Clinical trial results:
A Phase 2 Study to Investigate the Safety, Tolerability and Efficacy of ABT-122 in Subjects with Active Psoriatic Arthritis Who Have an Inadequate Response to Methotrexate

Summary

EudraCT number	2014-003558-15
Trial protocol	DE LV HU CZ ES BG
Global end of trial date	04 July 2016

Results information

Result version number	v1 (current)
This version publication date	13 July 2017
First version publication date	13 July 2017

Trial information

Trial identification

Sponsor protocol code	M14-197

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02349451
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	Nannette Englehardt, BS, AbbVie, nannette.englehardt@abbvie.com
Scientific contact	Paul Peloso, MD, AbbVie, paul.peloso@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	04 July 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	04 July 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study is a Phase 2 randomized, double-blind, double-dummy, active- and placebo-controlled, parallel-group study designed to assess the safety, tolerability, efficacy, pharmacokinetics and immunogenicity of multiple doses of ABT-122 in subjects with active psoriatic arthiritis (PsA) who are inadequately responding to methotrexate (MTX) treatment.

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	28 April 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 2
Country: Number of subjects enrolled	Bulgaria: 38
Country: Number of subjects enrolled	Czech Republic: 6
Country: Number of subjects enrolled	Germany: 2
Country: Number of subjects enrolled	Hungary: 2
Country: Number of subjects enrolled	Latvia: 26
Country: Number of subjects enrolled	New Zealand: 5
Country: Number of subjects enrolled	Poland: 103
Country: Number of subjects enrolled	Romania: 4
Country: Number of subjects enrolled	Spain: 10
Country: Number of subjects enrolled	United States: 42
Worldwide total number of subjects	240
EEA total number of subjects	191

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)	207
From 65 to 84 years	33
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

This study included a 30-day screening period conducted within 30 days of the first dose of study drug.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo EW

Arm description:

Double-blind placebo administered every week (EW) for 12 weeks

Arm type	Placebo
Investigational medicinal product name	placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo for ABT-122 lyophilized powder for solution for injection administered EW

Arm title	Adalimumab 40 mg EOW

Arm description:

Double-blind adalimumab 40 mg administered every other week (EOW) for 12 weeks

Arm type	Active comparator
Investigational medicinal product name	adalimumab
Investigational medicinal product code	
Other name	Humira
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Adalimumab, solution for injection 50 mg/mL (0.8 mL) pre-filled syringe (PFS) 40 mg administered EOW

Investigational medicinal product name	placebo for adalimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo for adalimumab solution for injection, 0.8 mL pre-filled syringe EOW

Arm title	ABT-122 120 mg EW

Arm description:

Double-blind ABT-122 120 mg administered EW for 12 weeks

Arm type	Experimental

Investigational medicinal product name	ABT-122
Investigational medicinal product code	ABT-122
Other name	remtolumab
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

ABT-122 lyophilized powder for solution for injection, 100 mg, 1.0 mL, vial 120 mg administered EW

Arm title	ABT-122 240 mg EW

Arm description:

Double-blind ABT-122 240 mg administered EW for 12 weeks

Arm type	Experimental
Investigational medicinal product name	ABT-122
Investigational medicinal product code	ABT-122
Other name	remtolumab
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

ABT-122 lyophilized powder for solution for injection, 100 mg, 1.0 mL, vial 240 mg administered EW

Number of subjects in period 1	Placebo EW	Adalimumab 40 mg EOW	ABT-122 120 mg EW
Started	24	72	71
Completed	24	71	69
Not completed	0	1	2
Consent withdrawn by subject	-	1	2

Number of subjects in period 1	ABT-122 240 mg EW
Started	73
Completed	72
Not completed	1
Consent withdrawn by subject	1

Baseline characteristics

Reporting groups	
Reporting group title	Placebo EW
Reporting group description:	
Double-blind placebo administered every week (EW) for 12 weeks	
Reporting group title	Adalimumab 40 mg EOW
Reporting group description:	
Double-blind adalimumab 40 mg administered every other week (EOW) for 12 weeks	
Reporting group title	ABT-122 120 mg EW
Reporting group description:	
Double-blind ABT-122 120 mg administered EW for 12 weeks	
Reporting group title	ABT-122 240 mg EW
Reporting group description:	
Double-blind ABT-122 240 mg administered EW for 12 weeks	

Reporting group values	Placebo EW	Adalimumab 40 mg EOW	ABT-122 120 mg EW
Number of subjects	24	72	71
Age categorical Units: Subjects			
Age Continuous Units: years arithmetic mean standard deviation	 47.7 ± 13.67	 50.5 ± 12.03	 51 ± 12.39
Gender categorical Units: Subjects			
Female	12	33	37
Male	12	39	34
Sex: Female, Male Units: Subjects			
Female	12	33	37
Male	12	39	34

Reporting group values	ABT-122 240 mg EW	Total	
Number of subjects	73	240	
Age categorical Units: Subjects			
Age Continuous Units: years arithmetic mean standard deviation	 47.4 ± 13.77	 -	
Gender categorical Units: Subjects			
Female	37	119	
Male	36	121	

Sex: Female, Male Units: Subjects			
Female	37	119	
Male	36	121	

End points

End points reporting groups

Reporting group title	Placebo EW
Reporting group description: Double-blind placebo administered every week (EW) for 12 weeks	
Reporting group title	Adalimumab 40 mg EOW
Reporting group description: Double-blind adalimumab 40 mg administered every other week (EOW) for 12 weeks	
Reporting group title	ABT-122 120 mg EW
Reporting group description: Double-blind ABT-122 120 mg administered EW for 12 weeks	
Reporting group title	ABT-122 240 mg EW
Reporting group description: Double-blind ABT-122 240 mg administered EW for 12 weeks	

Primary: American College of Rheumatology (ACR) 20 Response Rate at Week 12: ABT-122 Versus Placebo

End point title	American College of Rheumatology (ACR) 20 Response Rate at Week 12: ABT-122 Versus Placebo[1]

End point description:

Percentage of participants with an ACR20 response, defined as at least 20% improvement (compared to baseline values) in tender and swollen joint counts and at least 20% improvement in 3 of the remaining 5 core set measures (subject global assessment of pain, subject global assessment of disease activity, physician global assessment of disease activity, subject assessment of physical function and acute phase reactant high sensitivity C-reactive protein [hsCRP]). Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agresti-Coull method.

End point type	Primary

End point timeframe:

Week 12

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The primary endpoint was a comparison between ABT-122 and placebo only.

End point values	Placebo EW	ABT-122 120 mg EW	ABT-122 240 mg EW	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	24	71	73	
Units: percentage of participants				
number (confidence interval 95%)	25 (11.7 to 45.2)	64.8 (53.2 to 74.9)	75.3 (64.3 to 83.9)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo EW v ABT-122 120 mg EW

Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [2]
Method	Fisher exact
Parameter estimate	response rate difference
Point estimate	39.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	17.2
upper limit	57.7

Notes:

[2] - P-value is calculated by one-sided Fisher's exact test to test whether ABT-122 treatment group is superior to placebo group. The a priori statistical significance threshold is P = 0.025.

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo EW v ABT-122 240 mg EW
Number of subjects included in analysis	97
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [3]
Method	Fisher exact
Parameter estimate	response rate difference
Point estimate	50.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	28.1
upper limit	67.4

Notes:

[3] - P-value is calculated by one-sided Fisher's exact test to test whether ABT-122 treatment group is superior to placebo group. The a priori statistical significance threshold is P = 0.025.

Secondary: ACR20 Response Rate at Week 12: ABT-122 Versus Adalimumab

End point title	ACR20 Response Rate at Week 12: ABT-122 Versus Adalimumab[4]

End point description:

Percentage of participants with an ACR20 response, defined as at least 20% improvement (compared to baseline values) in tender and swollen joint counts and at least 20% improvement in 3 of the remaining 5 core set measures (subject global assessment of pain, subject global assessment of disease activity, physician global assessment of disease activity, subject assessment of physical function and acute phase reactant hsCRP). Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agresti-Coull method.

End point type	Secondary

End point timeframe:

Week 12

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This secondary endpoint was a comparison between ABT-122 and adalimumab only.

End point values	Adalimumab 40 mg EOW	ABT-122 120 mg EW	ABT-122 240 mg EW	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	72	71	73	
Units: percentage of participants				
number (confidence interval 95%)	68.1 (56.6 to 77.7)	64.8 (53.2 to 74.9)	75.3 (64.3 to 83.9)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Adalimumab 40 mg EOW v ABT-122 120 mg EW
Number of subjects included in analysis	143
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.723 [5]
Method	Fisher exact
Parameter estimate	response rate difference
Point estimate	-3.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.5
upper limit	12.1

Notes:

[5] - P-value is calculated by one-sided Fisher's exact test to test whether ABT-122 treatment group is superior to adalimumab group.

Statistical analysis title	Statistical Analysis 2
Comparison groups	Adalimumab 40 mg EOW v ABT-122 240 mg EW
Number of subjects included in analysis	145
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.215 [6]
Method	Fisher exact
Parameter estimate	response rate difference
Point estimate	7.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.4
upper limit	21.6

Notes:

[6] - P-value is calculated by one-sided Fisher's exact test to test whether ABT-122 treatment group is superior to adalimumab group.

Secondary: ACR50 Response Rate at Week 12

End point title	ACR50 Response Rate at Week 12

End point description:

Percentage of participants with an ACR50 response, defined as at least 50% improvement (compared to baseline values) in tender and swollen joint counts and at least 50% improvement in 3 of the remaining

5 core set measures (subject global assessment of pain, subject global assessment of disease activity, physician global assessment of disease activity, subject assessment of physical function and acute phase reactant hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agresti-Coull method.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo EW	Adalimumab 40 mg EOW	ABT-122 120 mg EW	ABT-122 240 mg EW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	72	71	73
Units: percentage of participants				
number (confidence interval 95%)	12.5 (3.5 to 31.8)	37.5 (27.2 to 49.1)	36.6 (26.3 to 48.3)	53.4 (42.1 to 64.4)

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo EW v ABT-122 120 mg EW
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.021 [7]
Method	Fisher exact
Parameter estimate	response rate difference
Point estimate	24.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.9
upper limit	39.3

Notes:

[7] - P-value is calculated by one-sided Fisher's exact test to test whether ABT-122 treatment group is superior to placebo group.

Statistical analysis title	Statistical Analysis 2
Comparison groups	Adalimumab 40 mg EOW v ABT-122 120 mg EW
Number of subjects included in analysis	143
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.611 [8]
Method	Fisher exact
Parameter estimate	response rate difference
Point estimate	-0.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.5
upper limit	14.8

Notes:

[8] - P-value is calculated by one-sided Fisher's exact test to test whether ABT-122 treatment group is superior to adalimumab group.

Statistical analysis title	Statistical Analysis 3
Comparison groups	Placebo EW v ABT-122 240 mg EW
Number of subjects included in analysis	97
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [9]
Method	Fisher exact
Parameter estimate	response rate difference
Point estimate	40.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	20.1
upper limit	55.8

Notes:

[9] - P-value is calculated by one-sided Fisher's exact test to test whether ABT-122 treatment group is superior to placebo group.

Statistical analysis title	Statistical Analysis 4
Comparison groups	Adalimumab 40 mg EOW v ABT-122 240 mg EW
Number of subjects included in analysis	145
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.039 [10]
Method	Fisher exact
Parameter estimate	response rate difference
Point estimate	15.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3
upper limit	31.3

Notes:

[10] - P-value is calculated by one-sided Fisher's exact test to test whether ABT-122 treatment group is superior to adalimumab group.

Secondary: ACR70 Response Rate at Week 12

End point title	ACR70 Response Rate at Week 12

End point description:

Percentage of participants with an ACR70 response, defined as at least 70% improvement (compared to baseline values) in tender and swollen joint counts and at least 70% improvement in 3 of the remaining 5 core set measures (subject global assessment of pain, subject global assessment of disease activity, physician global assessment of disease activity, subject assessment of physical function and acute phase reactant hsCRP. Estimates of the 95% confidence interval of the response rates for each treatment group were calculated using the Agresti-Coull method.

End point type	Secondary
End point timeframe:	
Week 12	

End point values	Placebo EW	Adalimumab 40 mg EOW	ABT-122 120 mg EW	ABT-122 240 mg EW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	72	71	73
Units: percentage of participants				
number (confidence interval 95%)	4.2 (0 to 21.9)	15.3 (8.6 to 25.5)	22.5 (14.3 to 33.6)	31.5 (22 to 42.9)

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo EW v ABT-122 120 mg EW
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.034 [11]
Method	Fisher exact
Parameter estimate	response rate difference
Point estimate	18.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.5
upper limit	29.7

Notes:

[11] - P-value is calculated by one-sided Fisher's exact test to test whether ABT-122 treatment group is superior to placebo group.

Statistical analysis title	Statistical Analysis 2
Comparison groups	Adalimumab 40 mg EOW v ABT-122 120 mg EW
Number of subjects included in analysis	143
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.185 [12]
Method	Fisher exact
Parameter estimate	response rate difference
Point estimate	7.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.8
upper limit	19.9

Notes:

[12] - P-value is calculated by one-sided Fisher's exact test to test whether ABT-122 treatment group is superior to adalimumab group.

Statistical analysis title	Statistical Analysis 3
Comparison groups	Placebo EW v ABT-122 240 mg EW
Number of subjects included in analysis	97
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004 [13]
Method	Fisher exact
Parameter estimate	response rate difference
Point estimate	27.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.6
upper limit	39

Notes:

[13] - P-value is calculated by one-sided Fisher's exact test to test whether ABT-122 treatment group is superior to placebo group.

Statistical analysis title	Statistical Analysis 4
Comparison groups	Adalimumab 40 mg EOW v ABT-122 240 mg EW
Number of subjects included in analysis	145
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.017 [14]
Method	Fisher exact
Parameter estimate	response rate difference
Point estimate	16.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.3
upper limit	29.3

Notes:

[14] - P-value is calculated by one-sided Fisher's exact test to test whether ABT-122 treatment group is superior to adalimumab group.

Secondary: ACRn at Week 12

End point title	ACRn at Week 12

End point description:

ACR measures percentage improvements in tender and swollen joint counts, patient assessments of pain, global disease activity and physical function, physician global assessment of disease activity and acute phase reactant. ACRn is a continuous variable based on the ACR criteria. Improvement from baseline in a component of the ACR composite variable was computed as the difference between the baseline value and the value at a given post-baseline visit. A positive value for improvement from baseline for an individual component indicates lesser severity of disease. The 95% confidence interval for mean is constructed using T-statistic with significance level alpha=5%.

End point type	Secondary

End point timeframe:

At Week 12

End point values	Placebo EW	Adalimumab 40 mg EOW	ABT-122 120 mg EW	ABT-122 240 mg EW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	72	71	73
Units: percentage improvement				
arithmetic mean (confidence interval 95%)	-20.3 (-59.6 to 19.1)	38.2 (29.2 to 47.2)	34.7 (25.5 to 44)	48.6 (41.1 to 56.1)

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo EW v ABT-122 120 mg EW
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [15]
Method	Kolmogorov-Smirnov test

Notes:

[15] - Kolmogorov-Smirnov test based on the empirical distribution function is applied to get the p-value of comparing the ABT-122 treatment group with placebo group.

Statistical analysis title	Statistical Analysis 2
Comparison groups	Adalimumab 40 mg EOW v ABT-122 120 mg EW
Number of subjects included in analysis	143
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.561 [16]
Method	Kolmogorov-Smirnov test

Notes:

[16] - Kolmogorov-Smirnov test based on the empirical distribution function is applied to get the p-value of comparing the ABT-122 treatment group with adalimumab group.

Statistical analysis title	Statistical Analysis 3
Comparison groups	Placebo EW v ABT-122 240 mg EW
Number of subjects included in analysis	97
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [17]
Method	Kolmogorov-Smirnov test

Notes:

[17] - Kolmogorov-Smirnov test based on the empirical distribution function is applied to get the p-value of comparing the ABT-122 treatment group with placebo group.

Statistical analysis title	Statistical Analysis 4
Comparison groups	Adalimumab 40 mg EOW v ABT-122 240 mg EW

Number of subjects included in analysis	145
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.106 [18]
Method	Kolmogorov-Smirnov test

Notes:

[18] - Kolmogorov-Smirnov test based on the empirical distribution function is applied to get the p-value of comparing the ABT-122 treatment group with adalimumab group.

Secondary: Change from Baseline in Disease Activity Score 28 (DAS28[hsCRP]) at Week 12

End point title	Change from Baseline in Disease Activity Score 28 (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.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo EW	Adalimumab 40 mg EOW	ABT-122 120 mg EW	ABT-122 240 mg EW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	72	71	73
Units: units on a scale				
least squares mean (confidence interval 95%)	-0.89 (-1.32 to -0.45)	-1.83 (-2.08 to -1.58)	-1.96 (-2.21 to -1.7)	-2.28 (-2.53 to -2.03)

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo EW v ABT-122 120 mg EW
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [19]
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-1.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.58
upper limit	-0.57

Notes:

[19] - Two-sided p-value is calculated from ANCOVA model with treatment group as the fixed factor and baseline value as the covariate.

Statistical analysis title	Statistical Analysis 2
Comparison groups	Adalimumab 40 mg EOW v ABT-122 120 mg EW
Number of subjects included in analysis	143
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.479 [20]
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.48
upper limit	0.23

Notes:

[20] - Two-sided p-value is calculated from ANCOVA model with treatment group as the fixed factor and baseline value as the covariate.

Statistical analysis title	Statistical Analysis 3
Comparison groups	Placebo EW v ABT-122 240 mg EW
Number of subjects included in analysis	97
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [21]
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	-0.89

Notes:

[21] - Two-sided p-value is calculated from ANCOVA model with treatment group as the fixed factor and baseline value as the covariate.

Statistical analysis title	Statistical Analysis 4
Comparison groups	Adalimumab 40 mg EOW v ABT-122 240 mg EW
Number of subjects included in analysis	145
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.012 [22]
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.81
upper limit	-0.1

Notes:

[22] - Two-sided p-value is calculated from ANCOVA model with treatment group as the fixed factor and baseline value as the covariate.

Secondary: Change From Baseline in Psoriatic Arthritis Disease Activity Score (PASDAS) at Week 12

End point title	Change From Baseline in Psoriatic Arthritis Disease Activity Score (PASDAS) at Week 12

End point description:

PASDAS is a continuous compound disease activity state score determined by the combined values of tender or swollen joint counts, subject-reported outcome and hsCRP lab test. Smaller values on PASDAS indicate a better condition; a negative change from baseline indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo EW	Adalimumab 40 mg EOW	ABT-122 120 mg EW	ABT-122 240 mg EW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	72	71	73
Units: units on a scale				
least squares mean (confidence interval 95%)	-1.46 (-2.01 to -0.9)	-2.53 (-2.85 to -2.22)	-2.62 (-2.94 to -2.31)	-2.86 (-3.18 to -2.55)

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo EW v ABT-122 120 mg EW
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [23]
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-1.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.81
upper limit	-0.53

Notes:

[23] - Two-sided p-value is calculated from ANCOVA model with treatment group as the fixed factor and baseline value as the covariate.

Statistical analysis title	Statistical Analysis 2
Comparison groups	Adalimumab 40 mg EOW v ABT-122 120 mg EW

Number of subjects included in analysis	143
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.696 [24]
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.54
upper limit	0.36

Notes:

[24] - Two-sided p-value is calculated from ANCOVA model with treatment group as the fixed factor and baseline value as the covariate.

Statistical analysis title	Statistical Analysis 3
Comparison groups	Placebo EW v ABT-122 240 mg EW
Number of subjects included in analysis	97
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [25]
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-1.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.04
upper limit	-0.77

Notes:

[25] - Two-sided p-value is calculated from ANCOVA model with treatment group as the fixed factor and baseline value as the covariate.

Statistical analysis title	Statistical Analysis 4
Comparison groups	Adalimumab 40 mg EOW v ABT-122 240 mg EW
Number of subjects included in analysis	145
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.151 [26]
Method	ANCOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.77
upper limit	0.12

Notes:

[26] - Two-sided p-value is calculated from ANCOVA model with treatment group as the fixed factor and baseline value as the covariate.

Secondary: Change From Baseline in Psoriasis Target Lesion Score at Week 12

End point title	Change From Baseline in Psoriasis Target Lesion Score at Week 12

End point description:

Target lesion score for psoriasis in participants with psoriatic arthritis is calculated by adding the scores of plaque erythema, scaling and thickness. Scores range from 0 (no erythema or evidence of plaque thickness) to 10 (severe erythema and evidence of plaque thickness).

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo EW	Adalimumab 40 mg EOW	ABT-122 120 mg EW	ABT-122 240 mg EW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	72	71	73
Units: units on a scale				
least squares mean (confidence interval 95%)	-1.81 (-2.65 to -0.96)	-4.16 (-4.65 to -3.67)	-4.98 (-5.47 to -4.49)	-4.53 (-5.02 to -4.05)

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo EW v ABT-122 120 mg EW
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [27]
Method	ANOVA
Parameter estimate	Least squares mean difference
Point estimate	-3.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.14
upper limit	-2.19

Notes:

[27] - Two-sided p-value is calculated from ANOVA model with treatment group as the fixed factor and baseline value as the covariate.

