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

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)			

Statistical analyses

No statistical analyses for this end point

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

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)			

Statistical analyses

No statistical analyses for this end point

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

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)			

Statistical analyses

No statistical analyses for this end point

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

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

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 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)	-27.3 (± 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

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

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

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

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 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)	-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

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. • Updated inclusion criteria concerning female and male reproductive language to be consistent with updated safety language. • 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). • Removed the 24-hour methylhistamine laboratory tests in the evaluation of a hypersensitivity reaction and urine drug screen. • 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. • 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. • Added investigational product information for the ABT-122 solution for PFS, including related information (e.g., packaging and labeling, storage). • 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 • Added new standard medical and nonmedical complaint language. • Updated the ABT-122 PFS dosing instructions.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported