate at Week 20[7] |
|---|---|

End point description:

Percentage of subjects with an ACR20 response, defined as at least 20% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 20 (Week 8 of Study M12-965)

Notes:

[7] - 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: Descriptive statistics are presented, per protocol.

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 39 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 71.4 (56.3 to 82.9) | 77.8 (61.7 to 88.5) | 82.1 (67 to 91.3) | 79.5 (64.2 to 89.5) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 156 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 77.6 (70.4 to 83.4) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: ACR20 Response Rate at Week 24

| End point title | ACR20 Response Rate at Week 24[8] |
|---|---|

End point description:

Percentage of subjects with an ACR20 response, defined as at least 20% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 24 (Week 12 of Study M12-965)

Notes:

[8] - 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: Descriptive statistics are presented, per protocol.

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 39 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 78.6 (63.8 to 88.5) | 77.8 (61.7 to 88.5) | 76.9 (61.5 to 87.6) | 84.6 (69.9 to 93.1) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 156 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 79.5 (72.4 to 85.1) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: ACR20 Response Rate at Week 28

| End point title | ACR20 Response Rate at Week 28[9] |
|---|---|

End point description:

Percentage of subjects with an ACR20 response, defined as at least 20% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 28 (Week 16 of Study M12-965)

Notes:

[9] - 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: Descriptive statistics are presented, per protocol.

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 39 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 73.8 (58.8 to 84.8) | 75 (58.7 to 86.4) | 74.4 (58.8 to 85.6) | 82.1 (67 to 91.3) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 156 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 76.3 (69 to 82.3) | | | |

### Statistical analyses

No statistical analyses for this end point

### Primary: ACR20 Response Rate at Week 32

| End point title | ACR20 Response Rate at Week 32[10] |
|---|---|

End point description:

Percentage of subjects with an ACR20 response, defined as at least 20% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data..

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

End point timeframe:

Week 32 (Week 20 of Study M12-965)

Notes:

[10] - 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: Descriptive statistics are presented, per protocol.

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 76.2 (61.3 to 86.7) | 72.2 (55.9 to 84.3) | 79.5 (64.2 to 89.5) | 80 (65 to 89.8) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 77.1 (69.9 to 83) | | | |

### Statistical analyses

No statistical analyses for this end point

### Primary: ACR20 Response Rate at Week 36

| End point title | ACR20 Response Rate at Week 36[11] |
|---|---|

End point description:

Percentage of subjects with an ACR20 response, defined as at least 20% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 36 (Week 24 of Study M12-965)

Notes:

[11] - 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: Descriptive statistics are presented, per protocol.

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 71.4 (56.3 to 82.9) | 72.2 (55.9 to 84.3) | 84.6 (69.9 to 93.1) | 85 (70.5 to 93.3) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 78.3 (71.2 to 84.1) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: ACR50 Response Rate at Week 2

| End point title | ACR50 Response Rate at Week 2[12] |
|---|---|

End point description:

Percentage of subjects with an ACR50 response, defined as at least 50% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 2 of Study M12-963

Notes:

[12] - 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: Descriptive statistics are presented, per protocol.

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 40 | 37 | 39 | 39 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 10 (3.4 to 23.6) | 8.1 (2.1 to 22) | 20.5 (10.5 to 35.8) | 23.1 (12.4 to 38.5) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 155 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 15.5 (10.6 to 22.1) | | | |

## Statistical analyses

No statistical analyses for this end point

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## Primary: ACR50 Response Rate at Week 4

| End point title | ACR50 Response Rate at Week 4[13] |
|---|---|

End point description:

Percentage of subjects with an ACR50 response, defined as at least 50% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 4 of Study M12-963

Notes:

[13] - 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: Descriptive statistics are presented, per protocol.

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 39 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 14.3 (6.3 to 28.2) | 29.7 (17.4 to 45.9) | 23.1 (12.4 to 38.5) | 35.9 (22.7 to 51.6) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 25.5 (19.3 to 32.8) | | | |

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## Statistical analyses

No statistical analyses for this end point

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## Primary: ACR50 Response Rate at Week 6

| End point title | ACR50 Response Rate at Week 6[14] |
|---|---|

End point description:

Percentage of subjects with an ACR50 response, defined as at least 50% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 6 of Study M12-963

Notes:

[14] - 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: Descriptive statistics are presented, per protocol.

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 33.3 (20.9 to 48.5) | 35.1 (21.8 to 51.3) | 38.5 (24.9 to 54.1) | 42.5 (28.5 to 57.8) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 158 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 37.3 (30.2 to 45.1) | | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: ACR50 Response Rate at Week 8

| End point title | ACR50 Response Rate at Week 8[15] |
|---|---|

End point description:

Percentage of subjects with an ACR50 response, defined as at least 50% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 8 of Study M12-963

Notes:

[15] - 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: Descriptive statistics are presented, per protocol.

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 45.2 (31.2 to 60.1) | 29.7 (17.4 to 45.9) | 41 (27.1 to 56.6) | 42.5 (28.5 to 57.8) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 158 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 39.9 (32.6 to 47.7) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: ACR50 Response Rate at Week 12

| End point title | ACR50 Response Rate at Week 12[16] |
|---|---|

End point description:

Percentage of subjects with an ACR50 response, defined as at least 50% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 12 of Study M12-963 (considered Week 0 of Study M12-965)

Notes:

[16] - 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: Descriptive statistics are presented, per protocol.

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 39 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 52.4 (37.7 to 66.6) | 37.8 (24 to 53.9) | 51.3 (36.2 to 66.1) | 46.2 (31.6 to 61.4) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 47.1 (39.5 to 54.9) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: ACR50 Response Rate at Week 16

| End point title | ACR50 Response Rate at Week 16[17] |
|---|---|

End point description:

Percentage of subjects with an ACR50 response, defined as at least 50% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 16 (Week 4 of Study M12-965)

Notes:

[17] - 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: Descriptive statistics are presented, per protocol.

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 41 | 35 | 37 | 39 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 36.6 (23.5 to 51.9) | 51.4 (35.6 to 67) | 56.8 (40.9 to 71.3) | 56.4 (41 to 70.7) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 152 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 50 (42.1 to 57.9) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: ACR50 Response Rate at Week 20

| End point title | ACR50 Response Rate at Week 20[18] |
|---|---|

End point description:

Percentage of subjects with an ACR50 response, defined as at least 50% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 20 (Week 8 of Study M12-965)

Notes:

[18] - 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: Descriptive statistics are presented, per protocol.

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 42.9 (29.1 to 57.8) | 52.8 (37 to 68) | 51.3 (36.2 to 66.1) | 52.5 (37.5 to 67.1) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 49.7 (42 to 57.4) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: ACR50 Response Rate at Week 24

| End point title | ACR50 Response Rate at Week 24[19] |
|---|---|

End point description:

Percentage of subjects with an ACR50 response, defined as at least 50% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 24 (Week 12 of Study M12-965)

Notes:

[19] - 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: Descriptive statistics are presented, per protocol.

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 39 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 40.5 (27 to 55.5) | 47.2 (32 to 63) | 53.8 (38.6 to 68.4) | 71.8 (56.1 to 83.6) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 156 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 53.2 (45.4 to 60.9) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: ACR50 Response Rate at Week 28

| End point title | ACR50 Response Rate at Week 28[20] |
|---|---|

**End point description:**

Percentage of subjects with an ACR50 response, defined as at least 50% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

**End point timeframe:**

Week 28 (Week 16 of Study M12-965)

**Notes:**

[20] - 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: Descriptive statistics are presented, per protocol.

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 39 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 50 (35.5 to 64.5) | 47.2 (32 to 63) | 51.3 (36.2 to 66.1) | 69.2 (53.5 to 81.5) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 156 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 54.5 (46.7 to 62.1) | | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: ACR50 Response Rate at Week 32

| End point title | ACR50 Response Rate at Week 32[21] |
|---|---|

**End point description:**

Percentage of subjects with an ACR50 response, defined as at least 50% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 32 (Week 20 of Study M12-965)

Notes:

[21] - 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: Descriptive statistics are presented, per protocol.

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 45.2 (31.2 to 60.1) | 58.3 (42.2 to 72.9) | 51.3 (36.2 to 66.1) | 62.5 (47 to 75.8) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 54.1 (46.3 to 61.7) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: ACR50 Response Rate at Week 36

| End point title | ACR50 Response Rate at Week 36[22] |
|---|---|

End point description:

Percentage of subjects with an ACR50 response, defined as at least 50% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 36 (Week 24 of Study M12-965)

Notes:

[22] - 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: Descriptive statistics are presented, per protocol.

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 45.2 (31.2 to 60.1) | 50 (34.5 to 65.5) | 53.8 (38.6 to 68.4) | 62.5 (47 to 75.8) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 52.9 (45.1 to 60.5) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: ACR70 Response Rate at Week 2

| End point title | ACR70 Response Rate at Week 2[23] |
|---|---|

End point description:

Percentage of subjects with an ACR70 response, defined as at least 70% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 2 of Study M12-963

Notes:

[23] - 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: Descriptive statistics are presented, per protocol.

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 40 | 37 | 39 | 39 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 0 (0 to 10.4) | 2.7 (0 to 15.1) | 5.1 (0.5 to 17.8) | 5.1 (0.5 to 17.8) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 155 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 3.2 (1.2 to 7.5) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: ACR70 Response Rate at Week 4

| End point title | ACR70 Response Rate at Week 4[24] |
|---|---|

End point description:

Percentage of subjects with an ACR70 response, defined as at least 70% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 4 of Study M12-963

Notes:

[24] - 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: Descriptive statistics are presented, per protocol.

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 4.8 (0.5 to 16.6) | 10.8 (3.7 to 25.3) | 10.3 (3.5 to 24.2) | 17.5 (8.4 to 32.3) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 158 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 10.8 (6.7 to 16.6) | | | |

## Statistical analyses

No statistical analyses for this end point

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## Primary: ACR70 Response Rate at Week 6

| End point title | ACR70 Response Rate at Week 6[25] |
|---|---|

End point description:

Percentage of subjects with an ACR70 response, defined as at least 70% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 6 of Study M12-963

Notes:

[25] - 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: Descriptive statistics are presented, per protocol.

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 16.7 (8 to 30.9) | 13.5 (5.4 to 28.5) | 17.9 (8.7 to 33) | 20 (10.2 to 35) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 158 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 17.1 (12 to 23.8) | | | |

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## Statistical analyses

No statistical analyses for this end point

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## Primary: ACR70 Response Rate at Week 8

| End point title | ACR70 Response Rate at Week 8[26] |
|---|---|

End point description:

Percentage of subjects with an ACR70 response, defined as at least 70% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 8 of Study M12-963

Notes:

[26] - 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: Descriptive statistics are presented, per protocol.

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 19 (9.7 to 33.6) | 8.1 (2.1 to 22) | 25.6 (14.4 to 41.2) | 27.5 (16 to 43) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 158 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 20.3 (14.7 to 27.2) | | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: ACR70 Response Rate at Week 12

| End point title | ACR70 Response Rate at Week 12[27] |
|---|---|

End point description:

Percentage of subjects with an ACR70 response, defined as at least 70% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 12 of Study M12-963 (considered Week 0 of Study M12-965)

Notes:

[27] - 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: Descriptive statistics are presented, per protocol.

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 23.8 (13.3 to 38.7) | 24.3 (13.2 to 40.3) | 20.5 (10.5 to 35.8) | 35 (22.1 to 50.5) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 158 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 25.9 (19.7 to 33.3) | | | |

### Statistical analyses

No statistical analyses for this end point

### Primary: ACR70 Response Rate at Week 16

| End point title | ACR70 Response Rate at Week 16[28] |
|---|---|

End point description:

Percentage of subjects with an ACR70 response, defined as at least 70% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 16 (Week 4 of Study M12-965)

Notes:

[28] - 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: Descriptive statistics are presented, per protocol.

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 40 | 36 | 36 | 39 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 15 (6.7 to 29.5) | 30.6 (17.9 to 47) | 33.3 (20.1 to 49.7) | 25.6 (14.4 to 41.2) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 151 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 25.8 (19.5 to 33.4) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: ACR70 Response Rate at Week 20

| End point title | ACR70 Response Rate at Week 20[29] |
|---|---|

End point description:

Percentage of subjects with an ACR70 response, defined as at least 70% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 20 (Week 8 of Study M12-965)

Notes:

[29] - 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: Descriptive statistics are presented, per protocol.

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 35 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 19 (9.7 to 33.6) | 31.4 (18.4 to 48.1) | 33.3 (20.6 to 49.1) | 32.5 (20 to 48.1) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 156 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 28.8 (22.3 to 36.4) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: ACR70 Response Rate at Week 24

| End point title | ACR70 Response Rate at Week 24[30] |
|---|---|

End point description:

Percentage of subjects with an ACR70 response, defined as at least 70% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 24 (Week 12 of Study M12-965)

Notes:

[30] - 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: Descriptive statistics are presented, per protocol.

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 19 (9.7 to 33.6) | 25 (13.6 to 41.3) | 28.2 (16.4 to 43.9) | 40 (26.3 to 55.4) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 28 (21.6 to 35.5) | | | |

## Statistical analyses

No statistical analyses for this end point

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## Primary: ACR70 Response Rate at Week 28

| End point title | ACR70 Response Rate at Week 28[31] |
|---|---|

End point description:

Percentage of subjects with an ACR70 response, defined as at least 70% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 28 (Week 16 of Study M12-965)

Notes:

[31] - 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: Descriptive statistics are presented, per protocol.

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 39 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 16.7 (8 to 30.9) | 27.8 (15.7 to 44.1) | 30.8 (18.5 to 46.5) | 41 (27.1 to 56.6) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 156 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 28.8 (22.3 to 36.4) | | | |

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## Statistical analyses

No statistical analyses for this end point

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## Primary: ACR70 Response Rate at Week 32

| End point title | ACR70 Response Rate at Week 32[32] |
|---|---|

**End point description:**

Percentage of subjects with an ACR70 response, defined as at least 70% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

**End point timeframe:**

Week 32 (Week 20 of Study M12-965)

**Notes:**

[32] - 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: Descriptive statistics are presented, per protocol.

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 16.7 (8 to 30.9) | 27.8 (15.7 to 44.1) | 23.1 (12.4 to 38.5) | 42.5 (28.5 to 57.8) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 27.4 (21 to 34.9) | | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: ACR70 Response Rate at Week 36

| End point title | ACR70 Response Rate at Week 36[33] |
|---|---|

**End point description:**

Percentage of subjects with an ACR70 response, defined as at least 70% reduction (improvement) compared with baseline in TJC68, SJC66, and at least 3 of the 5 remaining ACR core set measures: patient's assessment of pain, PtGA; PGA, HAQ-DI, and hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 36 (Week 24 of Study M12-965)

Notes:

[33] - 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: Descriptive statistics are presented, per protocol.

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 23.8 (13.3 to 38.7) | 30.6 (17.9 to 47) | 35.9 (22.7 to 51.6) | 45 (30.7 to 60.2) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 33.8 (26.8 to 41.5) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Summary of Treatment-Emergent Adverse Events (AEs), Serious AEs (SAEs), AEs Leading to Discontinuation, and Deaths

| End point title | Summary of Treatment-Emergent Adverse Events (AEs), Serious AEs (SAEs), AEs Leading to Discontinuation, and Deaths[34] |
|---|---|

End point description:

An AE is defined as any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. The investigator assessed the relationship of each event to the use of study drug as either probably related, possibly related, probably not related or not related. An SAE is an event that results in death, is life-threatening, requires or prolongs hospitalization, results in a congenital anomaly, persistent or significant disability/incapacity or is an important medical event that, based on medical judgment, may jeopardize the subject and may require medical or surgical intervention to prevent any of the outcomes listed above. Treatment-emergent events (TEAEs/TESAEs) are defined as any event that began or worsened in severity after the first dose of study drug. For more details on adverse events please see the Adverse Event section.

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

End point timeframe:

from the first dose of study drug in study M12-965 until 70 days after the last dose of study drug (up to 32 weeks)

Notes:

[34] - 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: Descriptive statistics are presented, per protocol.

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 40 |
| Units: Participants | | | | |
| number (not applicable) | | | | |
| Any AE | 17 | 15 | 19 | 14 |
| AE possibly study drug-related | 5 | 6 | 6 | 6 |
| SAE possibly study drug-related | 0 | 0 | 0 | 0 |
| Severe AE | 0 | 1 | 1 | 0 |
| SAE | 0 | 1 | 5 | 0 |
| AE leading to study drug discontinuation | 1 | 0 | 1 | 0 |
| AE leading to Death | 0 | 0 | 0 | 0 |
| Death (includes non-treatment-emergent) | 0 | 0 | 0 | 0 |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 158 | | | |
| Units: Participants | | | | |
| number (not applicable) | | | | |
| Any AE | 65 | | | |
| AE possibly study drug-related | 23 | | | |
| SAE possibly study drug-related | 0 | | | |
| Severe AE | 2 | | | |
| SAE | 6 | | | |
| AE leading to study drug discontinuation | 2 | | | |
| AE leading to Death | 0 | | | |
| Death (includes non-treatment-emergent) | 0 | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline In Tender Joint Count (TJC68) at Week 2

| End point title | Change From Baseline In Tender Joint Count (TJC68) at Week 2 |
|---|---|

End point description:

At each study visit, a joint evaluator assessed whether a particular joint was "tender or painful" where presence of tenderness was scored as "1" and the absence of tenderness was scored as "0," provided the joint was not replaced or could not be assessed due to other reasons. The total TJC68, which is based on 68 joints, was derived as the sum of all "1s" thus collected with no penalty considered for the joints not assessed or those which had been replaced. The range for TJC68 was 0 to 68, with a higher score indication a greater degree of tenderness. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had

an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 2 of Study M12-963

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 40 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -9.4 (± 10.28) | -11.6 (± 10.57) | -11 (± 11.12) | -12.9 (± 13.84) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 155 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -11.2 (± 11.52) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in TJC68 at Week 4

| End point title | Change From Baseline in TJC68 at Week 4 |
|---|---|

End point description:

At each study visit, a joint evaluator assessed whether a particular joint was "tender or painful" where presence of tenderness was scored as "1" and the absence of tenderness was scored as "0," provided the joint was not replaced or could not be assessed due to other reasons. The total TJC68, which is based on 68 joints, was derived as the sum of all "1s" thus collected with no penalty considered for the joints not assessed or those which had been replaced. The range for TJC68 was 0 to 68, with a higher score indication a greater degree of tenderness. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 4 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -13.1 (± 9.98) | -16.6 (± 12.48) | -13.6 (± 12) | -16.1 (± 12.77) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -14.8 (± 11.8) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in TJC68 at Week 6

| End point title | Change From Baseline in TJC68 at Week 6 |
|---|---|

End point description:

At each study visit, a joint evaluator assessed whether a particular joint was "tender or painful" where presence of tenderness was scored as "1" and the absence of tenderness was scored as "0," provided the joint was not replaced or could not be assessed due to other reasons. The total TJC68, which is based on 68 joints, was derived as the sum of all "1s" thus collected with no penalty considered for the joints not assessed or those which had been replaced. The range for TJC68 was 0 to 68, with a higher score indication a greater degree of tenderness. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 6 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -15.8 (± 10.18) | -16.9 (± 11.67) | -15.3 (± 11.05) | -16.6 (± 12.56) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -16.1 (± 11.28) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in TJC68 at Week 8

| End point title | Change From Baseline in TJC68 at Week 8 |
|---|---|

End point description:

At each study visit, a joint evaluator assessed whether a particular joint was "tender or painful" where presence of tenderness was scored as "1" and the absence of tenderness was scored as "0," provided the joint was not replaced or could not be assessed due to other reasons. The total TJC68, which is based on 68 joints, was derived as the sum of all "1s" thus collected with no penalty considered for the joints not assessed or those which had been replaced. The range for TJC68 was 0 to 68, with a higher score indication a greater degree of tenderness. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 8 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -17.3 (± 9.93) | -17.4 (± 10.85) | -17.1 (± 10.21) | -17.1 (± 13.33) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -17.2 (± | | | |

| 11.05) |
|--------|

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in TJC68 at Week 12

| End point title | Change From Baseline in TJC68 at Week 12 |
|-----------------|-------------------------------------------|

End point description:

At each study visit, a joint evaluator assessed whether a particular joint was "tender or painful" where presence of tenderness was scored as "1" and the absence of tenderness was scored as "0," provided the joint was not replaced or could not be assessed due to other reasons. The total TJC68, which is based on 68 joints, was derived as the sum of all "1s" thus collected with no penalty considered for the joints not assessed or those which had been replaced. The range for TJC68 was 0 to 68, with a higher score indication a greater degree of tenderness. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 12 of Study M12-963 (considered Week 0 of Study M12-965)

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|----------------------|-------------------------------------|---------------------------------|----------------------------------|---------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -18.4 (± 11.78) | -16.9 (± 10.9) | -18.6 (± 10.16) | -18 (± 12.64) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|----------------------|------------------------|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -18 (± 11.34) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in TJC68 at Week 16

| End point title | Change From Baseline in TJC68 at Week 16 |
|---|---|

End point description:

At each study visit, a joint evaluator assessed whether a particular joint was "tender or painful" where presence of tenderness was scored as "1" and the absence of tenderness was scored as "0," provided the joint was not replaced or could not be assessed due to other reasons. The total TJC68, which is based on 68 joints, was derived as the sum of all "1s" thus collected with no penalty considered for the joints not assessed or those which had been replaced. The range for TJC68 was 0 to 68, with a higher score indication a greater degree of tenderness. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 16 (Week 4 of Study M12-965)

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 41 | 36 | 37 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -18.3 (± 12.03) | -19.2 (± 10.57) | -17.6 (± 9.14) | -18.1 (± 12.38) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 154 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -18.3 (± 11.07) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in TJC68 at Week 20

| End point title | Change From Baseline in TJC68 at Week 20 |
|---|---|

End point description:

At each study visit, a joint evaluator assessed whether a particular joint was "tender or painful" where presence of tenderness was scored as "1" and the absence of tenderness was scored as "0," provided the joint was not replaced or could not be assessed due to other reasons. The total TJC68, which is based on 68 joints, was derived as the sum of all "1s" thus collected with no penalty considered for the joints not assessed or those which had been replaced. The range for TJC68 was 0 to 68, with a higher

score indication a greater degree of tenderness. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 20 (Week 8 of Study M12-965)

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -17.6 (± 11.93) | -19.7 (± 10.6) | -17.8 (± 10.31) | -19 (± 11.89) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -18.5 (± 11.16) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in TJC68 at Week 24

| End point title | Change From Baseline in TJC68 at Week 24 |
|---|---|

End point description:

At each study visit, a joint evaluator assessed whether a particular joint was "tender or painful" where presence of tenderness was scored as "1" and the absence of tenderness was scored as "0," provided the joint was not replaced or could not be assessed due to other reasons. The total TJC68, which is based on 68 joints, was derived as the sum of all "1s" thus collected with no penalty considered for the joints not assessed or those which had been replaced. The range for TJC68 was 0 to 68, with a higher score indication a greater degree of tenderness. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 24 (Week 12 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -19.3 (± 12.16) | -18.3 (± 10.27) | -17.4 (± 9.7) | -19.8 (± 12.32) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -18.7 (± 11.15) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in TJC68 at Week 28

| End point title | Change From Baseline in TJC68 at Week 28 |
|---|---|

End point description:

At each study visit, a joint evaluator assessed whether a particular joint was "tender or painful" where presence of tenderness was scored as "1" and the absence of tenderness was scored as "0," provided the joint was not replaced or could not be assessed due to other reasons. The total TJC68, which is based on 68 joints, was derived as the sum of all "1s" thus collected with no penalty considered for the joints not assessed or those which had been replaced. The range for TJC68 was 0 to 68, with a higher score indication a greater degree of tenderness. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 28 (Week 16 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -18.2 (± 10.88) | -18.9 (± 12.26) | -17.9 (± 10.31) | -21 (± 13.02) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -19 (± 11.6) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in TJC68 at Week 32

| End point title | Change From Baseline in TJC68 at Week 32 |
|---|---|

End point description:

At each study visit, a joint evaluator assessed whether a particular joint was "tender or painful" where presence of tenderness was scored as "1" and the absence of tenderness was scored as "0," provided the joint was not replaced or could not be assessed due to other reasons. The total TJC68, which is based on 68 joints, was derived as the sum of all "1s" thus collected with no penalty considered for the joints not assessed or those which had been replaced. The range for TJC68 was 0 to 68, with a higher score indication a greater degree of tenderness. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 32 (Week 20 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -18.2 (± 11.72) | -19.7 (± 11.04) | -17.9 (± 10.47) | -20.3 (± 13.38) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -19 (± 11.66) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in TJC68 at Week 36

| End point title | Change From Baseline in TJC68 at Week 36 |
|---|---|

End point description:

At each study visit, a joint evaluator assessed whether a particular joint was "tender or painful" where presence of tenderness was scored as "1" and the absence of tenderness was scored as "0," provided the joint was not replaced or could not be assessed due to other reasons. The total TJC68, which is based on 68 joints, was derived as the sum of all "1s" thus collected with no penalty considered for the joints not assessed or those which had been replaced. The range for TJC68 was 0 to 68, with a higher score indication a greater degree of tenderness. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 36 (Week 24 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -18.2 (± 10.92) | -18.5 (± 11.92) | -17.7 (± 10.06) | -20.3 (± 12.88) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -18.7 (± 11.42) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Swollen Joint Count (SJC66) at Week 2

| End point title | Change From Baseline in Swollen Joint Count (SJC66) at Week 2 |
|---|---|

End point description:

At each study visit, a joint evaluator assessed whether a particular joint was swollen where presence of swelling was scored as "1" and the absence of swelling
was scored as "0," provided the joint was not replaced or could not be assessed due to other reasons. The total SJC66, which is based on 66 joints, was derived as the sum of all "1s" thus collected with no penalty considered for the joints not assessed or those which had been replaced. The range for SJC66 was 0 to 66, with a higher score indicating a greater degree of swelling. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 2 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 40 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -8 (± 9.07) | -8.8 (± 8.5) | -8.6 (± 10.84) | -10.8 (± 9.34) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 155 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -9 (± 9.46) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in SJC66 at Week 4

| End point title | Change From Baseline in SJC66 at Week 4 |
|---|---|

End point description:

At each study visit, a joint evaluator assessed whether a particular joint was swollen where presence of swelling was scored as "1" and the absence of swelling
was scored as "0," provided the joint was not replaced or could not be assessed due to other reasons. The total SJC66, which is based on 66 joints, was derived as the sum of all "1s" thus collected with no penalty considered for the joints not assessed or those which had been replaced. The range for SJC66 was 0 to 66, with a higher score indicating a greater degree of swelling. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 4 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -8.8 (± 8.72) | -10.6 (± 8.04) | -10.3 (± 10.5) | -13.3 (± 9.29) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -10.7 (± 9.26) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in SJC66 at Week 6

| End point title | Change From Baseline in SJC66 at Week 6 |
|---|---|

End point description:

At each study visit, a joint evaluator assessed whether a particular joint was swollen where presence of swelling was scored as "1" and the absence of swelling
was scored as "0," provided the joint was not replaced or could not be assessed due to other reasons. The total SJC66, which is based on 66 joints, was derived as the sum of all "1s" thus collected with no penalty considered for the joints not assessed or those which had been replaced. The range for SJC66

was 0 to 66, with a higher score indicating a greater degree of swelling. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

| End point timeframe: |
|---|
| Week 6 of Study M12-963 |

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -11.8 (± 8.09) | -11.9 (± 7.71) | -12.3 (± 10.15) | -13.3 (± 9.31) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -12.3 (± 8.81) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in SJC66 at Week 8

| End point title | Change From Baseline in SJC66 at Week 8 |
|---|---|

End point description:

At each study visit, a joint evaluator assessed whether a particular joint was swollen where presence of swelling was scored as "1" and the absence of swelling
was scored as "0," provided the joint was not replaced or could not be assessed due to other reasons. The total SJC66, which is based on 66 joints, was derived as the sum of all "1s" thus collected with no penalty considered for the joints not assessed or those which had been replaced. The range for SJC66 was 0 to 66, with a higher score indicating a greater degree of swelling. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

| End point timeframe: |
|---|
| Week 8 of Study M12-963 |

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -12.2 (± 8.26) | -12.4 (± 7.76) | -13.8 (± 9.32) | -14.3 (± 9.43) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -13.2 (± 8.7) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in SJC66 at Week 12

| End point title | Change From Baseline in SJC66 at Week 12 |
|---|---|

End point description:

At each study visit, a joint evaluator assessed whether a particular joint was swollen where presence of swelling was scored as "1" and the absence of swelling
was scored as "0," provided the joint was not replaced or could not be assessed due to other reasons. The total SJC66, which is based on 66 joints, was derived as the sum of all "1s" thus collected with no penalty considered for the joints not assessed or those which had been replaced. The range for SJC66 was 0 to 66, with a higher score indicating a greater degree of swelling. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 12 of Study M12-963 (considered Week 0 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -12.6 (± 8.73) | -11.8 (± 9.51) | -13.4 (± 9.13) | -14.8 (± 9) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -13.2 (± 9.06) | | | |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Change From Baseline in SJC66 at Week 16**

| End point title | Change From Baseline in SJC66 at Week 16 |
|---|---|

End point description:

At each study visit, a joint evaluator assessed whether a particular joint was swollen where presence of swelling was scored as "1" and the absence of swelling
was scored as "0," provided the joint was not replaced or could not be assessed due to other reasons. The total SJC66, which is based on 66 joints, was derived as the sum of all "1s" thus collected with no penalty considered for the joints not assessed or those which had been replaced. The range for SJC66 was 0 to 66, with a higher score indicating a greater degree of swelling. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 16 (Week 4 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 41 | 36 | 37 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -13 (± 8.5) | -13.5 (± 9.6) | -13.8 (± 8.9) | -14.5 (± 8.69) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 154 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -13.7 (± 8.84) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in SJC66 at Week 20

| End point title | Change From Baseline in SJC66 at Week 20 |
|---|---|

End point description:

At each study visit, a joint evaluator assessed whether a particular joint was swollen where presence of swelling was scored as "1" and the absence of swelling was scored as "0," provided the joint was not replaced or could not be assessed due to other reasons. The total SJC66, which is based on 66 joints, was derived as the sum of all "1s" thus collected with no penalty considered for the joints not assessed or those which had been replaced. The range for SJC66 was 0 to 66, with a higher score indicating a greater degree of swelling. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 20 (Week 8 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -12.2 (± 7.47) | -14.6 (± 8.97) | -13.8 (± 10.3) | -15.4 (± 8.95) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -14 (± 8.95) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in SJC66 at Week 24

| End point title | Change From Baseline in SJC66 at Week 24 |
|---|---|

End point description:

At each study visit, a joint evaluator assessed whether a particular joint was swollen where presence of swelling was scored as "1" and the absence of swelling was scored as "0," provided the joint was not replaced or could not be assessed due to other reasons. The total SJC66, which is based on 66 joints, was derived as the sum of all "1s" thus collected with no penalty considered for the joints not assessed or those which had been replaced. The range for SJC66 was 0 to 66, with a higher score indicating a greater degree of swelling. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 24 (Week 12 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -14 (± 8.21) | -13.8 (± 8.68) | -14.6 (± 9.87) | -15.6 (± 9.16) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -14.5 (± 8.93) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in SJC66 at Week 28

| End point title | Change From Baseline in SJC66 at Week 28 |
|---|---|

End point description:

At each study visit, a joint evaluator assessed whether a particular joint was swollen where presence of swelling was scored as "1" and the absence of swelling was scored as "0," provided the joint was not replaced or could not be assessed due to other reasons. The total SJC66, which is based on 66 joints, was derived as the sum of all "1s" thus collected with no penalty considered for the joints not assessed or those which had been replaced. The range for SJC66 was 0 to 66, with a higher score indicating a greater degree of swelling. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 28 (Week 16 of Study M12-965)

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -13.3 (± 6.88) | -14 (± 10.12) | -14.9 (± 9.49) | -15.8 (± 9.29) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -14.5 (± 8.94) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in SJC66 at Week 32

| End point title | Change From Baseline in SJC66 at Week 32 |
|---|---|

End point description:

At each study visit, a joint evaluator assessed whether a particular joint was swollen where presence of swelling was scored as "1" and the absence of swelling was scored as "0," provided the joint was not replaced or could not be assessed due to other reasons. The total SJC66, which is based on 66 joints, was derived as the sum of all "1s" thus collected with no penalty considered for the joints not assessed or those which had been replaced. The range for SJC66 was 0 to 66, with a higher score indicating a greater degree of swelling. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had

an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 32 (Week 20 of Study M12-965)

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -13.1 (± 8.14) | -13.9 (± 10.34) | -14.3 (± 9.81) | -14.9 (± 9.71) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -14.1 (± 9.43) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in SJC66 at Week 36

| End point title | Change From Baseline in SJC66 at Week 36 |
|---|---|

End point description:

At each study visit, a joint evaluator assessed whether a particular joint was swollen where presence of swelling was scored as "1" and the absence of swelling was scored as "0," provided the joint was not replaced or could not be assessed due to other reasons. The total SJC66, which is based on 66 joints, was derived as the sum of all "1s" thus collected with no penalty considered for the joints not assessed or those which had been replaced. The range for SJC66 was 0 to 66, with a higher score indicating a greater degree of swelling. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 36 (Week 24 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -12.4 (± 7.76) | -14 (± 10.55) | -15 (± 9.57) | -14.8 (± 9.82) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -14 (± 9.4) | | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change From Baseline in Patient's Assessment of Pain at Week 2

| End point title | Change From Baseline in Patient's Assessment of Pain at Week 2 |
|---|---|

End point description:

Subjects assessed their pain in the previous week using a Patient's Global Assessment Pain visual analogue scale (VAS). The range is 0 to 100 mm with no pain being indicated by 0 and severe pain by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 2 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 40 | 36 | 39 | 39 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -17.9 (± 22.82) | -20.1 (± 16.83) | -22.4 (± 23.49) | -22.3 (± 22.46) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 154 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -20.7 (± 21.53) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Patient's Assessment of Pain at Week 4

| End point title | Change From Baseline in Patient's Assessment of Pain at Week 4 |
|---|---|

End point description:

Subjects assessed their pain in the previous week using a Patient's Global Assessment Pain visual analogue scale (VAS). The range is 0 to 100 mm with no pain being indicated by 0 and severe pain by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 4 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -24.5 (± 20.24) | -28.7 (± 20.76) | -24.8 (± 26.57) | -29.3 (± 23.07) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -26.8 (± 22.68) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Patient's Assessment of Pain at Week 6

| End point title | Change From Baseline in Patient's Assessment of Pain at Week 6 |
|---|---|

End point description:

Subjects assessed their pain in the previous week using a Patient's Global Assessment Pain visual analogue scale (VAS). The range is 0 to 100 mm with no pain being indicated by 0 and severe pain by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 6 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -31.8 (± 21.24) | -29.1 (± 22.48) | -29.8 (± 27.07) | -29.9 (± 21.36) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -30.2 (± 22.92) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Patient's Assessment of Pain at Week 8

| End point title | Change From Baseline in Patient's Assessment of Pain at Week 8 |
|---|---|

End point description:

Subjects assessed their pain in the previous week using a Patient's Global Assessment Pain visual analogue scale (VAS). The range is 0 to 100 mm with no pain being indicated by 0 and severe pain by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 8 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
| --- | --- | --- | --- | --- |
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -30.5 (± 24.64) | -29.8 (± 21.56) | -30.2 (± 27.89) | -36 (± 23.11) |

| End point values | All ABT-122 120 mg EOW | | | |
| --- | --- | --- | --- | --- |
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -31.7 (± 24.36) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Patient's Assessment of Pain at Week 12

| End point title | Change From Baseline in Patient's Assessment of Pain at Week 12 |
| --- | --- |

End point description:

Subjects assessed their pain in the previous week using a Patient's Global Assessment Pain visual analogue scale (VAS). The range is 0 to 100 mm with no pain being indicated by 0 and severe pain by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 12 of Study M12-963 (considered Week 0 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -36.2 (± 19.91) | -29.3 (± 22.34) | -37.9 (± 27.18) | -36.5 (± 23.52) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -35.1 (± 23.34) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Patient's Assessment of Pain at Week 16

| End point title | Change From Baseline in Patient's Assessment of Pain at Week 16 |
|---|---|

End point description:

Subjects assessed their pain in the previous week using a Patient's Global Assessment Pain visual analogue scale (VAS). The range is 0 to 100 mm with no pain being indicated by 0 and severe pain by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 16 (Week 4 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 41 | 36 | 37 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -31.9 (± 24.68) | -33 (± 24.11) | -35 (± 28.43) | -38.5 (± 22.92) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 154 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -34.6 (± 24.96) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Patient's Assessment of Pain at Week 20

| End point title | Change From Baseline in Patient's Assessment of Pain at Week 20 |
|---|---|

End point description:

Subjects assessed their pain in the previous week using a Patient's Global Assessment Pain visual analogue scale (VAS). The range is 0 to 100 mm with no pain being indicated by 0 and severe pain by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 20 (Week 8 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -30.2 (± 22.48) | -40.3 (± 24.12) | -37.8 (± 28.78) | -36.8 (± 21.72) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -36.1 (± 24.44) | | | |

## Statistical analyses

No statistical analyses for this end point

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## Secondary: Change From Baseline in Patient's Assessment of Pain at Week 24

| End point title | Change From Baseline in Patient's Assessment of Pain at Week 24 |
|---|---|

End point description:

Subjects assessed their pain in the previous week using a Patient's Global Assessment Pain visual analogue scale (VAS). The range is 0 to 100 mm with no pain being indicated by 0 and severe pain by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 24 (Week 12 of Study M12-965)

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -31.7 (± 21.86) | -35.9 (± 23.28) | -32 (± 30.31) | -39.4 (± 23.64) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -34.7 (± 24.92) | | | |

## Statistical analyses

No statistical analyses for this end point

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## Secondary: Change From Baseline in Patient's Assessment of Pain at Week 28

| End point title | Change From Baseline in Patient's Assessment of Pain at Week 28 |
|---|---|

End point description:

Subjects assessed their pain in the previous week using a Patient's Global Assessment Pain visual analogue scale (VAS). The range is 0 to 100 mm with no pain being indicated by 0 and severe pain by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 28 (Week 16 of Study M12-965)

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -28.5 (± 22.39) | -36.2 (± 28.88) | -35.3 (± 28.64) | -40.1 (± 22.61) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -34.9 (± 25.79) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Patient's Assessment of Pain at Week 32

| End point title | Change From Baseline in Patient's Assessment of Pain at Week 32 |
|---|---|

End point description:

Subjects assessed their pain in the previous week using a Patient's Global Assessment Pain visual analogue scale (VAS). The range is 0 to 100 mm with no pain being indicated by 0 and severe pain by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -27.3 (± 22.16) | -37.4 (± 25.63) | -34.3 (± 32.99) | -42.8 (± 25.31) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -35.3 (± 27.1) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Patient's Assessment of Pain at Week 36

| End point title | Change From Baseline in Patient's Assessment of Pain at Week 36 |
|---|---|

End point description:

Subjects assessed their pain in the previous week using a Patient's Global Assessment Pain visual analogue scale (VAS). The range is 0 to 100 mm with no pain being indicated by 0 and severe pain by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 36 (Week 24 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -31.3 (± 23.36) | -36.1 (± 28.9) | -39.3 (± 31.37) | -41.8 (± 28.21) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -37 (± 28.03) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in Patient's Global Assessment of Disease Activity at Week 2

| End point title | Change from Baseline in Patient's Global Assessment of Disease Activity at Week 2 |
|---|---|

End point description:

Subjects assessed their disease activity for the past 24 hours using a Patient's Global Assessment of Disease VAS. The range is 0 to 100 mm with no activity being indicated by 0 and severe activity by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 2 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 40 | 36 | 39 | 39 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -18.1 (± 23.77) | -14.2 (± 16.41) | -21.3 (± 19.92) | -17.2 (± 23.06) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 154 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -17.7 (± 21.03) | | | |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Change from Baseline in Patient's Global Assessment of Disease Activity at Week 4**

| End point title | Change from Baseline in Patient's Global Assessment of Disease Activity at Week 4 |
|---|---|

End point description:

Subjects assessed their disease activity for the past 24 hours using a Patient's Global Assessment of Disease VAS. The range is 0 to 100 mm with no activity being indicated by 0 and severe activity by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 4 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -20.6 (± 21.73) | -25.6 (± 22.33) | -20.7 (± 24.62) | -26.6 (± 21.79) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -23.3 (± 22.58) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in Patient's Global Assessment of Disease Activity at Week 6

| End point title | Change from Baseline in Patient's Global Assessment of Disease Activity at Week 6 |
|---|---|

End point description:

Subjects assessed their disease activity for the past 24 hours using a Patient's Global Assessment of Disease VAS. The range is 0 to 100 mm with no activity being indicated by 0 and severe activity by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 6 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -26.5 (± 20.97) | -23.2 (± 22.21) | -26.9 (± 24.17) | -27.9 (± 21.14) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -26.2 (± 21.98) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in Patient's Global Assessment of Disease Activity at Week 8

| End point title | Change from Baseline in Patient's Global Assessment of Disease Activity at Week 8 |
|---|---|

End point description:

Subjects assessed their disease activity for the past 24 hours using a Patient's Global Assessment of Disease VAS. The range is 0 to 100 mm with no activity being indicated by 0 and severe activity by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 8 of Study M12-963

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -27.1 (± 24.33) | -26.8 (± 23.25) | -31.8 (± 25.54) | -34.1 (± 22.93) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -30 (± 24.02) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in Patient's Global Assessment of Disease Activity at Week 12

| End point title | Change from Baseline in Patient's Global Assessment of Disease Activity at Week 12 |
|---|---|

End point description:

Subjects assessed their disease activity for the past 24 hours using a Patient's Global Assessment of Disease VAS. The range is 0 to 100 mm with no activity being indicated by 0 and severe activity by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 12 of Study M12-963 (considered Week 0 of Study M12-965)

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -29.2 (± 23.39) | -29 (± 25.11) | -34.1 (± 21.41) | -35.6 (± 25.62) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -32 (± 23.86) | | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in Patient's Global Assessment of Disease Activity at Week 16

| End point title | Change from Baseline in Patient's Global Assessment of Disease Activity at Week 16 |
|---|---|

End point description:

Subjects assessed their disease activity for the past 24 hours using a Patient's Global Assessment of Disease VAS. The range is 0 to 100 mm with no activity being indicated by 0 and severe activity by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 16 (Week 4 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 41 | 36 | 37 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -26.8 (± 24.09) | -29.3 (± 24.91) | -34.8 (± 20.59) | -35.8 (± 22.51) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 154 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -31.6 (± 23.18) | | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in Patient's Global Assessment of Disease Activity at Week 20

| End point title | Change from Baseline in Patient's Global Assessment of Disease Activity at Week 20 |
|---|---|

End point description:

Subjects assessed their disease activity for the past 24 hours using a Patient's Global Assessment of Disease VAS. The range is 0 to 100 mm with no activity being indicated by 0 and severe activity by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 20 (Week 8 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -28.5 (± 20.98) | -35.6 (± 24.56) | -35.4 (± 26.44) | -35.4 (± 22.95) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -33.6 (± 23.72) | | | |

**Statistical analyses**

No statistical analyses for this end point

## Secondary: Change from Baseline in Patient's Global Assessment of Disease Activity at Week 24

| End point title | Change from Baseline in Patient's Global Assessment of Disease Activity at Week 24 |
|---|---|

End point description:

Subjects assessed their disease activity for the past 24 hours using a Patient's Global Assessment of Disease VAS. The range is 0 to 100 mm with no activity being indicated by 0 and severe activity by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 24 (Week 12 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -31.5 (± 22.81) | -33.1 (± 24.25) | -32.7 (± 25.16) | -38.9 (± 23.63) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -34 (± 23.89) | | | |

## Statistical analyses

No statistical analyses for this end point

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## Secondary: Change from Baseline in Patient's Global Assessment of Disease Activity at Week 28

| End point title | Change from Baseline in Patient's Global Assessment of Disease Activity at Week 28 |
|---|---|

End point description:

Subjects assessed their disease activity for the past 24 hours using a Patient's Global Assessment of Disease VAS. The range is 0 to 100 mm with no activity being indicated by 0 and severe activity by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 28 (Week 16 of Study M12-965)

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -25 (± 23.25) | -33.1 (± 27.93) | -32.6 (± 27.33) | -39.7 (± 25.57) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -32.5 (± 26.29) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in Patient's Global Assessment of Disease Activity at Week 32

| End point title | Change from Baseline in Patient's Global Assessment of Disease Activity at Week 32 |
|---|---|

End point description:

Subjects assessed their disease activity for the past 24 hours using a Patient's Global Assessment of Disease VAS. The range is 0 to 100 mm with no activity being indicated by 0 and severe activity by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 32 (Week 20 of Study M12-965)

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -27.4 (± 23.87) | -34.2 (± 26.17) | -32.8 (± 28.91) | -43.8 (± 23.56) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -34.5 (± 26.12) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in Patient's Global Assessment of Disease Activity at Week 36

| End point title | Change from Baseline in Patient's Global Assessment of Disease Activity at Week 36 |
|---|---|

End point description:

Subjects assessed their disease activity for the past 24 hours using a Patient's Global Assessment of Disease VAS. The range is 0 to 100 mm with no activity being indicated by 0 and severe activity by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 36 (Week 24 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -29.5 (± 26.04) | -32.5 (± 26.16) | -37.5 (± 25.73) | -38.3 (± 29.65) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -34.4 (± 26.96) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Physician's Global Assessment of Disease Activity at Week 2

| End point title | Change From Baseline in Physician's Global Assessment of Disease Activity at Week 2 |
|---|---|

End point description:

The physician assessed the subject's disease activity at the time of visit using a Physician's Global Assessment of Disease VAS. The range is 0 to 100 mm with no activity being indicated by 0 and severe activity by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 2 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 39 | 36 | 39 | 39 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -24.5 (± 21.8) | -25.8 (± 17.29) | -29.5 (± 21.25) | -26.5 (± 21.54) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 153 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -26.6 (± 20.49) | | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change From Baseline in Physician's Global Assessment of Disease Activity at Week 4

| End point title | Change From Baseline in Physician's Global Assessment of Disease Activity at Week 4 |
|---|---|

End point description:

The physician assessed the subject's disease activity at the time of visit using a Physician's Global Assessment of Disease VAS. The range is 0 to 100 mm with no activity being indicated by 0 and severe activity by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 4 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 39 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -28.6 (± 20.49) | -35.5 (± 21.15) | -34.5 (± 21.58) | -37.3 (± 23) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 156 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -33.8 (± 21.61) | | | |

**Statistical analyses**

No statistical analyses for this end point

## Secondary: Change From Baseline in Physician's Global Assessment of Disease Activity at Week 6

| End point title | Change From Baseline in Physician's Global Assessment of Disease Activity at Week 6 |
|---|---|

End point description:

The physician assessed the subject's disease activity at the time of visit using a Physician's Global Assessment of Disease VAS. The range is 0 to 100 mm with no activity being indicated by 0 and severe activity by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 6 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 39 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -38.5 (± 18.77) | -39 (± 22.76) | -40.3 (± 23.63) | -40.1 (± 20.94) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 156 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -39.5 (± 21.33) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Physician's Global Assessment of Disease Activity at Week 8

| End point title | Change From Baseline in Physician's Global Assessment of Disease Activity at Week 8 |
|---|---|

End point description:

The physician assessed the subject's disease activity at the time of visit using a Physician's Global Assessment of Disease VAS. The range is 0 to 100 mm with no activity being indicated by 0 and severe activity by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 8 of Study M12-963

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 39 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -41 (± 17.82) | -39.6 (± 20.94) | -45.6 (± 21.16) | -43.4 (± 22.87) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 156 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -42.4 (± 20.65) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Physician's Global Assessment of Disease Activity at Week 12

| End point title | Change From Baseline in Physician's Global Assessment of Disease Activity at Week 12 |
|---|---|

End point description:

The physician assessed the subject's disease activity at the time of visit using a Physician's Global Assessment of Disease VAS. The range is 0 to 100 mm with no activity being indicated by 0 and severe activity by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 12 of Study M12-963 (considered Week 0 of Study M12-965)

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 39 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -44.4 (± 20.3) | -42.9 (± 20.9) | -49.7 (± 20.54) | -47.6 (± 19.86) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 156 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -46.2 (± 20.36) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Physician's Global Assessment of Disease Activity at Week 16

| End point title | Change From Baseline in Physician's Global Assessment of Disease Activity at Week 16 |
|---|---|

End point description:

The physician assessed the subject's disease activity at the time of visit using a Physician's Global Assessment of Disease VAS. The range is 0 to 100 mm with no activity being indicated by 0 and severe activity by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

| End point timeframe: |
|---|

Week 16 (Week 4 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 40 | 35 | 36 | 37 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -46 (± 17.04) | -45.3 (± 24.23) | -47.3 (± 20.99) | -47.3 (± 21.46) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 148 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -46.4 (± 20.77) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Physician's Global Assessment of Disease Activity at Week 20

| End point title | Change From Baseline in Physician's Global Assessment of Disease Activity at Week 20 |
|---|---|

End point description:

The physician assessed the subject's disease activity at the time of visit using a Physician's Global Assessment of Disease VAS. The range is 0 to 100 mm with no activity being indicated by 0 and severe activity by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

| End point timeframe: |
|---|

Week 20 (Week 8 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 35 | 38 | 38 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -44.3 (± 19.08) | -46.1 (± 20.28) | -45.6 (± 22.89) | -49.3 (± 21.64) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 153 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -46.3 (± 20.86) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Physician's Global Assessment of Disease Activity at Week 24

| End point title | Change From Baseline in Physician's Global Assessment of Disease Activity at Week 24 |
|---|---|

End point description:

The physician assessed the subject's disease activity at the time of visit using a Physician's Global Assessment of Disease VAS. The range is 0 to 100 mm with no activity being indicated by 0 and severe activity by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 24 (Week 12 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 39 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -45.8 (± 18.06) | -46.7 (± 22) | -47.4 (± 23.02) | -49.9 (± 23.05) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 156 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -47.4 (± 21.4) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Physician's Global Assessment of Disease Activity at Week 28

| End point title | Change From Baseline in Physician's Global Assessment of Disease Activity at Week 28 |
|---|---|

End point description:

The physician assessed the subject's disease activity at the time of visit using a Physician's Global Assessment of Disease VAS. The range is 0 to 100 mm with no activity being indicated by 0 and severe activity by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 28 (Week 16 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 39 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -44.5 (± 20.72) | -48.7 (± 22.19) | -48.2 (± 22.85) | -51.7 (± 20.85) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 156 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -48.2 (± 21.59) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Physician's Global Assessment of Disease Activity at Week 32

| End point title | Change From Baseline in Physician's Global Assessment of Disease Activity at Week 32 |
|---|---|

End point description:

The physician assessed the subject's disease activity at the time of visit using a Physician's Global Assessment of Disease VAS. The range is 0 to 100 mm with no activity being indicated by 0 and severe activity by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 32 (Week 20 of Study M12-965)

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 39 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -45.2 (± 23.07) | -50 (± 24.46) | -49.9 (± 24.42) | -51.7 (± 25.03) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 156 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -49.1 (± 24.12) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Physician's Global Assessment of Disease Activity at Week 36

| End point title | Change From Baseline in Physician's Global Assessment of Disease Activity at Week 36 |
|---|---|

End point description:

The physician assessed the subject's disease activity at the time of visit using a Physician's Global Assessment of Disease VAS. The range is 0 to 100 mm with no activity being indicated by 0 and severe activity by 100. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 36 (Week 24 of Study M12-965)

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 39 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -42.4 (± 23.72) | -48 (± 23.1) | -50.5 (± 24.55) | -51.8 (± 24.24) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 156 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -48.1 (± 23.98) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Health Assessment Questionnaire Disability Index (HAQ-DI) at Week 2

| End point title | Change From Baseline in Health Assessment Questionnaire Disability Index (HAQ-DI) at Week 2 |
|---|---|

End point description:

HAQ-DI is a self-reported subject outcome measurement. It is calculated as the mean of the scores from 8 following categories with a range 0 – 3: Dressing and Grooming, Rising, Eating, Walking, Hygiene, Reach, Grip, and Activities. The higher the score, the more likely to associate with morbidity and mortality for the subject. The minimum clinically important difference in HAQ-DI was defined as change

from baseline ≤ −0.22.  For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 2 of Study M12-963

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
| --- | --- | --- | --- | --- |
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 40 | 36 | 39 | 39 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -0.25 (± 0.486) | -0.31 (± 0.463) | -0.29 (± 0.481) | -0.4 (± 0.538) |

| **End point values** | All ABT-122 120 mg EOW | | | |
| --- | --- | --- | --- | --- |
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 154 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -0.31 (± 0.492) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in HAQ-DI at Week 4

| End point title | Change From Baseline in HAQ-DI at Week 4 |
| --- | --- |

End point description:

HAQ-DI is a self-reported subject outcome measurement. It is calculated as the mean of the scores from 8 following categories with a range 0 – 3: Dressing and Grooming, Rising, Eating, Walking, Hygiene, Reach, Grip, and Activities. The higher the score, the more likely to associate with morbidity and mortality for the subject. The minimum clinically important difference in HAQ-DI was defined as change from baseline ≤ −0.22.  For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 4 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -0.37 (± 0.552) | -0.4 (± 0.58) | -0.47 (± 0.625) | -0.62 (± 0.711) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -0.47 (± 0.622) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in HAQ-DI at Week 6

| End point title | Change From Baseline in HAQ-DI at Week 6 |
|---|---|

End point description:

HAQ-DI is a self-reported subject outcome measurement. It is calculated as the mean of the scores from 8 following categories with a range 0 – 3: Dressing and Grooming, Rising, Eating, Walking, Hygiene, Reach, Grip, and Activities. The higher the score, the more likely to associate with morbidity and mortality for the subject. The minimum clinically important difference in HAQ-DI was defined as change from baseline ≤ −0.22.  For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 6 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -0.53 (± 0.601) | -0.46 (± 0.607) | -0.63 (± 0.711) | -0.64 (± 0.584) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -0.57 (± 0.626) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in HAQ-DI at Week 8

| End point title | Change From Baseline in HAQ-DI at Week 8 |
|---|---|

End point description:

HAQ-DI is a self-reported subject outcome measurement. It is calculated as the mean of the scores from 8 following categories with a range 0 – 3: Dressing and Grooming, Rising, Eating, Walking, Hygiene, Reach, Grip, and Activities. The higher the score, the more likely to associate with morbidity and mortality for the subject. The minimum clinically important difference in HAQ-DI was defined as change from baseline ≤ −0.22.  For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.).

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

End point timeframe:

Week 8 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -0.56 (± 0.619) | -0.52 (± 0.525) | -0.65 (± 0.648) | -0.71 (± 0.711) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -0.61 (± 0.63) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in HAQ-DI at Week 12

| End point title | Change From Baseline in HAQ-DI at Week 12 |
|---|---|

End point description:

HAQ-DI is a self-reported subject outcome measurement. It is calculated as the mean of the scores from 8 following categories with a range 0 – 3: Dressing and Grooming, Rising, Eating, Walking, Hygiene, Reach, Grip, and Activities. The higher the score, the more likely to associate with morbidity and mortality for the subject. The minimum clinically important difference in HAQ-DI was defined as change from baseline ≤ −0.22.  For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 12 of Study M12-963 (considered Week 0 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -0.69 (± 0.654) | -0.55 (± 0.611) | -0.66 (± 0.701) | -0.88 (± 0.677) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -0.7 (± 0.667) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in HAQ-DI at Week 16

| End point title | Change From Baseline in HAQ-DI at Week 16 |
|---|---|

End point description:

HAQ-DI is a self-reported subject outcome measurement. It is calculated as the mean of the scores from 8 following categories with a range 0 – 3: Dressing and Grooming, Rising, Eating, Walking, Hygiene, Reach, Grip, and Activities. The higher the score, the more likely to associate with morbidity and mortality for the subject. The minimum clinically important difference in HAQ-DI was defined as change from baseline ≤ −0.22.  For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 16 (Week 4 of Study M12-965)

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 41 | 36 | 37 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -0.59 (± 0.616) | -0.67 (± 0.631) | -0.67 (± 0.689) | -0.9 (± 0.649) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 154 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -0.71 (± 0.651) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in HAQ-DI at Week 20

| End point title | Change From Baseline in HAQ-DI at Week 20 |
|---|---|

End point description:

HAQ-DI is a self-reported subject outcome measurement. It is calculated as the mean of the scores from 8 following categories with a range 0 – 3: Dressing and Grooming, Rising, Eating, Walking, Hygiene, Reach, Grip, and Activities. The higher the score, the more likely to associate with morbidity and mortality for the subject. The minimum clinically important difference in HAQ-DI was defined as change from baseline ≤ −0.22.  For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 20 (Week 8 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -0.54 (± 0.662) | -0.73 (± 0.555) | -0.7 (± 0.788) | -0.88 (± 0.69) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -0.71 (± 0.685) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in HAQ-DI at Week 24

| End point title | Change From Baseline in HAQ-DI at Week 24 |
|---|---|

End point description:

HAQ-DI is a self-reported subject outcome measurement. It is calculated as the mean of the scores from 8 following categories with a range 0 – 3: Dressing and Grooming, Rising, Eating, Walking, Hygiene, Reach, Grip, and Activities. The higher the score, the more likely to associate with morbidity and mortality for the subject. The minimum clinically important difference in HAQ-DI was defined as change from baseline ≤ −0.22.  For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 24 (Week 12 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -0.63 (± 0.604) | -0.74 (± 0.617) | -0.6 (± 0.805) | -0.91 (± 0.704) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -0.72 (± 0.691) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in HAQ-DI at Week 28

| End point title | Change From Baseline in HAQ-DI at Week 28 |
|---|---|

End point description:

HAQ-DI is a self-reported subject outcome measurement. It is calculated as the mean of the scores from 8 following categories with a range 0 – 3: Dressing and Grooming, Rising, Eating, Walking, Hygiene, Reach, Grip, and Activities. The higher the score, the more likely to associate with morbidity and mortality for the subject. The minimum clinically important difference in HAQ-DI was defined as change from baseline ≤ −0.22.  For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 28 (Week 16 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -0.6 (± 0.6) | -0.77 (± 0.63) | -0.69 (± 0.727) | -0.99 (± 0.699) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -0.76 (± 0.676) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in HAQ-DI at Week 32

| End point title | Change From Baseline in HAQ-DI at Week 32 |
|---|---|

End point description:

HAQ-DI is a self-reported subject outcome measurement. It is calculated as the mean of the scores from 8 following categories with a range 0 – 3: Dressing and Grooming, Rising, Eating, Walking, Hygiene, Reach, Grip, and Activities. The higher the score, the more likely to associate with morbidity and mortality for the subject. The minimum clinically important difference in HAQ-DI was defined as change from baseline ≤ −0.22.  For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 32 (Week 20 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -0.54 (± 0.576) | -0.76 (± 0.674) | -0.66 (± 0.794) | -0.91 (± 0.659) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -0.71 (± 0.686) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in HAQ-DI at Week 36

| End point title | Change From Baseline in HAQ-DI at Week 36 |
|---|---|

End point description:

HAQ-DI is a self-reported subject outcome measurement. It is calculated as the mean of the scores from 8 following categories with a range 0 – 3: Dressing and Grooming, Rising, Eating, Walking, Hygiene, Reach, Grip, and Activities. The higher the score, the more likely to associate with morbidity and mortality for the subject. The minimum clinically important difference in HAQ-DI was defined as change from baseline ≤ −0.22.  For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 36 (Week 24 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -0.62 (± 0.619) | -0.73 (± 0.698) | -0.71 (± 0.674) | -0.81 (± 0.749) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -0.72 (± 0.683) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in High-Sensitivity C-Reactive Protein (hsCRP) at Week 2

| End point title | Change From Baseline in High-Sensitivity C-Reactive Protein (hsCRP) at Week 2 |
|---|---|

End point description:

For analysis purposes, all baseline are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 2 of Study M12-963

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 40 | 36 | 39 | 40 |
| Units: mg/L | | | | |
| arithmetic mean (standard deviation) | -12.6 (± 25.19) | -9.9 (± 12.89) | -12.6 (± 18.56) | -14.9 (± 25.7) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 155 | | | |
| Units: mg/L | | | | |
| arithmetic mean (standard deviation) | -12.5 (± 21.3) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in hsCRP at Week 4

| End point title | Change From Baseline in hsCRP at Week 4 |
|---|---|

End point description:

For analysis purposes, all baseline are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 4 of Study M12-963

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: mg/L | | | | |
| arithmetic mean (standard deviation) | -13.3 (± 25.4) | -8 (± 12.37) | -11.7 (± 17.43) | -14.6 (± 26.51) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: mg/L | | | | |
| arithmetic mean (standard deviation) | -12 (± 21.43) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in hsCRP at Week 6

| End point title | Change From Baseline in hsCRP at Week 6 |
|---|---|

End point description:

For analysis purposes, all baseline are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 6 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: mg/L | | | | |
| arithmetic mean (standard deviation) | -13.3 (± 25.15) | -8 (± 11.98) | -10.7 (± 18.84) | -14.9 (± 26.56) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: mg/L | | | | |
| arithmetic mean (standard deviation) | -11.8 (± 21.63) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in hsCRP at Week 8

| End point title | Change From Baseline in hsCRP at Week 8 |
|---|---|

End point description:

For analysis purposes, all baseline are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 8 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: mg/L | | | | |
| arithmetic mean (standard deviation) | -12.2 (± 24.96) | -8 (± 13.13) | -10.7 (± 19) | -12.9 (± 28.42) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|

| Subject group type | Subject analysis set | | | |
|---|---|---|---|---|
| Number of subjects analysed | 157 | | | |
| Units: mg/L | | | | |
| arithmetic mean (standard deviation) | -11 (± 22.26) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in hsCRP at Week 12

| End point title | Change From Baseline in hsCRP at Week 12 |
|---|---|

End point description:

For analysis purposes, all baseline are defined as the last measurement on or before the first dose of study drug in Study M12-963. Safety Analysis Set: all subjects who received ≥ 1 dose of study medication in M12-965 and had a baseline and post-baseline assessment. LOCF used for missing data; LOCF imputation was conducted separately for M12-963 and M12-965 (ie, data from M12-963 was not carried forward to visits in M12-965).

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

End point timeframe:

Week 12 of Study M12-963 (considered Week 0 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: mg/L | | | | |
| arithmetic mean (standard deviation) | -12.3 (± 25.56) | -6.5 (± 14.05) | -10.8 (± 17.27) | -14.6 (± 25.22) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: mg/L | | | | |
| arithmetic mean (standard deviation) | -11.2 (± 21.36) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in hsCRP at Week 16

| End point title | Change From Baseline in hsCRP at Week 16 |
|---|---|
| End point description: | |

For analysis purposes, all baseline are defined as the last measurement on or before the first dose of study drug in Study M12-963. Safety Analysis Set: all subjects who received ≥ 1 dose of study medication in M12-965 and had a baseline and post-baseline assessment. LOCF used for missing data; LOCF imputation was conducted separately for M12-963 and M12-965 (ie, data from M12-963 was not carried forward to visits in M12-965).

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

Week 16 (Week 4 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 41 | 36 | 37 | 39 |
| Units: mg/L | | | | |
| arithmetic mean (standard deviation) | -13.5 (± 24.92) | -5.5 (± 17.44) | -10.8 (± 16.26) | -12.5 (± 24.65) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 153 | | | |
| Units: mg/L | | | | |
| arithmetic mean (standard deviation) | -10.7 (± 21.39) | | | |

## Statistical analyses

No statistical analyses for this end point

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## Secondary: Change From Baseline in hsCRP at Week 20

| End point title | Change From Baseline in hsCRP at Week 20 |
|---|---|
| End point description: | |

For analysis purposes, all baseline are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

Week 20 (Week 8 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: mg/L | | | | |
| arithmetic mean (standard deviation) | -11.6 (± 24.46) | -6.4 (± 14.07) | -10.3 (± 18.66) | -11.6 (± 25.06) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: mg/L | | | | |
| arithmetic mean (standard deviation) | -10.1 (± 21.16) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in hsCRP at Week 24

| End point title | Change From Baseline in hsCRP at Week 24 |
|---|---|

End point description:

For analysis purposes, all baseline are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 24 (Week 12 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: mg/L | | | | |
| arithmetic mean (standard deviation) | -11.3 (± 23.41) | -6.7 (± 13.93) | -9.1 (± 17.96) | -10.8 (± 27.79) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|

| Subject group type | Subject analysis set | | | |
|---|---|---|---|---|
| Number of subjects analysed | 157 | | | |
| Units: mg/L | | | | |
| arithmetic mean (standard deviation) | -9.6 (± 21.5) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in hsCRP at Week 28

| End point title | Change From Baseline in hsCRP at Week 28 |
|---|---|

End point description:

For analysis purposes, all baseline are defined as the last measurement on or before the first dose of study drug in Study M12-963. Safety Analysis Set: all subjects who received ≥ 1 dose of study medication in M12-965 and had a baseline and post-baseline assessment. LOCF used for missing data; LOCF imputation was conducted separately for M12-963 and M12-965 (ie, data from M12-963 was not carried forward to visits in M12-965).

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

End point timeframe:

Week 28 (Week 16 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: mg/L | | | | |
| arithmetic mean (standard deviation) | -3.5 (± 48.65) | -6.3 (± 17.24) | -11.3 (± 18.37) | -6.8 (± 26.24) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: mg/L | | | | |
| arithmetic mean (standard deviation) | -6.9 (± 30.84) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in hsCRP at Week 32

| End point title | Change From Baseline in hsCRP at Week 32 |
|---|---|

End point description:

For analysis purposes, all baseline are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 32 (Week 20 of Study M12-965)

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: mg/L | | | | |
| arithmetic mean (standard deviation) | -9.8 (± 26.15) | -7.6 (± 14.59) | -8 (± 20.16) | -10.4 (± 26.24) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: mg/L | | | | |
| arithmetic mean (standard deviation) | -9 (± 22.36) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in hsCRP at Week 36

| End point title | Change From Baseline in hsCRP at Week 36 |
|---|---|

End point description:

For analysis purposes, all baseline are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 36 (Week 24 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: mg/L | | | | |
| arithmetic mean (standard deviation) | -8.7 (± 26.17) | -6 (± 16.47) | -8.7 (± 17.56) | -9 (± 28.55) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: mg/L | | | | |
| arithmetic mean (standard deviation) | -8.1 (± 22.83) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in Disease Activity Score 28 (DAS28[hsCRP]) at Week 2

| End point title | Change from Baseline in Disease Activity Score 28 (DAS28[hsCRP]) at Week 2 |
|---|---|

End point description:

The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 to 10, with higher scores indicating more disease activity. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 2 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 40 | 37 | 39 | 39 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -1.5 (± 1.23) | -1.5 (± 1.06) | -1.8 (± 1.27) | -1.7 (± 1.13) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 155 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -1.6 (± 1.17) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in DAS28 (hsCRP) at Week 4

| End point title | Change from Baseline in DAS28 (hsCRP) at Week 4 |
|---|---|

End point description:

The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 to 10, with higher scores indicating more disease activity. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 4 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -1.9 (± 1.2) | -2.1 (± 1.37) | -2.1 (± 1.26) | -2.3 (± 1.2) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 158 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -2.1 (± 1.25) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in DAS28 (hsCRP) at Week 6

| End point title | Change from Baseline in DAS28 (hsCRP) at Week 6 |
|---|---|

End point description:

The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 to 10, with higher scores indicating more disease activity. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 6 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -2.4 (± 1.37) | -2.2 (± 1.34) | -2.5 (± 1.27) | -2.4 (± 1.21) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 158 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -2.4 (± 1.29) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in DAS28 (hsCRP) at Week 8

| End point title | Change from Baseline in DAS28 (hsCRP) at Week 8 |
|---|---|

End point description:

The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 to 10, with higher scores indicating more disease activity. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 8 of Study M12-963

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -2.4 (± 1.29) | -2.3 (± 1.25) | -2.7 (± 1.3) | -2.6 (± 1.32) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 158 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -2.5 (± 1.28) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in DAS28 (hsCRP) at Week 12

| End point title | Change from Baseline in DAS28 (hsCRP) at Week 12 |
|---|---|

End point description:

The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 to 10, with higher scores indicating more disease activity. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 12 of Study M12-963 (considered Week 0 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -2.6 (± 1.32) | -2.3 (± 1.49) | -2.8 (± 1.17) | -2.7 (± 1.14) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 158 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -2.6 (± 1.28) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in DAS28 (hsCRP) at Week 16

| End point title | Change from Baseline in DAS28 (hsCRP) at Week 16 |
|---|---|

End point description:

The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 to 10, with higher scores indicating more disease activity. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 16 (Week 4 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 41 | 36 | 37 | 39 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -2.7 (± 1.21) | -2.6 (± 1.54) | -2.8 (± 1.19) | -2.6 (± 0.92) |

| End point values | All ABT-122 | | | |
|---|---|---|---|---|

| | 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 153 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -2.7 (± 1.22) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in DAS28 (hsCRP) at Week 20

| End point title | Change from Baseline in DAS28 (hsCRP) at Week 20 |
|---|---|

End point description:

The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 to 10, with higher scores indicating more disease activity. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 20 (Week 8 of Study M12-965)

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -2.7 (± 1.31) | -2.8 (± 1.37) | -2.7 (± 1.25) | -2.8 (± 1.08) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -2.7 (± 1.24) | | | |

## Statistical analyses

No statistical analyses for this end point

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## Secondary: Change from Baseline in DAS28 (hsCRP) at Week 24

| End point title | Change from Baseline in DAS28 (hsCRP) at Week 24 |
|---|---|

End point description:

The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 to 10, with higher scores indicating more disease activity. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 24 (Week 12 of Study M12-965)

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -2.8 (± 1.26) | -2.6 (± 1.47) | -2.7 (± 1.41) | -2.9 (± 1.14) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -2.8 (± 1.31) | | | |

### Statistical analyses

No statistical analyses for this end point

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## Secondary: Change from Baseline in DAS28 (hsCRP) at Week 28

| End point title | Change from Baseline in DAS28 (hsCRP) at Week 28 |
|---|---|

End point description:

The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 to 10, with higher scores indicating more disease activity. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -2.5 (± 1.45) | -2.7 (± 1.46) | -2.9 (± 1.24) | -2.9 (± 1.06) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -2.7 (± 1.31) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in DAS28 (hsCRP) at Week 32

| End point title | Change from Baseline in DAS28 (hsCRP) at Week 32 |
|---|---|

End point description:

The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 to 10, with higher scores indicating more disease activity. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 32 (Week 20 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -2.6 (± 1.44) | -2.8 (± 1.45) | -2.7 (± 1.17) | -2.9 (± 1.25) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -2.8 (± 1.32) | | | |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Change from Baseline in DAS28 (hsCRP) at Week 36**

| End point title | Change from Baseline in DAS28 (hsCRP) at Week 36 |
|---|---|

End point description:

The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 to 10, with higher scores indicating more disease activity. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 36 (Week 24 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -2.6 (± 1.45) | -2.6 (± 1.48) | -2.8 (± 1.22) | -2.8 (± 1.32) |

| End point values | All ABT-122 | | | |
|---|---|---|---|---|

| | 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -2.7 (± 1.36) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in Clinical Disease Activity Index (CDAI) at Week 2

| End point title | Change from Baseline in Clinical Disease Activity Index (CDAI) at Week 2 |
|---|---|

End point description:

CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 2 of Study M12-963

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 39 | 37 | 39 | 38 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -15.9 (± 15.74) | -17.4 (± 13.45) | -17.5 (± 14.61) | -18.2 (± 14.96) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 153 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -17.3 (± 14.6) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in CDAI at Week 4

| End point title | Change from Baseline in CDAI at Week 4 |
|---|---|

End point description:

CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 4 of Study M12-963

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 39 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -20.3 (± 14.27) | -24.6 (± 15.61) | -22.1 (± 13.95) | -24.3 (± 14.03) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -22.7 (± 14.43) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in CDAI at Week 6

| End point title | Change from Baseline in CDAI at Week 6 |
|---|---|

End point description:

CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. For analysis purposes, all

baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

| End point timeframe: | |
|---|---|

Week 6 of Study M12-963

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 39 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -25.7 (± 14.64) | -25.6 (± 14.71) | -25.8 (± 13.1) | -25.6 (± 13.83) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -25.7 (± 13.95) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in CDAI at Week 8

| End point title | Change from Baseline in CDAI at Week 8 |
|---|---|

End point description:

CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

| End point timeframe: | |
|---|---|

Week 8 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 39 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -26.7 (± 13.68) | -27 (± 13.69) | -28.2 (± 12.66) | -27.4 (± 13.92) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -27.3 (± 13.38) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in CDAI at Week 12

| End point title | Change from Baseline in CDAI at Week 12 |
|---|---|

End point description:

CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 12 of Study M12-963 (considered Week 0 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 39 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -28.4 (± 14.33) | -27.2 (± 16.72) | -29.7 (± 12.1) | -28.8 (± 11.88) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -28.5 (± 13.76) | | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in CDAI at Week 16

| End point title | Change from Baseline in CDAI at Week 16 |
|---|---|

End point description:

CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 16 (Week 4 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 40 | 35 | 36 | 37 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -28.1 (± 13.07) | -29.9 (± 16.04) | -28.5 (± 12.11) | -29.6 (± 10.03) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 148 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -29 (± 12.84) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in CDAI at Week 20

| End point title | Change from Baseline in CDAI at Week 20 |
|---|---|

End point description:

CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 20 (Week 8 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 35 | 38 | 38 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -28.1 (± 13.05) | -31.8 (± 14.47) | -28.2 (± 13.93) | -31.1 (± 11.44) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 153 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -29.7 (± 13.22) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in CDAI at Week 24

| End point title | Change from Baseline in CDAI at Week 24 |
|---|---|

End point description:

CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 24 (Week 12 of Study M12-965)

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 39 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -30.7 (± 13.81) | -30.1 (± 15.05) | -28.8 (± 14.09) | -31 (± 13.15) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 156 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -30.1 (± 13.91) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in CDAI at Week 28

| End point title | Change from Baseline in CDAI at Week 28 |
|---|---|

End point description:

CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

End point timeframe:

Week 28 (Week 16 of Study M12-965)

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 39 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -28.1 (± 13.27) | -31.4 (± 15.09) | -29.8 (± 12.77) | -32.7 (± 12.79) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 156 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -30.4 (± 13.46) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in CDAI at Week 32

| End point title | Change from Baseline in CDAI at Week 32 |
|---|---|

End point description:

CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

Week 32 (Week 20 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 39 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -28.5 (± 15.08) | -32.4 (± 14.63) | -29.1 (± 13.4) | -31.6 (± 15.08) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 156 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -30.3 (± 14.52) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in CDAI at Week 36

| End point title | Change from Baseline in CDAI at Week 36 |
|---|---|
| End point description: | |

CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. For analysis purposes, all baseline values are defined as the last measurement on or before the first dose of study drug in Study M12-963.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF was used for missing data.

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

Week 36 (Week 24 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 39 |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -27.6 (± 14.87) | -30.9 (± 15.22) | -30 (± 12.28) | -30.9 (± 14.34) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 156 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -29.8 (± 14.15) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Low Disease Activity (LDA) or Clinical Remission (CR) Response Rate per DAS28 (hsCRP) at Week 2

| End point title | Low Disease Activity (LDA) or Clinical Remission (CR) Response Rate per DAS28 (hsCRP) at Week 2 |
|---|---|

End point description:

Percentage of subjects achieving LDA or CR on the DAS28 (hsCRP). The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 (no disease activity) to 10 (highest degree of disease activity). LDA was defined as a score from 2.6 to < 3.2, and CR was defined as a score < 2.6. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 2 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 40 | 37 | 39 | 39 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 12.5 (5 to 26.6) | 8.1 (2.1 to 22) | 28.2 (16.4 to 43.9) | 25.6 (14.4 to 41.2) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 155 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 18.7 (13.3 to 25.6) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: LDA or CR Response Rate per DAS28 (hsCRP) at Week 4

| End point title | LDA or CR Response Rate per DAS28 (hsCRP) at Week 4 |
|---|---|

End point description:

Percentage of subjects achieving LDA or CR on the DAS28 (hsCRP). The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 (no disease activity) to 10 (highest degree of disease activity). LDA was defined as a score from 2.6 to < 3.2, and CR was defined as a score < 2.6. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 4 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 31 (19 to 46.1) | 32.4 (19.5 to 48.6) | 30.8 (18.5 to 46.5) | 45 (30.7 to 60.2) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 158 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 34.8 (27.8 to 42.5) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: LDA or CR Response Rate per DAS28 (hsCRP) at Week 6

| End point title | LDA or CR Response Rate per DAS28 (hsCRP) at Week 6 |
|---|---|

End point description:

Percentage of subjects achieving LDA or CR on the DAS28 (hsCRP). The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 (no disease activity) to 10 (highest degree of disease activity). LDA was defined as a score from 2.6 to < 3.2, and CR was defined as a score < 2.6. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 6 of Study M12-963

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 45.2 (31.2 to 60.1) | 24.3 (13.2 to 40.3) | 43.6 (29.3 to 59) | 50 (35.2 to 64.8) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 158 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 41.1 (33.8 to 48.9) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: LDA or CR Response Rate per DAS28 (hsCRP) at Week 8

| End point title | LDA or CR Response Rate per DAS28 (hsCRP) at Week 8 |
|---|---|

End point description:

Percentage of subjects achieving LDA or CR on the DAS28 (hsCRP). The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 (no disease activity) to 10 (highest degree of disease activity). LDA was defined as a score from 2.6 to < 3.2, and CR was defined as a score < 2.6. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method. Safety Analysis Set: all subjects who received ≥ 1 dose of study medication in M12-965 and had a baseline and post-baseline assessment. LOCF used for missing data; LOCF imputation was conducted separately for M12-963 and M12-965 (ie, data from M12-963 was not carried forward to visits in M12-965).

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

End point timeframe:

Week 8 of Study M12-963

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 45.2 (31.2 to 60.1) | 27 (15.2 to 43.1) | 53.8 (38.6 to 68.4) | 55 (39.8 to 69.3) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 158 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 45.6 (38 to 53.3) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: LDA or CR Response Rate per DAS28 (hsCRP) at Week 12

| End point title | LDA or CR Response Rate per DAS28 (hsCRP) at Week 12 |
|---|---|

End point description:

Percentage of subjects achieving LDA or CR on the DAS28 (hsCRP). The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 (no disease activity) to 10 (highest degree of disease activity). LDA was defined as a score from 2.6 to < 3.2, and CR was defined as a score < 2.6. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 12 of Study M12-963 (considered Week 0 of Study M12-965)

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 50 (35.5 to 64.5) | 35.1 (21.8 to 51.3) | 56.4 (41 to 70.7) | 52.5 (37.5 to 67.1) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 158 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 48.7 (41.1 to 56.5) | | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: LDA or CR Response Rate per DAS28 (hsCRP) at Week 16

| End point title | LDA or CR Response Rate per DAS28 (hsCRP) at Week 16 |
|---|---|

End point description:

Percentage of subjects achieving LDA or CR on the DAS28 (hsCRP). The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 (no disease activity) to 10 (highest degree of disease activity). LDA was defined as a score from 2.6 to < 3.2, and CR was defined as a score < 2.6. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 16 (Week 4 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 41 | 36 | 37 | 39 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 51.2 (36.5 to 65.7) | 52.8 (37 to 68) | 62.2 (46.1 to 76) | 48.7 (33.9 to 63.8) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 153 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 53.6 (45.7 to 61.3) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: LDA or CR Response Rate per DAS28 (hsCRP) at Week 20

| End point title | LDA or CR Response Rate per DAS28 (hsCRP) at Week 20 |
|---|---|

End point description:

Percentage of subjects achieving LDA or CR on the DAS28 (hsCRP). The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 (no disease activity) to 10 (highest degree of disease activity). LDA was defined as a score from 2.6 to < 3.2, and CR was defined as a score < 2.6. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 20 (Week 8 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 54.8 (39.9 to 68.8) | 55.6 (39.6 to 70.5) | 56.4 (41 to 70.7) | 60 (44.6 to 73.7) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 56.7 (48.9 to 64.2) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: LDA or CR Response Rate per DAS28 (hsCRP) at Week 24

| End point title | LDA or CR Response Rate per DAS28 (hsCRP) at Week 24 |
|---|---|

End point description:

Percentage of subjects achieving LDA or CR on the DAS28 (hsCRP). The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 (no disease activity) to 10 (highest degree of disease activity). LDA was defined as a score from 2.6 to < 3.2, and CR was defined as a score < 2.6. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 24 (Week 12 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 61.9 (46.8 to 75) | 44.4 (29.5 to 60.4) | 56.4 (41 to 70.7) | 60 (44.6 to 73.7) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 56.1 (48.2 to 63.6) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: LDA or CR Response Rate per DAS28 (hsCRP) at Week 28

| End point title | LDA or CR Response Rate per DAS28 (hsCRP) at Week 28 |
|---|---|

End point description:

Percentage of subjects achieving LDA or CR on the DAS28 (hsCRP). The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 (no disease activity) to 10 (highest degree of disease activity). LDA was defined as a score from 2.6 to < 3.2, and CR was defined as a score < 2.6. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 28 (Week 16 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 47.6 (33.4 to 62.3) | 41.7 (27.1 to 57.8) | 56.4 (41 to 70.7) | 55 (39.8 to 69.3) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 50.3 (42.6 to 58) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: LDA or CR Response Rate per DAS28 (hsCRP) at Week 32

| End point title | LDA or CR Response Rate per DAS28 (hsCRP) at Week 32 |
|---|---|

End point description:

Percentage of subjects achieving LDA or CR on the DAS28 (hsCRP). The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 (no disease activity) to 10 (highest degree of disease activity). LDA was defined as a score from 2.6 to < 3.2, and CR was defined as a score < 2.6. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 32 (Week 20 of Study M12-965)

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 52.4 (37.7 to 66.6) | 52.8 (37 to 68) | 61.5 (45.9 to 75.1) | 60 (44.6 to 73.7) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 56.7 (48.9 to 64.2) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: LDA or CR Response Rate per DAS28 (hsCRP) at Week 36

| End point title | LDA or CR Response Rate per DAS28 (hsCRP) at Week 36 |
|---|---|

End point description:

Percentage of subjects achieving LDA or CR on the DAS28 (hsCRP). The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 (no disease activity) to 10 (highest degree of disease activity). LDA was defined as a score from 2.6 to < 3.2, and CR was defined as a score < 2.6. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 36 (Week 24 of Study M12-965)

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
| --- | --- | --- | --- | --- |
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 54.8 (39.9 to 68.8) | 41.7 (27.1 to 57.8) | 59 (43.4 to 72.9) | 47.5 (32.9 to 62.5) |

| **End point values** | All ABT-122 120 mg EOW | | | |
| --- | --- | --- | --- | --- |
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 51 (43.2 to 58.7) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: CR Response Rate Per DAS28 (hsCRP) at Week 2

| End point title | CR Response Rate Per DAS28 (hsCRP) at Week 2 |
| --- | --- |

End point description:

Percentage of subjects achieving CR on the DAS28 (hsCRP). The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 (no disease activity) to 10 (highest degree of disease activity). LDA was defined as a score from 2.6 to < 3.2, and CR was defined as a score < 2.6. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 2 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 40 | 37 | 39 | 39 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 5 (0.5 to 17.4) | 5.4 (0.6 to 18.6) | 12.8 (5.1 to 27.2) | 10.3 (3.5 to 24.2) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 155 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 8.4 (4.9 to 13.9) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: CR Response Rate Per DAS28 (hsCRP) at Week 4

| End point title | CR Response Rate Per DAS28 (hsCRP) at Week 4 |
|---|---|

End point description:

Percentage of subjects achieving CR on the DAS28 (hsCRP). The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 (no disease activity) to 10 (highest degree of disease activity). LDA was defined as a score from 2.6 to < 3.2, and CR was defined as a score < 2.6. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 4 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 14.3 (6.3 to 28.2) | 8.1 (2.1 to 22) | 23.1 (12.4 to 38.5) | 25 (14 to 40.4) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 158 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 17.7 (12.5 to 24.5) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: CR Response Rate Per DAS28 (hsCRP) at Week 6

| End point title | CR Response Rate Per DAS28 (hsCRP) at Week 6 |
|---|---|

End point description:

Percentage of subjects achieving CR on the DAS28 (hsCRP). The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 (no disease activity) to 10 (highest degree of disease activity). LDA was defined as a score from 2.6 to < 3.2, and CR was defined as a score < 2.6. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 6 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 31 (19 to 46.1) | 18.9 (9.2 to 34.5) | 33.3 (20.6 to 49.1) | 27.5 (16 to 43) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 158 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 27.8 (21.4 to 35.3) | | | |

## Statistical analyses

No statistical analyses for this end point

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## Secondary: CR Response Rate Per DAS28 (hsCRP) at Week 8

| End point title | CR Response Rate Per DAS28 (hsCRP) at Week 8 |
|---|---|

End point description:

Percentage of subjects achieving CR on the DAS28 (hsCRP). The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 (no disease activity) to 10 (highest degree of disease activity). LDA was defined as a score from 2.6 to < 3.2, and CR was defined as a score < 2.6. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 8 of Study M12-963

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 28.6 (17.1 to 43.7) | 21.6 (11.1 to 37.4) | 38.5 (24.9 to 54.1) | 37.5 (24.2 to 53) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 158 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 31.6 (24.9 to 39.3) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: CR Response Rate Per DAS28 (hsCRP) at Week 12

| End point title | CR Response Rate Per DAS28 (hsCRP) at Week 12 |
|---|---|

End point description:

Percentage of subjects achieving CR on the DAS28 (hsCRP). The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 (no disease activity) to 10 (highest degree of disease activity). LDA was defined as a score from 2.6 to < 3.2, and CR was defined as a score < 2.6. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 12 of Study M12-963 (considered Week 0 of Study M12-965)

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 31 (19 to 46.1) | 21.6 (11.1 to 37.4) | 38.5 (24.9 to 54.1) | 40 (26.3 to 55.4) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 158 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 32.9 (26.1 to 40.6) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: CR Response Rate Per DAS28 (hsCRP) at Week 16

| End point title | CR Response Rate Per DAS28 (hsCRP) at Week 16 |
|---|---|

End point description:

Percentage of subjects achieving CR on the DAS28 (hsCRP). The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 (no disease activity) to 10 (highest degree of disease activity). LDA was defined as a score from 2.6 to < 3.2, and CR was defined as a score < 2.6. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

| End point type | Secondary |
|---|---|
| End point timeframe: | |
| Week 16 (Week 4 of Study M12-965) | |

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 41 | 36 | 37 | 39 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 39 (25.6 to 54.3) | 30.6 (17.9 to 47) | 37.8 (24 to 53.9) | 30.8 (18.5 to 46.5) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 153 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 34.6 (27.6 to 42.5) | | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: CR Response Rate Per DAS28 (hsCRP) at Week 20

| End point title | CR Response Rate Per DAS28 (hsCRP) at Week 20 |
|---|---|

End point description:

Percentage of subjects achieving CR on the DAS28 (hsCRP). The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 (no disease activity) to 10 (highest degree of disease activity). LDA was defined as a score from 2.6 to < 3.2, and CR was defined as a score < 2.6. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

| End point type | Secondary |
|---|---|
| End point timeframe: | |
| Week 20 (Week 8 of Study M12-965) | |

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 40.5 (27 to 55.5) | 36.1 (22.4 to 52.5) | 25.6 (14.4 to 41.2) | 37.5 (24.2 to 53) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 35 (28 to 42.8) | | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: CR Response Rate Per DAS28 (hsCRP) at Week 24

| End point title | CR Response Rate Per DAS28 (hsCRP) at Week 24 |
|---|---|

End point description:

Percentage of subjects achieving CR on the DAS28 (hsCRP). The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 (no disease activity) to 10 (highest degree of disease activity). LDA was defined as a score from 2.6 to < 3.2, and CR was defined as a score < 2.6. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 24 (Week 12 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 33.3 (20.9 to 48.5) | 30.6 (17.9 to 47) | 38.5 (24.9 to 54.1) | 45 (30.7 to 60.2) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 36.9 (29.8 to 44.7) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: CR Response Rate Per DAS28 (hsCRP) at Week 28

| End point title | CR Response Rate Per DAS28 (hsCRP) at Week 28 |
|---|---|

End point description:

Percentage of subjects achieving CR on the DAS28 (hsCRP). The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 (no disease activity) to 10 (highest degree of disease activity). LDA was defined as a score from 2.6 to < 3.2, and CR was defined as a score < 2.6. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 28 (Week 16 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 33.3 (20.9 to 48.5) | 27.8 (15.7 to 44.1) | 38.5 (24.9 to 54.1) | 42.5 (28.5 to 57.8) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 35.7 (28.6 to 43.4) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: CR Response Rate Per DAS28 (hsCRP) at Week 32

| End point title | CR Response Rate Per DAS28 (hsCRP) at Week 32 |
|---|---|

End point description:

Percentage of subjects achieving CR on the DAS28 (hsCRP). The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 (no disease activity) to 10 (highest degree of disease activity). LDA was defined as a score from 2.6 to < 3.2, and CR was defined as a score < 2.6. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 32 (Week 20 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 38.1 (25 to 53.2) | 38.9 (24.8 to 55.2) | 35.9 (22.7 to 51.6) | 45 (30.7 to 60.2) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 39.5 (32.2 to 47.3) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: CR Response Rate Per DAS28 (hsCRP) at Week 36

| End point title | CR Response Rate Per DAS28 (hsCRP) at Week 36 |
|---|---|

End point description:

Percentage of subjects achieving CR on the DAS28 (hsCRP). The DAS28 (hsCRP) is a validated index of rheumatoid arthritis disease activity. Twenty-eight tender joint counts, 28 swollen joint counts, hsCRP, and general health are included in the DAS28 (hsCRP) score. Scores range from 0 (no disease activity) to 10 (highest degree of disease activity). LDA was defined as a score from 2.6 to < 3.2, and CR was defined as a score < 2.6. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 36 (Week 24 of Study M12-965)

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 38.1 (25 to 53.2) | 19.4 (9.4 to 35.3) | 43.6 (29.3 to 59) | 37.5 (24.2 to 53) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 35 (28 to 42.8) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: LDA or CR Response Rate per CDAI at Week 2

| End point title | LDA or CR Response Rate per CDAI at Week 2 |
|---|---|

End point description:

Percentage of subjects achieving LDA or CR per CDAI criteria. The CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. LDA was defined as a score from 2.8 to ≤ 10; CR was defined as a score ≤ 2.8. Estimates of the 95% confidence interval of the response rates for each

treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 2 of Study M12-963

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 39 | 37 | 39 | 39 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 7.7 (1.9 to 21) | 5.4 (0.6 to 18.6) | 12.8 (5.1 to 27.2) | 15.4 (6.9 to 30.1) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 154 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 10.4 (6.4 to 16.3) | | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: LDA or CR Response Rate per CDAI at Week 4

| End point title | LDA or CR Response Rate per CDAI at Week 4 |
|---|---|

End point description:

Percentage of subjects achieving LDA or CR per CDAI criteria. The CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. LDA was defined as a score from 2.8 to ≤ 10; CR was defined as a score ≤ 2.8. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 4 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 23.8 (13.3 to 38.7) | 21.6 (11.1 to 37.4) | 23.1 (12.4 to 38.5) | 35 (22.1 to 50.5) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 158 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 25.9 (19.7 to 33.3) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: LDA or CR Response Rate per CDAI at Week 6

| End point title | LDA or CR Response Rate per CDAI at Week 6 |
|---|---|

End point description:

Percentage of subjects achieving LDA or CR per CDAI criteria. The CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. LDA was defined as a score from 2.8 to ≤ 10; CR was defined as a score ≤ 2.8. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 6 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 40.5 (27 to 55.5) | 21.6 (11.1 to 37.4) | 43.6 (29.3 to 59) | 45 (30.7 to 60.2) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 158 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 38 (30.8 to 45.7) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: LDA or CR Response Rate per CDAI at Week 8

| End point title | LDA or CR Response Rate per CDAI at Week 8 |
|---|---|

End point description:

Percentage of subjects achieving LDA or CR per CDAI criteria. The CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. LDA was defined as a score from 2.8 to ≤ 10; CR was defined as a score ≤ 2.8. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 8 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 35.7 (22.9 to 50.9) | 27 (15.2 to 43.1) | 46.2 (31.6 to 61.4) | 47.5 (32.9 to 62.5) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 158 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 39.2 (32 to 47) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: LDA or CR Response Rate per CDAI at Week 12

| End point title | LDA or CR Response Rate per CDAI at Week 12 |
|---|---|

End point description:

Percentage of subjects achieving LDA or CR per CDAI criteria. The CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. LDA was defined as a score from 2.8 to ≤ 10; CR was defined as a score ≤ 2.8. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 12 of Study M12-963 (considered Week 0 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 40.5 (27 to 55.5) | 37.8 (24 to 53.9) | 46.2 (31.6 to 61.4) | 50 (35.2 to 64.8) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 158 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 43.7 (36.2 to 51.5) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: LDA or CR Response Rate per CDAI at Week 16

| End point title | LDA or CR Response Rate per CDAI at Week 16 |
|---|---|

End point description:

Percentage of subjects achieving LDA or CR per CDAI criteria. The CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. LDA was defined as a score from 2.8 to ≤ 10; CR was defined as a score ≤ 2.8. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 16 (Week 4 of Study M12-965)

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 40 | 35 | 36 | 38 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 47.5 (32.9 to 62.5) | 45.7 (30.5 to 61.8) | 55.6 (39.6 to 70.5) | 50 (34.8 to 65.2) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 149 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 49.7 (41.7 to 57.6) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: LDA or CR Response Rate per CDAI at Week 20

| End point title | LDA or CR Response Rate per CDAI at Week 20 |
|---|---|

End point description:

Percentage of subjects achieving LDA or CR per CDAI criteria. The CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. LDA was defined as a score from 2.8 to ≤ 10; CR was defined as a score ≤ 2.8. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 20 (Week 8 of Study M12-965)

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 35 | 38 | 39 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 47.6 (33.4 to 62.3) | 45.7 (30.5 to 61.8) | 36.8 (23.3 to 52.8) | 56.4 (41 to 70.7) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 154 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 46.8 (39 to 54.6) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: LDA or CR Response Rate per CDAI at Week 24

| End point title | LDA or CR Response Rate per CDAI at Week 24 |
|---|---|

End point description:

Percentage of subjects achieving LDA or CR per CDAI criteria. The CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. LDA was defined as a score from 2.8 to ≤ 10; CR was

defined as a score ≤ 2.8.  Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 24 (Week 12 of Study M12-965)

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 54.8 (39.9 to 68.8) | 44.4 (29.5 to 60.4) | 43.6 (29.3 to 59) | 60 (44.6 to 73.7) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 51 (43.2 to 58.7) | | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: LDA or CR Response Rate per CDAI at Week 28

| End point title | LDA or CR Response Rate per CDAI at Week 28 |
|---|---|

End point description:

Percentage of subjects achieving LDA or CR per CDAI criteria. The CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. LDA was defined as a score from 2.8 to ≤ 10; CR was defined as a score ≤ 2.8.  Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 28 (Week 16 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 47.6 (33.4 to 62.3) | 44.4 (29.5 to 60.4) | 48.7 (33.9 to 63.8) | 60 (44.6 to 73.7) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 50.3 (42.6 to 58) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: LDA or CR Response Rate per CDAI at Week 32

| End point title | LDA or CR Response Rate per CDAI at Week 32 |
|---|---|

End point description:

Percentage of subjects achieving LDA or CR per CDAI criteria. The CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. LDA was defined as a score from 2.8 to ≤ 10; CR was defined as a score ≤ 2.8. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 32 (Week 20 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 42.9 (29.1 to 57.8) | 55.6 (39.6 to 70.5) | 51.3 (36.2 to 66.1) | 60 (44.6 to 73.7) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 52.2 (44.5 to 59.9) | | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: LDA or CR Response Rate per CDAI at Week 36

| End point title | LDA or CR Response Rate per CDAI at Week 36 |
|---|---|

End point description:

Percentage of subjects achieving LDA or CR per CDAI criteria. The CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. LDA was defined as a score from 2.8 to ≤ 10; CR was defined as a score ≤ 2.8. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 36 (Week 24 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 52.4 (37.7 to 66.6) | 44.4 (29.5 to 60.4) | 59 (43.4 to 72.9) | 60 (44.6 to 73.7) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 54.1 (46.3 to 61.7) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: CR Response Rate Per CDAI Criteria at Week 2

| End point title | CR Response Rate Per CDAI Criteria at Week 2 |
|---|---|

End point description:

Percentage of subjects achieving CR per CDAI criteria. The CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. CR was defined as a score ≤ 2.8. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 2 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 39 | 37 | 39 | 39 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 0 (0 to 10.7) | 0 (0 to 11.2) | 2.6 (0 to 14.4) | 0 (0 to 10.7) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 154 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 0.6 (0 to 4) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: CR Response Rate Per CDAI Criteria at Week 4

| End point title | CR Response Rate Per CDAI Criteria at Week 4 |
|---|---|

End point description:

Percentage of subjects achieving CR per CDAI criteria. The CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. CR was defined as a score ≤ 2.8. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 4 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 0 (0 to 10) | 2.7 (0 to 15.1) | 5.1 (0.5 to 17.8) | 5 (0.5 to 17.4) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 158 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 3.2 (1.2 to 7.4) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: CR Response Rate Per CDAI Criteria at Week 6

| End point title | CR Response Rate Per CDAI Criteria at Week 6 |
|---|---|

End point description:

Percentage of subjects achieving CR per CDAI criteria. The CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. CR was defined as a score ≤ 2.8. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 6 of Study M12-963

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 2.4 (0 to 13.4) | 0 (0 to 11.2) | 10.3 (3.5 to 24.2) | 5 (0.5 to 17.4) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 158 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 4.4 (2 to 9) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: CR Response Rate Per CDAI Criteria at Week 8

| End point title | CR Response Rate Per CDAI Criteria at Week 8 |
|---|---|

End point description:

Percentage of subjects achieving CR per CDAI criteria. The CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. CR was defined as a score ≤ 2.8. Estimates of the 95%

confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 8 of Study M12-963

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 4.8 (0.5 to 16.6) | 0 (0 to 11.2) | 17.9 (8.7 to 33) | 17.5 (8.4 to 32.3) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 158 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 10.1 (6.2 to 15.9) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: CR Response Rate Per CDAI Criteria at Week 12

| End point title | CR Response Rate Per CDAI Criteria at Week 12 |
|---|---|

End point description:

Percentage of subjects achieving CR per CDAI criteria. The CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. CR was defined as a score ≤ 2.8. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 12 of Study M12-963 (considered Week 0 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 37 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 7.1 (1.8 to 19.7) | 8.1 (2.1 to 22) | 12.8 (5.1 to 27.2) | 12.5 (5 to 26.6) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 158 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 10.1 (6.2 to 15.9) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: CR Response Rate Per CDAI Criteria at Week 16

| End point title | CR Response Rate Per CDAI Criteria at Week 16 |
|---|---|

End point description:

Percentage of subjects achieving CR per CDAI criteria. The CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. CR was defined as a score ≤ 2.8. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 16 (Week 4 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 40 | 35 | 36 | 38 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 7.5 (1.9 to 20.6) | 5.7 (0.6 to 19.6) | 11.1 (3.8 to 25.9) | 15.8 (7.1 to 30.8) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 149 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 10.1 (6.1 to 16) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: CR Response Rate Per CDAI Criteria at Week 20

| End point title | CR Response Rate Per CDAI Criteria at Week 20 |
|---|---|

End point description:

Percentage of subjects achieving CR per CDAI criteria. The CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. CR was defined as a score ≤ 2.8. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 20 (Week 8 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 35 | 38 | 39 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 9.5 (3.2 to 22.6) | 11.4 (3.9 to 26.5) | 15.8 (7.1 to 30.8) | 17.9 (8.7 to 33) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 154 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 13.6 (9 to 20) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: CR Response Rate Per CDAI Criteria at Week 24

| End point title | CR Response Rate Per CDAI Criteria at Week 24 |
|---|---|

End point description:

Percentage of subjects achieving CR per CDAI criteria. The CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. CR was defined as a score ≤ 2.8. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 24 (Week 12 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 7.1 (1.8 to 19.7) | 5.6 (0.6 to 19.1) | 23.1 (12.4 to 38.5) | 20 (10.2 to 35) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 14 (9.4 to 20.4) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: CR Response Rate Per CDAI Criteria at Week 28

| End point title | CR Response Rate Per CDAI Criteria at Week 28 |
|---|---|

End point description:

Percentage of subjects achieving CR per CDAI criteria. The CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. CR was defined as a score ≤ 2.8. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 28 (Week 16 of Study M12-965)

| End point values | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 9.5 (3.2 to 22.6) | 5.6 (0.6 to 19.1) | 20.5 (10.5 to 35.8) | 20 (10.2 to 35) |

| End point values | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 14 (9.4 to 20.4) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: CR Response Rate Per CDAI Criteria at Week 32

| End point title | CR Response Rate Per CDAI Criteria at Week 32 |
|---|---|

End point description:

Percentage of subjects achieving CR per CDAI criteria. The CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. CR was defined as a score ≤ 2.8. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 32 (Week 20 of Study M12-965)

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 7.1 (1.8 to 19.7) | 5.6 (0.6 to 19.1) | 12.8 (5.1 to 27.2) | 15 (6.7 to 29.5) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 10.2 (6.3 to 16) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: CR Response Rate Per CDAI Criteria at Week 36

| End point title | CR Response Rate Per CDAI Criteria at Week 36 |
|---|---|

End point description:

Percentage of subjects achieving CR per CDAI criteria. The CDAI is a composite index for assessing disease activity based on the summation of the counts of TJC28 and SJC28, patient global assessment of disease activity measured on a VAS from 0 to 10 cm, and physician global assessment of disease activity measured on a VAS from 0 to 10 cm. The total CDAI score ranges from 0 to 78 with higher scores indicating higher disease activity. CR was defined as a score ≤ 2.8. Estimates of the 95%

confidence interval of the response rates for each treatment group were calculated using the Agrestil-Coull method.

Safety Analysis Set: all subjects who received at least 1 dose of study medication in M12-965 and had an assessment. LOCF used for missing data.

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

End point timeframe:

Week 36 (Week 24 of Study M12-965)

| **End point values** | ADA 40 mg EOW / ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW | ABT-122 120 mg EW / 120 mg EOW |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 36 | 39 | 40 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 9.5 (3.2 to 22.6) | 11.1 (3.8 to 25.9) | 17.9 (8.7 to 33) | 15 (6.7 to 29.5) |

| **End point values** | All ABT-122 120 mg EOW | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 157 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 13.4 (8.8 to 19.7) | | | |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Protocol-related treatment-emergent AEs (TEAEs) and Treatment-emergent serious adverse events (TESAEs) were collected from the first dose of study drug in study M12-965 until 70 days after the last dose of study drug (up to 32 weeks).

Adverse event reporting additional description:

A protocol-related TEAE or TESAE is defined as any AE with onset or worsening reported by a participant from the first dose of study drug in study M12-965 until 70 days have elapsed following discontinuation of ABT-122 administration. Events were collected whether elicited or spontaneously reported by the participant.

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

### Dictionary used

| Dictionary name | MedDRA |
|---|---|
| Dictionary version | 17.1 |

### Reporting groups

| Reporting group title | ADA 40 mg EOW/ABT-122 120 mg EOW |
|---|---|

Reporting group description:

Double-blind ADA 40 mg EOW for 11 weeks. Open-label ABT-122 120 mg EOW.

| Reporting group title | ABT-122 60 mg EOW / 120 mg EOW |
|---|---|

Reporting group description:

Double-blind ABT-122 60 mg EOW for 11 weeks. Open-label ABT-122 120 mg EOW.

| Reporting group title | ABT-122 120 mg EOW / 120 mg EOW |
|---|---|

Reporting group description:

Double-blind ABT-122 120 mg EOW for 11 weeks. Open-label ABT-122 120 mg EOW.

| Reporting group title | ABT-122 120 mg EW / 120 mg EOW |
|---|---|

Reporting group description:

Double-blind ABT-122 120 mg EW for 11 weeks. Open-label ABT-122 120 mg EOW.

| Reporting group title | All ABT-122 120 mg EOW |
|---|---|

Reporting group description:

Open-label ABT-122 120 mg EOW.

| Serious adverse events | ADA 40 mg EOW/ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 1 / 37 (2.70%) | 5 / 39 (12.82%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | | | |
| Injury, poisoning and procedural complications | | | |
| HUMERUS FRACTURE | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 1 / 39 (2.56%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| INFLAMMATION OF WOUND | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 1 / 39 (2.56%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| JOINT DISLOCATION | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 1 / 39 (2.56%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| MYOCARDIAL ISCHAEMIA | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 1 / 37 (2.70%) | 0 / 39 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| ANAEMIA | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 1 / 39 (2.56%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| ENTEROCOLITIS | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 1 / 39 (2.56%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| MENORRHAGIA | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 1 / 39 (2.56%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| SKIN ULCER | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 1 / 39 (2.56%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | ABT-122 120 mg EW / 120 mg EOW | All ABT-122 120 mg EOW | |
|---|---|---|---|

| | | | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 6 / 158 (3.80%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | | | |
| Injury, poisoning and procedural complications | | | |
| HUMERUS FRACTURE | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| INFLAMMATION OF WOUND | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| JOINT DISLOCATION | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorders | | | |
| MYOCARDIAL ISCHAEMIA | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood and lymphatic system disorders | | | |
| ANAEMIA | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| ENTEROCOLITIS | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Reproductive system and breast disorders | | | |
| MENORRHAGIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| **Skin and subcutaneous tissue disorders** | | | |
| SKIN ULCER | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

Frequency threshold for reporting non-serious adverse events: 0 %

| **Non-serious adverse events** | ADA 40 mg EOW/ABT-122 120 mg EOW | ABT-122 60 mg EOW / 120 mg EOW | ABT-122 120 mg EOW / 120 mg EOW |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 17 / 42 (40.48%) | 14 / 37 (37.84%) | 16 / 39 (41.03%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| BASAL CELL CARCINOMA | | | |
| subjects affected / exposed | 1 / 42 (2.38%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vascular disorders | | | |
| HYPERTENSION | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 1 / 39 (2.56%) |
| occurrences (all) | 0 | 0 | 1 |
| HAEMATOMA | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 1 / 39 (2.56%) |
| occurrences (all) | 0 | 0 | 1 |
| VARICOSE VEIN | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| NODULE | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 1 / 37 (2.70%) | 0 / 39 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Immune system disorders | | | |

| | | | |
|---|---|---|---|
| FOOD ALLERGY | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| | | | |
| HYPERSENSITIVITY | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 1 / 37 (2.70%) | 0 / 39 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| **Reproductive system and breast disorders** | | | |
| ADNEXA UTERI CYST | | | |
| subjects affected / exposed | 1 / 42 (2.38%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| | | | |
| OVARIAN CYST | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| **Investigations** | | | |
| ALANINE AMINOTRANSFERASE ABNORMAL | | | |
| subjects affected / exposed | 1 / 42 (2.38%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| | | | |
| ALANINE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 1 / 42 (2.38%) | 0 / 37 (0.00%) | 1 / 39 (2.56%) |
| occurrences (all) | 1 | 0 | 1 |
| | | | |
| ASPARTATE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 1 / 42 (2.38%) | 0 / 37 (0.00%) | 1 / 39 (2.56%) |
| occurrences (all) | 2 | 0 | 1 |
| | | | |
| BLOOD CHOLESTEROL INCREASED | | | |
| subjects affected / exposed | 1 / 42 (2.38%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| | | | |
| BLOOD SODIUM DECREASED | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 1 / 39 (2.56%) |
| occurrences (all) | 0 | 0 | 1 |
| | | | |
| BLOOD TRIGLYCERIDES INCREASED | | | |
| subjects affected / exposed | 1 / 42 (2.38%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| | | | |
| EOSINOPHIL COUNT INCREASED | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| **HAEMOGLOBIN DECREASED** | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 1 / 39 (2.56%) |
| occurrences (all) | 0 | 0 | 1 |
| **HEPATIC ENZYME INCREASED** | | | |
| subjects affected / exposed | 1 / 42 (2.38%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| **LIVER FUNCTION TEST ABNORMAL** | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 1 / 37 (2.70%) | 0 / 39 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| **TRANSAMINASES INCREASED** | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 1 / 37 (2.70%) | 0 / 39 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| **Injury, poisoning and procedural complications** | | | |
| **CHEST INJURY** | | | |
| subjects affected / exposed | 1 / 42 (2.38%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| **CONTUSION** | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| **LIMB INJURY** | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| **RIB FRACTURE** | | | |
| subjects affected / exposed | 1 / 42 (2.38%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| **SKIN ABRASION** | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| **SUBCUTANEOUS HAEMATOMA** | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 1 / 39 (2.56%) |
| occurrences (all) | 0 | 0 | 1 |
| **THERMAL BURN** | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

**Nervous system disorders**
DIZZINESS

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 42 (0.00%) | 1 / 37 (2.70%) | 1 / 39 (2.56%) |
| occurrences (all) | 0 | 1 | 1 |

**Ear and labyrinth disorders**
VERTIGO

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

**Gastrointestinal disorders**
ABDOMINAL PAIN UPPER

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 1 / 39 (2.56%) |
| occurrences (all) | 0 | 0 | 1 |

DENTAL CARIES

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

GASTRITIS

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 42 (0.00%) | 1 / 37 (2.70%) | 0 / 39 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

NAUSEA

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 1 / 39 (2.56%) |
| occurrences (all) | 0 | 0 | 1 |

VOMITING

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 42 (0.00%) | 1 / 37 (2.70%) | 1 / 39 (2.56%) |
| occurrences (all) | 0 | 1 | 1 |

**Hepatobiliary disorders**
HEPATIC STEATOSIS

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

HEPATOBILIARY DISEASE

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

LIVER DISORDER

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 1 / 39 (2.56%) |
| occurrences (all) | 0 | 0 | 1 |

**Skin and subcutaneous tissue disorders**

| | | | |
|---|---|---|---|
| DERMATITIS ALLERGIC | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 1 / 37 (2.70%) | 0 / 39 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| PRURITUS | | | |
| subjects affected / exposed | 1 / 42 (2.38%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| NAIL DISCOLOURATION | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 1 / 39 (2.56%) |
| occurrences (all) | 0 | 0 | 1 |
| RASH | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 1 / 37 (2.70%) | 0 / 39 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| RASH PRURITIC | | | |
| subjects affected / exposed | 1 / 42 (2.38%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| RASH VESICULAR | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| **Renal and urinary disorders** | | | |
| NEPHROLITHIASIS | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| **Musculoskeletal and connective tissue disorders** | | | |
| ARTHRALGIA | | | |
| subjects affected / exposed | 2 / 42 (4.76%) | 1 / 37 (2.70%) | 4 / 39 (10.26%) |
| occurrences (all) | 2 | 1 | 4 |
| ARTHRITIS | | | |
| subjects affected / exposed | 2 / 42 (4.76%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| INTERVERTEBRAL DISC DEGENERATION | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 1 / 39 (2.56%) |
| occurrences (all) | 0 | 0 | 1 |
| BURSITIS | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 1 / 37 (2.70%) | 0 / 39 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| MUSCULOSKELETAL PAIN | | | |

|  | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 1 / 39 (2.56%) |
| occurrences (all) | 0 | 0 | 1 |
| **OSTEOARTHRITIS** | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 1 / 37 (2.70%) | 1 / 39 (2.56%) |
| occurrences (all) | 0 | 1 | 1 |
| **OSTEOPOROSIS** | | | |
| subjects affected / exposed | 1 / 42 (2.38%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| **PAIN IN EXTREMITY** | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 2 / 39 (5.13%) |
| occurrences (all) | 0 | 0 | 3 |
| **RHEUMATOID ARTHRITIS** | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 3 / 37 (8.11%) | 1 / 39 (2.56%) |
| occurrences (all) | 0 | 3 | 1 |
| **TENDON DISORDER** | | | |
| subjects affected / exposed | 1 / 42 (2.38%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| **Infections and infestations** | | | |
| **ATYPICAL PNEUMONIA** | | | |
| subjects affected / exposed | 1 / 42 (2.38%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| **BRONCHITIS** | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 3 / 37 (8.11%) | 0 / 39 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| **CYSTITIS** | | | |
| subjects affected / exposed | 1 / 42 (2.38%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| **HERPES VIRUS INFECTION** | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 1 / 37 (2.70%) | 0 / 39 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| **NASOPHARYNGITIS** | | | |
| subjects affected / exposed | 4 / 42 (9.52%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 6 | 0 | 0 |
| **ORAL HERPES** | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 1 / 39 (2.56%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|---|---|---|---|
| **PARAMETRITIS** | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 1 / 39 (2.56%) |
| occurrences (all) | 0 | 0 | 1 |
| **PARONYCHIA** | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| **PHARYNGITIS** | | | |
| subjects affected / exposed | 1 / 42 (2.38%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| **PNEUMONIA** | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 1 / 39 (2.56%) |
| occurrences (all) | 0 | 0 | 1 |
| **PULPITIS DENTAL** | | | |
| subjects affected / exposed | 1 / 42 (2.38%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| **RASH PUSTULAR** | | | |
| subjects affected / exposed | 1 / 42 (2.38%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| **RESPIRATORY TRACT INFECTION** | | | |
| subjects affected / exposed | 1 / 42 (2.38%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| **SINUSITIS** | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 1 / 39 (2.56%) |
| occurrences (all) | 0 | 0 | 1 |
| **TONSILLITIS** | | | |
| subjects affected / exposed | 1 / 42 (2.38%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| **UPPER RESPIRATORY TRACT INFECTION** | | | |
| subjects affected / exposed | 1 / 42 (2.38%) | 3 / 37 (8.11%) | 6 / 39 (15.38%) |
| occurrences (all) | 1 | 3 | 10 |
| **URINARY TRACT INFECTION** | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 37 (0.00%) | 1 / 39 (2.56%) |
| occurrences (all) | 0 | 0 | 1 |
| **VARICELLA** | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 42 (0.00%) | 1 / 37 (2.70%) | 0 / 39 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| VIRAL UPPER RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 1 / 42 (2.38%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| HYPERCHOLESTEROLAEMIA | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 1 / 37 (2.70%) | 0 / 39 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| DIABETES MELLITUS | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 1 / 37 (2.70%) | 0 / 39 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| HYPERLIPIDAEMIA | | | |
| subjects affected / exposed | 1 / 42 (2.38%) | 0 / 37 (0.00%) | 0 / 39 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| **Non-serious adverse events** | ABT-122 120 mg EW / 120 mg EOW | All ABT-122 120 mg EOW | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 14 / 40 (35.00%) | 61 / 158 (38.61%) | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| BASAL CELL CARCINOMA | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) | |
| occurrences (all) | 0 | 1 | |
| Vascular disorders | | | |
| HYPERTENSION | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 2 / 158 (1.27%) | |
| occurrences (all) | 1 | 2 | |
| HAEMATOMA | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) | |
| occurrences (all) | 0 | 1 | |
| VARICOSE VEIN | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 1 / 158 (0.63%) | |
| occurrences (all) | 1 | 1 | |
| General disorders and administration site conditions | | | |

| | | | |
|---|---|---|---|
| NODULE | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) | |
| occurrences (all) | 0 | 1 | |
| **Immune system disorders** | | | |
| FOOD ALLERGY | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 1 / 158 (0.63%) | |
| occurrences (all) | 2 | 2 | |
| HYPERSENSITIVITY | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 2 / 158 (1.27%) | |
| occurrences (all) | 1 | 2 | |
| **Reproductive system and breast disorders** | | | |
| ADNEXA UTERI CYST | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) | |
| occurrences (all) | 0 | 1 | |
| OVARIAN CYST | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 1 / 158 (0.63%) | |
| occurrences (all) | 1 | 1 | |
| **Investigations** | | | |
| ALANINE AMINOTRANSFERASE ABNORMAL | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) | |
| occurrences (all) | 0 | 1 | |
| ALANINE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 2 / 158 (1.27%) | |
| occurrences (all) | 0 | 2 | |
| ASPARTATE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 2 / 158 (1.27%) | |
| occurrences (all) | 0 | 3 | |
| BLOOD CHOLESTEROL INCREASED | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 2 / 158 (1.27%) | |
| occurrences (all) | 1 | 2 | |
| BLOOD SODIUM DECREASED | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) | |
| occurrences (all) | 0 | 1 | |
| BLOOD TRIGLYCERIDES INCREASED | | | |

| | | |
|---|---|---|
| subjects affected / exposed | 1 / 40 (2.50%) | 2 / 158 (1.27%) |
| occurrences (all) | 1 | 2 |
| **EOSINOPHIL COUNT INCREASED** | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 1 / 158 (0.63%) |
| occurrences (all) | 1 | 1 |
| **HAEMOGLOBIN DECREASED** | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |
| occurrences (all) | 0 | 1 |
| **HEPATIC ENZYME INCREASED** | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |
| occurrences (all) | 0 | 1 |
| **LIVER FUNCTION TEST ABNORMAL** | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |
| occurrences (all) | 0 | 1 |
| **TRANSAMINASES INCREASED** | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |
| occurrences (all) | 0 | 1 |
| **Injury, poisoning and procedural complications** | | |
| CHEST INJURY | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |
| occurrences (all) | 0 | 1 |
| CONTUSION | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 1 / 158 (0.63%) |
| occurrences (all) | 1 | 1 |
| LIMB INJURY | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 1 / 158 (0.63%) |
| occurrences (all) | 1 | 1 |
| RIB FRACTURE | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |
| occurrences (all) | 0 | 1 |
| SKIN ABRASION | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 1 / 158 (0.63%) |
| occurrences (all) | 1 | 1 |
| SUBCUTANEOUS HAEMATOMA | | |

| | | |
|---|---|---|
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |
| occurrences (all) | 0 | 1 |
| **THERMAL BURN** | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 1 / 158 (0.63%) |
| occurrences (all) | 1 | 1 |

**Nervous system disorders**
DIZZINESS

| | | |
|---|---|---|
| subjects affected / exposed | 0 / 40 (0.00%) | 2 / 158 (1.27%) |
| occurrences (all) | 0 | 2 |

**Ear and labyrinth disorders**
VERTIGO

| | | |
|---|---|---|
| subjects affected / exposed | 1 / 40 (2.50%) | 1 / 158 (0.63%) |
| occurrences (all) | 1 | 1 |

**Gastrointestinal disorders**
ABDOMINAL PAIN UPPER

| | | |
|---|---|---|
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |
| occurrences (all) | 0 | 1 |
| **DENTAL CARIES** | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 1 / 158 (0.63%) |
| occurrences (all) | 1 | 1 |
| **GASTRITIS** | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |
| occurrences (all) | 0 | 1 |
| **NAUSEA** | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |
| occurrences (all) | 0 | 1 |
| **VOMITING** | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 2 / 158 (1.27%) |
| occurrences (all) | 0 | 2 |

**Hepatobiliary disorders**
HEPATIC STEATOSIS

| | | |
|---|---|---|
| subjects affected / exposed | 1 / 40 (2.50%) | 1 / 158 (0.63%) |
| occurrences (all) | 1 | 1 |
| **HEPATOBILIARY DISEASE** | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 1 / 158 (0.63%) |
| occurrences (all) | 1 | 1 |

LIVER DISORDER

| | | |
|---|---|---|
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |
| occurrences (all) | 0 | 1 |

**Skin and subcutaneous tissue disorders**

DERMATITIS ALLERGIC

| | | |
|---|---|---|
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |
| occurrences (all) | 0 | 1 |

PRURITUS

| | | |
|---|---|---|
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |
| occurrences (all) | 0 | 1 |

NAIL DISCOLOURATION

| | | |
|---|---|---|
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |
| occurrences (all) | 0 | 1 |

RASH

| | | |
|---|---|---|
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |
| occurrences (all) | 0 | 1 |

RASH PRURITIC

| | | |
|---|---|---|
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |
| occurrences (all) | 0 | 1 |

RASH VESICULAR

| | | |
|---|---|---|
| subjects affected / exposed | 1 / 40 (2.50%) | 1 / 158 (0.63%) |
| occurrences (all) | 1 | 1 |

**Renal and urinary disorders**

NEPHROLITHIASIS

| | | |
|---|---|---|
| subjects affected / exposed | 1 / 40 (2.50%) | 1 / 158 (0.63%) |
| occurrences (all) | 1 | 1 |

**Musculoskeletal and connective tissue disorders**

ARTHRALGIA

| | | |
|---|---|---|
| subjects affected / exposed | 2 / 40 (5.00%) | 9 / 158 (5.70%) |
| occurrences (all) | 2 | 9 |

ARTHRITIS

| | | |
|---|---|---|
| subjects affected / exposed | 0 / 40 (0.00%) | 2 / 158 (1.27%) |
| occurrences (all) | 0 | 4 |

INTERVERTEBRAL DISC DEGENERATION

| | | |
|---|---|---|
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |
| occurrences (all) | 0 | 1 |

BURSITIS

| | | |
|---|---|---|
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |
| occurrences (all) | 0 | 1 |

**MUSCULOSKELETAL PAIN**

| | | |
|---|---|---|
| subjects affected / exposed | 1 / 40 (2.50%) | 2 / 158 (1.27%) |
| occurrences (all) | 1 | 2 |

**OSTEOARTHRITIS**

| | | |
|---|---|---|
| subjects affected / exposed | 1 / 40 (2.50%) | 3 / 158 (1.90%) |
| occurrences (all) | 1 | 3 |

**OSTEOPOROSIS**

| | | |
|---|---|---|
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |
| occurrences (all) | 0 | 1 |

**PAIN IN EXTREMITY**

| | | |
|---|---|---|
| subjects affected / exposed | 0 / 40 (0.00%) | 2 / 158 (1.27%) |
| occurrences (all) | 0 | 3 |

**RHEUMATOID ARTHRITIS**

| | | |
|---|---|---|
| subjects affected / exposed | 0 / 40 (0.00%) | 4 / 158 (2.53%) |
| occurrences (all) | 0 | 4 |

**TENDON DISORDER**

| | | |
|---|---|---|
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |
| occurrences (all) | 0 | 1 |

Infections and infestations
ATYPICAL PNEUMONIA

| | | |
|---|---|---|
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |
| occurrences (all) | 0 | 1 |

**BRONCHITIS**

| | | |
|---|---|---|
| subjects affected / exposed | 0 / 40 (0.00%) | 3 / 158 (1.90%) |
| occurrences (all) | 0 | 3 |

**CYSTITIS**

| | | |
|---|---|---|
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |
| occurrences (all) | 0 | 1 |

**HERPES VIRUS INFECTION**

| | | |
|---|---|---|
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |
| occurrences (all) | 0 | 1 |

**NASOPHARYNGITIS**

| | | |
|---|---|---|
| subjects affected / exposed | 0 / 40 (0.00%) | 4 / 158 (2.53%) |
| occurrences (all) | 0 | 6 |

| | | |
|---|---|---|
| ORAL HERPES | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |
| occurrences (all) | 0 | 1 |
| PARAMETRITIS | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |
| occurrences (all) | 0 | 1 |
| PARONYCHIA | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 1 / 158 (0.63%) |
| occurrences (all) | 1 | 1 |
| PHARYNGITIS | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 2 / 158 (1.27%) |
| occurrences (all) | 1 | 2 |
| PNEUMONIA | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |
| occurrences (all) | 0 | 1 |
| PULPITIS DENTAL | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |
| occurrences (all) | 0 | 1 |
| RASH PUSTULAR | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |
| occurrences (all) | 0 | 1 |
| RESPIRATORY TRACT INFECTION | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |
| occurrences (all) | 0 | 1 |
| SINUSITIS | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |
| occurrences (all) | 0 | 1 |
| TONSILLITIS | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |
| occurrences (all) | 0 | 1 |
| UPPER RESPIRATORY TRACT INFECTION | | |
| subjects affected / exposed | 5 / 40 (12.50%) | 15 / 158 (9.49%) |
| occurrences (all) | 7 | 21 |
| URINARY TRACT INFECTION | | |

|  | subjects affected / exposed | 1 / 40 (2.50%) | 2 / 158 (1.27%) |  |
|---|---|---|---|---|
|  | occurrences (all) | 2 | 3 |  |
| **VARICELLA** |  |  |  |  |
|  | subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |  |
|  | occurrences (all) | 0 | 1 |  |
| **VIRAL UPPER RESPIRATORY TRACT INFECTION** |  |  |  |  |
|  | subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |  |
|  | occurrences (all) | 0 | 1 |  |
| **Metabolism and nutrition disorders** |  |  |  |  |
| **HYPERCHOLESTEROLAEMIA** |  |  |  |  |
|  | subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |  |
|  | occurrences (all) | 0 | 1 |  |
| **DIABETES MELLITUS** |  |  |  |  |
|  | subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |  |
|  | occurrences (all) | 0 | 1 |  |
| **HYPERLIPIDAEMIA** |  |  |  |  |
|  | subjects affected / exposed | 0 / 40 (0.00%) | 1 / 158 (0.63%) |  |
|  | occurrences (all) | 0 | 1 |  |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol?  Yes

| Date | Amendment |
|---|---|
| 01 May 2015 | • Revised the investigational plan to include self-administration of ABT-122 once the prefilled syringe (PFS) was approved and the subject was trained on self-administration.  Once self-administration began, site visits were allowed to occur monthly rather than EOW.<br>• Updated inclusion criteria concerning female and male reproductive language to be consistent with updated safety language.<br>• Updated the electrocardiogram procedure to clarify that a 12-lead electrocardiogram (ECG) was to be obtained at the timepoint indicated in the Table of Study Activities (Week 24).<br>• Removed the 24-hour methylhistamine laboratory tests in the evaluation of a hypersensitivity reaction and urine drug screen.<br>• Added injection site reaction language to allow sites to further assess and investigate skin reactions (e.g., photographs or skin biopsies).  An injection site assessment was to be completed by the investigator only for an injection site reaction.<br>• Updated the study drug section to describe the PFS, in order to enable a more convenient drug self-administration and to eliminate the site burden of reconstituting ABT-122.<br>• Added investigational product information for the ABT-122 solution for PFS, including related information (e.g., packaging and labeling, storage).<br>• Added written instructions for self-administration and dosing diary to allow subjects to follow site training on self-administration and to allow the subject to document dosing information on a subject diary. |
| 29 September 2015 | • Revised to reflect the: increase in planned enrollment from 160 to 225, to reflect the update in planned enrollment into RCT Study M12-963; increase in the number of randomized subjects from approximately 80 to approximately 160, to allow all subjects enrolled in Study M12-963 to enroll in the OLE Study M13-965; decrease in the number of study sites from approximately 60 to approximately 32, i.e. those sites that enrolled subjects into Study M12-963<br>• Added new standard medical and nonmedical complaint language.<br>• Updated the ABT-122 PFS dosing instructions. |

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial?  No

### Limitations and caveats

 None reported