Statistical analysis title	Statistical Analysis 2
Comparison groups	Adalimumab 40 mg EOW v ABT-122 120 mg EW
Number of subjects included in analysis	143
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.021 [28]
Method	ANOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.81

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.51
upper limit	-0.12

Notes:

[28] - Two-sided p-value is calculated from ANOVA model with treatment group as the fixed factor and baseline value as the covariate.

Statistical analysis title	Statistical Analysis 3
Comparison groups	Placebo EW v ABT-122 240 mg EW
Number of subjects included in analysis	97
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [29]
Method	ANOVA
Parameter estimate	Least squares mean difference
Point estimate	-2.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.7
upper limit	-1.75

Notes:

[29] - Two-sided p-value is calculated from ANOVA model with treatment group as the fixed factor and baseline value as the covariate.

Statistical analysis title	Statistical Analysis 4
Comparison groups	Adalimumab 40 mg EOW v ABT-122 240 mg EW
Number of subjects included in analysis	145
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.288 [30]
Method	ANOVA
Parameter estimate	Least squares mean difference
Point estimate	-0.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.06
upper limit	0.32

Notes:

[30] - Two-sided p-value is calculated from ANOVA model with treatment group as the fixed factor and baseline value as the covariate.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Treatment-emergent adverse events (TEAEs) were collected from first dose of study drug until 70 days after the last dose of study drug (up to 21 weeks); serious adverse events (AEs) were collected from the time informed consent was obtained (25.5 weeks).

Adverse event reporting additional description:

A TEAE is defined as any AE with onset or worsening reported by a participant from the time that the first dose of adalimumab or ABT-122 is administered until 5 half-lives (70 days) have elapsed following discontinuation of adalimumab or ABT-122 administration. TEAEs were collected whether elicited or spontaneously reported by the participant.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.1

Reporting groups

Reporting group title	Placebo EW

Reporting group description:

Double-blind placebo administered EW for 12 weeks

Reporting group title	Adalimumab 40 mg EOW

Reporting group description:

Double-blind adalimumab 40 mg administered EOW for 12 weeks

Reporting group title	ABT-122 120 mg EW

Reporting group description:

Double-blind ABT-122 120 mg administered EW for 12 weeks

Reporting group title	ABT-122 240 mg EW

Reporting group description:

Double-blind ABT-122 240 mg administered EW for 12 weeks

Serious adverse events	Placebo EW	Adalimumab 40 mg EOW	ABT-122 120 mg EW
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 24 (4.17%)	0 / 72 (0.00%)	0 / 71 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Investigations			
HEART RATE DECREASED			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
ROAD TRAFFIC ACCIDENT			

subjects affected / exposed	1 / 24 (4.17%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SKIN ABRASION			
subjects affected / exposed	1 / 24 (4.17%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER LIMB FRACTURE			
subjects affected / exposed	1 / 24 (4.17%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
SYNCOPE			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	ABT-122 240 mg EW		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 73 (1.37%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Investigations			
HEART RATE DECREASED			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
ROAD TRAFFIC ACCIDENT			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
SKIN ABRASION			

subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
UPPER LIMB FRACTURE			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
SYNCOPE			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Placebo EW	Adalimumab 40 mg EOW	ABT-122 120 mg EW
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 24 (41.67%)	39 / 72 (54.17%)	33 / 71 (46.48%)
Vascular disorders			
HYPERTENSION			
subjects affected / exposed	0 / 24 (0.00%)	2 / 72 (2.78%)	1 / 71 (1.41%)
occurrences (all)	0	2	1
PHLEBITIS			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
FATIGUE			
subjects affected / exposed	0 / 24 (0.00%)	2 / 72 (2.78%)	1 / 71 (1.41%)
occurrences (all)	0	2	1
GAIT DISTURBANCE			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1

INJECTION SITE BRUISING			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
INJECTION SITE ERYTHEMA			
subjects affected / exposed	0 / 24 (0.00%)	3 / 72 (4.17%)	1 / 71 (1.41%)
occurrences (all)	0	6	1
INJECTION SITE HAEMATOMA			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
INJECTION SITE INDURATION			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE OEDEMA			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
INJECTION SITE PAPULE			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
INJECTION SITE PRURITUS			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	2	0
PERIPHERAL SWELLING			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
VESSEL PUNCTURE SITE PHLEBITIS			
subjects affected / exposed	1 / 24 (4.17%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences (all)	1	0	0
Social circumstances			
ECONOMIC PROBLEM			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
CATARRH			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
COUGH			

subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
DYSPNOEA			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
RHINITIS ALLERGIC			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
SINUS PAIN			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
THROAT IRRITATION			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Psychiatric disorders			
ANXIETY			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
DEPRESSION			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
INSOMNIA			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	1 / 71 (1.41%)
occurrences (all)	0	1	2
STRESS			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 24 (0.00%)	2 / 72 (2.78%)	5 / 71 (7.04%)
occurrences (all)	0	2	5
ASPARTATE AMINOTRANSFERASE INCREASED			

subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	3 / 71 (4.23%)
occurrences (all)	0	1	3
BLOOD CALCIUM INCREASED			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
BLOOD CHOLESTEROL INCREASED			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
BLOOD PRESSURE INCREASED			
subjects affected / exposed	0 / 24 (0.00%)	2 / 72 (2.78%)	1 / 71 (1.41%)
occurrences (all)	0	2	1
BLOOD TRIGLYCERIDES INCREASED			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	2 / 71 (2.82%)
occurrences (all)	0	1	2
BLOOD URIC ACID INCREASED			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
BODY TEMPERATURE INCREASED			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
CRYSTAL URINE PRESENT			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
HAEMOGLOBIN INCREASED			
subjects affected / exposed	1 / 24 (4.17%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences (all)	1	0	0
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	0 / 24 (0.00%)	2 / 72 (2.78%)	0 / 71 (0.00%)
occurrences (all)	0	4	0
MONOCYTE COUNT INCREASED			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
NEUTROPHIL COUNT DECREASED			

subjects affected / exposed	0 / 24 (0.00%)	3 / 72 (4.17%)	2 / 71 (2.82%)
occurrences (all)	0	3	2
TRANSAMINASES ABNORMAL			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	2 / 71 (2.82%)
occurrences (all)	0	0	2
URINE OUTPUT DECREASED			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
WEIGHT INCREASED			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 24 (0.00%)	3 / 72 (4.17%)	0 / 71 (0.00%)
occurrences (all)	0	3	0
Injury, poisoning and procedural complications			
ANIMAL SCRATCH			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
CONTUSION			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
FALL			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
FOOT FRACTURE			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
INJURY			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
LIGAMENT RUPTURE			

subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
ROAD TRAFFIC ACCIDENT			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
SPINAL COMPRESSION FRACTURE			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
SPLINTER			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Congenital, familial and genetic disorders			
HYDROCELE			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Cardiac disorders			
PALPITATIONS			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
SINUS TACHYCARDIA			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
HEADACHE			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
NEUROPATHY PERIPHERAL			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
SOMNOLENCE			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
GRANULOCYTOPENIA			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0

LEUKOPENIA			
subjects affected / exposed	0 / 24 (0.00%)	2 / 72 (2.78%)	1 / 71 (1.41%)
occurrences (all)	0	2	1
LYMPHADENOPATHY			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
LYMPHOCYTOSIS			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
LYMPHOPENIA			
subjects affected / exposed	0 / 24 (0.00%)	2 / 72 (2.78%)	0 / 71 (0.00%)
occurrences (all)	0	2	0
NEUTROPENIA			
subjects affected / exposed	0 / 24 (0.00%)	2 / 72 (2.78%)	2 / 71 (2.82%)
occurrences (all)	0	2	2
Ear and labyrinth disorders			
VERTIGO			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Eye disorders			
BLEPHARITIS			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
ERYTHEMA OF EYELID			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
MYOPIA			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
RETINAL VASCULAR DISORDER			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
ABDOMINAL PAIN			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
DIARRHOEA			

subjects affected / exposed	1 / 24 (4.17%)	1 / 72 (1.39%)	1 / 71 (1.41%)
occurrences (all)	1	1	1
DYSPEPSIA			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
FOOD POISONING			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
HAEMATOCHEZIA			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	2	0
INGUINAL HERNIA			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
NAUSEA			
subjects affected / exposed	1 / 24 (4.17%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	2	0	1
ORAL MUCOSA EROSION			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
STOMATITIS			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
TOOTHACHE			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	1 / 71 (1.41%)
occurrences (all)	0	1	1
VOMITING			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
BILE DUCT OBSTRUCTION			

subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
HYPERTRANSAMINASAEMIA			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
ACNE			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
DERMATITIS ALLERGIC			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
ERYTHEMA			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
PRURITUS			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	1 / 71 (1.41%)
occurrences (all)	0	1	1
PSORIASIS			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
RASH			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
RASH ERYTHEMATOUS			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Renal and urinary disorders			
CRYSTALLURIA			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
MICTURITION URGENCY			

subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
POLLAKIURIA			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
PROTEINURIA			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	2 / 71 (2.82%)
occurrences (all)	0	1	2
Musculoskeletal and connective tissue disorders			
BACK PAIN			
subjects affected / exposed	2 / 24 (8.33%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences (all)	2	0	0
INTERVERTEBRAL DISC PROTRUSION			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
MYALGIA			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
OSTEOARTHRITIS			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
OSTEOPOROSIS			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
PSORIATIC ARTHROPATHY			
subjects affected / exposed	1 / 24 (4.17%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	1	1	0
ROTATOR CUFF SYNDROME			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
SPINAL PAIN			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Infections and infestations			

ACUTE SINUSITIS			
subjects affected / exposed	0 / 24 (0.00%)	2 / 72 (2.78%)	0 / 71 (0.00%)
occurrences (all)	0	2	0
BRONCHITIS			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	1 / 71 (1.41%)
occurrences (all)	0	1	1
CONJUNCTIVITIS			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
FOLLICULITIS			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
FURUNCLE			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
GASTROENTERITIS			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
GASTROENTERITIS VIRAL			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
HORDEOLUM			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
INFLUENZA			
subjects affected / exposed	0 / 24 (0.00%)	3 / 72 (4.17%)	0 / 71 (0.00%)
occurrences (all)	0	3	0
LARYNGITIS			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
NASOPHARYNGITIS			
subjects affected / exposed	0 / 24 (0.00%)	6 / 72 (8.33%)	4 / 71 (5.63%)
occurrences (all)	0	6	4
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1

ORAL HERPES			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
PARONYCHIA			
subjects affected / exposed	1 / 24 (4.17%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences (all)	2	0	0
PHARYNGITIS			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	2	0
PNEUMONIA			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
RHINITIS			
subjects affected / exposed	1 / 24 (4.17%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences (all)	1	0	0
SINUSITIS			
subjects affected / exposed	1 / 24 (4.17%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	1	0	1
SUBCUTANEOUS ABSCESS			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	2 / 71 (2.82%)
occurrences (all)	0	0	2
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	2 / 24 (8.33%)	5 / 72 (6.94%)	1 / 71 (1.41%)
occurrences (all)	2	5	2
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	2 / 71 (2.82%)
occurrences (all)	0	1	2
URINARY TRACT INFECTION BACTERIAL			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
VIRAL PHARYNGITIS			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
VIRAL UPPER RESPIRATORY TRACT INFECTION			

subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
DIABETES MELLITUS			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	2 / 71 (2.82%)
occurrences (all)	0	0	2
DYSLIPIDAEMIA			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
HYPERCHOLESTEROLAEMIA			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	2 / 71 (2.82%)
occurrences (all)	0	0	2
HYPERLIPIDAEMIA			
subjects affected / exposed	0 / 24 (0.00%)	2 / 72 (2.78%)	0 / 71 (0.00%)
occurrences (all)	0	2	0
HYPERTRIGLYCERIDAEMIA			
subjects affected / exposed	0 / 24 (0.00%)	0 / 72 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
HYPERURICAEMIA			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 24 (0.00%)	1 / 72 (1.39%)	0 / 71 (0.00%)
occurrences (all)	0	3	0

Non-serious adverse events	ABT-122 240 mg EW		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	33 / 73 (45.21%)		
Vascular disorders			
HYPERTENSION			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
PHLEBITIS			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			

FATIGUE				
subjects affected / exposed	1 / 73 (1.37%)			
occurrences (all)	1			
GAIT DISTURBANCE				
subjects affected / exposed	1 / 73 (1.37%)			
occurrences (all)	1			
INFLUENZA LIKE ILLNESS				
subjects affected / exposed	0 / 73 (0.00%)			
occurrences (all)	0			
INJECTION SITE BRUISING				
subjects affected / exposed	0 / 73 (0.00%)			
occurrences (all)	0			
INJECTION SITE ERYTHEMA				
subjects affected / exposed	2 / 73 (2.74%)			
occurrences (all)	3			
INJECTION SITE HAEMATOMA				
subjects affected / exposed	1 / 73 (1.37%)			
occurrences (all)	1			
INJECTION SITE INDURATION				
subjects affected / exposed	1 / 73 (1.37%)			
occurrences (all)	1			
INJECTION SITE OEDEMA				
subjects affected / exposed	1 / 73 (1.37%)			
occurrences (all)	1			
INJECTION SITE PAPULE				
subjects affected / exposed	0 / 73 (0.00%)			
occurrences (all)	0			
INJECTION SITE PRURITUS				
subjects affected / exposed	1 / 73 (1.37%)			
occurrences (all)	2			
PERIPHERAL SWELLING				
subjects affected / exposed	0 / 73 (0.00%)			
occurrences (all)	0			
VESSEL PUNCTURE SITE PHLEBITIS				
subjects affected / exposed	0 / 73 (0.00%)			
occurrences (all)	0			

Social circumstances			
ECONOMIC PROBLEM			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
CATARRH			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
COUGH			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
DYSPNOEA			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
OROPHARYNGEAL PAIN			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
RHINITIS ALLERGIC			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
SINUS PAIN			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
THROAT IRRITATION			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
ANXIETY			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
DEPRESSION			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
INSOMNIA			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		

STRESS			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	3 / 73 (4.11%)		
occurrences (all)	4		
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	2 / 73 (2.74%)		
occurrences (all)	2		
BLOOD CALCIUM INCREASED			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
BLOOD CHOLESTEROL INCREASED			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
BLOOD PRESSURE INCREASED			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
BLOOD TRIGLYCERIDES INCREASED			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
BLOOD URIC ACID INCREASED			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
BODY TEMPERATURE INCREASED			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
CRYSTAL URINE PRESENT			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
HAEMOGLOBIN INCREASED			

subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
MONOCYTE COUNT INCREASED			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
TRANSAMINASES ABNORMAL			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
URINE OUTPUT DECREASED			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
WEIGHT INCREASED			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
ANIMAL SCRATCH			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
CONTUSION			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
FALL			

subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
FOOT FRACTURE			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
INJURY			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
LIGAMENT RUPTURE			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
ROAD TRAFFIC ACCIDENT			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
SPINAL COMPRESSION FRACTURE			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
SPLINTER			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Congenital, familial and genetic disorders			
HYDROCELE			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
PALPITATIONS			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
SINUS TACHYCARDIA			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
Nervous system disorders			
HEADACHE			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
NEUROPATHY PERIPHERAL			

subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
SOMNOLENCE			
subjects affected / exposed	2 / 73 (2.74%)		
occurrences (all)	2		
Blood and lymphatic system disorders			
GRANULOCYTOPENIA			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
LEUKOPENIA			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	2		
LYMPHADENOPATHY			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
LYMPHOCYTOSIS			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
LYMPHOPENIA			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
NEUTROPENIA			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
Ear and labyrinth disorders			
VERTIGO			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Eye disorders			
BLEPHARITIS			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
ERYTHEMA OF EYELID			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
MYOPIA			

subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
RETINAL VASCULAR DISORDER			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
Gastrointestinal disorders			
ABDOMINAL PAIN			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
DIARRHOEA			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
DYSPEPSIA			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
FOOD POISONING			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
HAEMATOCHEZIA			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
INGUINAL HERNIA			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
NAUSEA			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
ORAL MUCOSA EROSION			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
STOMATITIS			

subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
TOOTHACHE			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
VOMITING			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
Hepatobiliary disorders			
BILE DUCT OBSTRUCTION			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
HYPERBILIRUBINAEMIA			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
HYPERTRANSAMINASAEMIA			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
ACNE			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
DERMATITIS ALLERGIC			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
ERYTHEMA			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
PRURITUS			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
PSORIASIS			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
RASH			

subjects affected / exposed	2 / 73 (2.74%)		
occurrences (all)	2		
RASH ERYTHEMATOUS			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
CRYSTALLURIA			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
MICTURITION URGENCY			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
POLLAKIURIA			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
PROTEINURIA			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	2		
Musculoskeletal and connective tissue disorders			
BACK PAIN			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
INTERVERTEBRAL DISC PROTRUSION			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
MYALGIA			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
OSTEOARTHRITIS			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
OSTEOPOROSIS			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
PSORIATIC ARTHROPATHY			

subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
ROTATOR CUFF SYNDROME			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
SPINAL PAIN			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Infections and infestations			
ACUTE SINUSITIS			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
BRONCHITIS			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
CONJUNCTIVITIS			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
FOLLICULITIS			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
FURUNCLE			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
GASTROENTERITIS			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
GASTROENTERITIS VIRAL			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
HORDEOLUM			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
INFLUENZA			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		

LARYNGITIS				
subjects affected / exposed	0 / 73 (0.00%)			
occurrences (all)	0			
NASOPHARYNGITIS				
subjects affected / exposed	3 / 73 (4.11%)			
occurrences (all)	4			
ORAL CANDIDIASIS				
subjects affected / exposed	1 / 73 (1.37%)			
occurrences (all)	1			
ORAL HERPES				
subjects affected / exposed	0 / 73 (0.00%)			
occurrences (all)	0			
PARONYCHIA				
subjects affected / exposed	0 / 73 (0.00%)			
occurrences (all)	0			
PHARYNGITIS				
subjects affected / exposed	0 / 73 (0.00%)			
occurrences (all)	0			
PNEUMONIA				
subjects affected / exposed	1 / 73 (1.37%)			
occurrences (all)	1			
RHINITIS				
subjects affected / exposed	1 / 73 (1.37%)			
occurrences (all)	1			
SINUSITIS				
subjects affected / exposed	1 / 73 (1.37%)			
occurrences (all)	1			
SUBCUTANEOUS ABSCESS				
subjects affected / exposed	0 / 73 (0.00%)			
occurrences (all)	0			
UPPER RESPIRATORY TRACT INFECTION				
subjects affected / exposed	7 / 73 (9.59%)			
occurrences (all)	9			
URINARY TRACT INFECTION				

subjects affected / exposed	4 / 73 (5.48%)		
occurrences (all)	5		
URINARY TRACT INFECTION BACTERIAL			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
VIRAL PHARYNGITIS			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
VIRAL UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
DIABETES MELLITUS			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
DYSLIPIDAEMIA			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
HYPERCHOLESTEROLAEMIA			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences (all)	1		
HYPERLIPIDAEMIA			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
HYPERTRIGLYCERIDAEMIA			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
HYPERURICAEMIA			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 February 2015	The substantive change in this amendment was updating Exclusion Criterion 8 and 23 and adding Exclusion Criterion 17 and 22 to ensure the appropriate subject population was enrolled.
23 July 2015	Substantive changes in this amendment were as follows: ● Revising total number of sites to approximately 110 globally. ● Clarifying rescreening and laboratory retesting requirements to make clear timing of rescreening and the requirements for retesting. ● Adding interim analysis to review the cumulative safety and dose response relationship during the trial. ● Identifying additional personnel who can be unblinded for analysis purposes during the trial. ● Updating female and male reproductive language in Inclusion Criterion 8 and 9 to ensure that only highly effective contraceptive measures were allowed, consistent with the recommendations related to contraception and pregnancy testing in clinical trials by the Clinical Trial Facilitation Group (CTFG) of the Heads of Medicinal Agencies (HMA). ● Updating Exclusion Criterion 1 to facilitate enrollment such that patients exposed to prior TNF inhibitors were allowed to enroll so long as the prior TNF inhibitor excludes prior adalimumab and also if the reason for discontinuation of the prior TNF inhibitor was not related to a lack of efficacy or safety. ● Clarifying chest x-ray (CXR) language to allow the Principal Investigator (PI) or physician delegate to complete the assessment of CXR. ● Removing 24-hour methylhistamine laboratory test and urine drug screen as they were no longer required. ● Updating injection site reaction language to allow sites to further assess and investigate injection site reactions as deemed by the PI. ● Adding Complaint and Product Complaint definition as well as the reporting requirements for Product Complaints to implement a standard process for the collection of Product Quality Complaints in clinical trials. ● Adding Electronic Patient Reported Outcomes (ePRO) language to include information on the use of the ePRO device as a source for collecting data.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported