Clinical trial results:
A Phase 3, Multicenter, Randomized, Double-blind Study Evaluating the Efficacy and Safety of ABP 501 Compared with Adalimumab in Subjects with Moderate to Severe Plaque Psoriasis

Summary

EudraCT number	2013-000537-12
Trial protocol	HU DE PL FR
Global end of trial date	18 March 2015

Results information

Result version number	v1 (current)
This version publication date	01 April 2016
First version publication date	01 April 2016

Trial information

Trial identification

Sponsor protocol code	20120263

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01970488
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Amgen, Inc.
Sponsor organisation address	One Amgen Center Drive, Thousand Oaks, CA, United States, 91320
Public contact	IHQ Medical Info-Clinical Trials, Amgen (Europe) GmbH, Medinfointernational@amgen.com
Scientific contact	IHQ Medical Info-Clinical Trials, Amgen (EUROPE) GmbH, Medinfointernational@amgen.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	18 March 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	18 March 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective for this study was to evaluate the efficacy of ABP 501 in subjects with moderate to severe plaque psoriasis, as measured by the percent improvement from baseline in the Psoriasis Area and Severity Index (PASI), compared with adalimumab.

Protection of trial subjects:

This study was conducted in accordance with the Note for Guidance on GCP, the general guidelines indicated in the Declaration of Helsinki and all applicable regulatory requirements.
Before initiating the study, the investigator/institution obtained written and dated approval/favorable opinion from the IRB/IEC for the study protocol, amendments, and the informed consent form (ICF).
The investigator explained the benefits and risks of study participation to each subject or the subject's legal representative. Written informed consent was obtained before the subject entered the study and before initiation of any study-related procedure.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 October 2013
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	Poland: 100
Country: Number of subjects enrolled	France: 6
Country: Number of subjects enrolled	Germany: 80
Country: Number of subjects enrolled	Hungary: 41
Country: Number of subjects enrolled	Canada: 89
Country: Number of subjects enrolled	Australia: 34
Worldwide total number of subjects	350
EEA total number of subjects	227

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)	327
From 65 to 84 years	23
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

After a 4-week screening period, subjects were randomized (1:1) to ABP 501 or adalimumab. Randomization was stratified based on prior biologic use for psoriasis and geographic region. At week 16, participants with a PASI50 response (50% or greater improvement from baseline in PASI score) were re-randomized to receive either ABP 501 or adalimumab.

Period 1

Period 1 title	Part 1: Through Week 16
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Part 1: ABP 501

Arm description:

Participants received ABP 501 80 mg subcutaneously on Week 1/Day 1 (initial loading dose) and 40 mg at Week 2 and every 2 weeks thereafter until Week 16.

Arm type	Experimental
Investigational medicinal product name	ABP 501
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Initial loading dose of 80 mg administered by subcutaneous injection on Week 1/Day 1 and 40 mg at Week 2 and every 2 weeks thereafter.

Arm title	Part 1: Adalimumab

Arm description:

Participants received adalimumab 80 mg subcutaneously on Week 1/Day 1 (initial loading dose) and 40 mg at Week 2 and every 2 weeks thereafter until Week 16.

Arm type	Active comparator
Investigational medicinal product name	Adalimumab
Investigational medicinal product code	
Other name	Humira
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Initial loading dose of 80 mg administered by subcutaneous injection on Week 1/Day 1 and 40 mg at Week 2 and every 2 weeks thereafter.

Number of subjects in period 1	Part 1: ABP 501	Part 1: Adalimumab
Started	175	175
Received Treatment	174	173
Completed	164	162
Not completed	11	13
Consent withdrawn by subject	3	2
Adverse event, non-fatal	6	5
Protocol violations	1	2
Lost to follow-up	-	2
Protocol-specified criteria	1	2

Period 2

Period 2 title	Part 2: Post Week 16
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Blinding implementation details:

Subjects who continued treatment beyond week 16 were re-randomized in a blinded fashion such that all subjects initially randomized to ABP 501 continued treatment with ABP 501 and subjects initially randomized to adalimumab were re-randomized (1:1) in a blinded fashion to continue treatment with adalimumab or transition to ABP 501.

Arms

Are arms mutually exclusive?	Yes
Arm title	Part 2: ABP 501/ABP 501

Arm description:

Participants who received ABP 501 in Part 1 with a PASI50 response at Week 16 continued to receive ABP 501, 40 mg every 2 weeks until Week 48.

Arm type	Experimental
Investigational medicinal product name	ABP 501
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

40 mg administered by subcutaneous injection every 2 weeks.

Arm title	Part 2: Adalimumab/Adalimumab

Arm description:

Participants who received adalimumab in Part 1 with a PASI50 response at Week 16 continued to receive adalimumab, 40 mg every 2 weeks until Week 48.

Arm type	Active comparator

Investigational medicinal product name	Adalimumab
Investigational medicinal product code	
Other name	Humira
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

40 mg administered by subcutaneous injection every 2 weeks.

Arm title	Part 2: Adalimumab/ABP 501

Arm description:

Participants who received adalimumab in Part 1 with a PASI50 response at Week 16 were transitioned to receive ABP 501, 40 mg every 2 weeks until Week 48.

Arm type	Experimental
Investigational medicinal product name	ABP 501
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

40 mg administered by subcutaneous injection every 2 weeks.

Number of subjects in period 2[1]	Part 2: ABP 501/ABP 501	Part 2: Adalimumab/Adalimumab	Part 2: Adalimumab/ABP 501
Started	152	79	77
Completed	135	71	69
Not completed	17	8	8
Consent withdrawn by subject	8	3	3
Physician decision	-	-	1
Adverse event, non-fatal	5	1	1
Non-compliance	1	-	-
Lost to follow-up	1	1	2
Lack of efficacy	2	3	1

Notes:

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

Justification: Only participants with a PASI50 response continued into Part 2 of the study.

Baseline characteristics

Reporting groups	
Reporting group title	Part 1: ABP 501
Reporting group description:	
Participants received ABP 501 80 mg subcutaneously on Week 1/Day 1 (initial loading dose) and 40 mg at Week 2 and every 2 weeks thereafter until Week 16.	
Reporting group title	Part 1: Adalimumab
Reporting group description:	
Participants received adalimumab 80 mg subcutaneously on Week 1/Day 1 (initial loading dose) and 40 mg at Week 2 and every 2 weeks thereafter until Week 16.	

Reporting group values	Part 1: ABP 501	Part 1: Adalimumab	Total
Number of subjects	175	175	350
Age categorical Units: Subjects			
< 65 years	164	163	327
≥ 65 years	11	12	23
Age continuous Units: years			
arithmetic mean	45.1	44	
standard deviation	± 12.95	± 13.68	-
Gender categorical Units: Subjects			
Female	63	59	122
Male	112	116	228
Race Units: Subjects			
White	167	157	324
Black or African American	0	2	2
Asian	5	8	13
Native Hawaiian or Other Pacific Islander	0	1	1
Mixed Race	0	1	1
Other	1	3	4
Unknown	2	3	5
Prior Biological Use for Psoriasis Units: Subjects			
Yes	33	30	63
No	142	145	287
Region Units: Subjects			
Eastern Europe	71	70	141
Western Europe	43	43	86
Other	61	62	123
Static Physician's Global Assessment (sPGA)			
The sPGA is a 6-point scale ranging from 0 (clear) to 5 (very severe) used to measure the severity of disease (induration, scaling, and erythema).			
Units: Subjects			

Clear	0	0	0
Almost Clear	0	0	0
Mild	0	0	0
Mderate	106	102	208
Severe	61	61	122
Very Severe	7	10	17
Missing	1	2	3
Psoriasis Area and Severity Index (PASI) Score			
The PASI measures the average redness (erythema), thickness (induration), and scaliness (each graded on a 0 to 4 scale) of psoriasis lesions, weighted by the area of involvement. The total PASI score ranges from 0 to 72. The higher the total score, the more severe the disease. Data are reported for 174 and 173 participants in each reporting group respectively.			
Units: units on a scale			
arithmetic mean	19.68	20.48	
standard deviation	± 8.1	± 7.88	-
Body Surface Area (BSA) Affected by Psoriasis			
Data are reported for 174 and 173 participants in each treatment group respectively.			
Units: percentage of BSA			
arithmetic mean	25.3	28.5	
standard deviation	± 15.02	± 16.82	-

End points

End points reporting groups

Reporting group title	Part 1: ABP 501
Reporting group description:	
Participants received ABP 501 80 mg subcutaneously on Week 1/Day 1 (initial loading dose) and 40 mg at Week 2 and every 2 weeks thereafter until Week 16.	
Reporting group title	Part 1: Adalimumab
Reporting group description:	
Participants received adalimumab 80 mg subcutaneously on Week 1/Day 1 (initial loading dose) and 40 mg at Week 2 and every 2 weeks thereafter until Week 16.	
Reporting group title	Part 2: ABP 501/ABP 501
Reporting group description:	
Participants who received ABP 501 in Part 1 with a PASI50 response at Week 16 continued to receive ABP 501, 40 mg every 2 weeks until Week 48.	
Reporting group title	Part 2: Adalimumab/Adalimumab
Reporting group description:	
Participants who received adalimumab in Part 1 with a PASI50 response at Week 16 continued to receive adalimumab, 40 mg every 2 weeks until Week 48.	
Reporting group title	Part 2: Adalimumab/ABP 501
Reporting group description:	
Participants who received adalimumab in Part 1 with a PASI50 response at Week 16 were transitioned to receive ABP 501, 40 mg every 2 weeks until Week 48.	

Primary: Percent Improvement from Baseline in Psoriasis Area and Severity Index (PASI) at Week 16

End point title	Percent Improvement from Baseline in Psoriasis Area and Severity Index (PASI) at Week 16
End point description:	
The PASI measures the average redness (erythema), thickness (induration), and scaliness (each graded on a 0 to 4 scale) of psoriasis lesions, weighted by the area of involvement in the four main body areas (i.e., head and neck, trunk, upper extremities, and lower extremities). PASI scores can range from 0.0 to 72.0, with higher scores indicating greater severity and/or more extensive psoriasis. Percent improvement from baseline is calculated as (value at baseline – value at post-baseline visit) X 100 / (value at baseline). This analysis was performed using the full analysis set which includes all participants initially randomized in the study. Last observation carried forward (LOCF) imputation was used.	
End point type	Primary
End point timeframe:	
Baseline and Week 16	

End point values	Part 1: ABP 501	Part 1: Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	172[1]	173[2]		
Units: percent change				
arithmetic mean (standard deviation)	80.91 (± 24.237)	83.06 (± 25.195)		

Notes:

[1] - Full analysis set with at least 1 post-baseline value

[2] - Full analysis set with at least 1 post-baseline value

Statistical analyses

Statistical analysis title	Treatment Difference
Comparison groups	Part 1: ABP 501 v Part 1: Adalimumab
Number of subjects included in analysis	345
Analysis specification	Pre-specified
Analysis type	equivalence[3]
Parameter estimate	Least-squares (LS) mean difference
Point estimate	-2.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.39
upper limit	3.02

Notes:

[3] - Clinical equivalence was evaluated by comparing the 2-sided 95% confidence interval (CI) of the difference of PASI percent improvement from baseline to Week 16 between ABP 501 and adalimumab with an equivalence margin of ± 15.

Secondary: Percentage of Participants With a PASI 75 Response at Week 16

End point title	Percentage of Participants With a PASI 75 Response at Week 16

End point description:

A PASI 75 response is a 75% or greater improvement (reduction) from baseline in PASI score.
The PASI measures the average redness (erythema), thickness (induration), and scaliness (each graded on a 0 to 4 scale) of psoriasis lesions, weighted by the area of involvement in the four main body areas (i.e., head and neck, trunk, upper extremities, and lower extremities). PASI scores can range from 0.0 to 72.0, with higher scores indicating greater severity and/or more extensive psoriasis.
This analysis was performed in the full analysis set using LOCF.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Part 1: ABP 501	Part 1: Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	172[4]	173[5]		
Units: percentage of participants				
number (not applicable)	74.4	82.7		

Notes:

[4] - Full analysis set with at least 1 post-baseline value

[5] - Full analysis set with at least 1 post-baseline value

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a PASI 75 Response at Week 32

End point title	Percentage of Participants With a PASI 75 Response at Week 32

End point description:

A PASI 75 response is a 75% or greater improvement (reduction) from baseline in PASI score.
The PASI measures the average redness (erythema), thickness (induration), and scaliness (each graded on a 0 to 4 scale) of psoriasis lesions, weighted by the area of involvement in the four main body areas (i.e., head and neck, trunk, upper extremities, and lower extremities). PASI scores can range from 0.0 to 72.0, with higher scores indicating greater severity and/or more extensive psoriasis.
This analysis was performed in the re-randomized analysis set which includes all participants who were re-randomized at Week 16 in the study.

End point type	Secondary

End point timeframe:

Baseline and Week 32

End point values	Part 2: ABP 501/ABP 501	Part 2: Adalimumab/Adalimumab	Part 2: Adalimumab/ABP 501	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	143[6]	72[7]	71[8]	
Units: percentage of participants				
number (not applicable)	82.5	84.7	84.5	

Notes:

[6] - Re-randomized analysis set with available data

[7] - Re-randomized analysis set with available data

[8] - Re-randomized analysis set with available data

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a PASI 75 Response at Week 50

End point title	Percentage of Participants With a PASI 75 Response at Week 50

End point description:

A PASI 75 response is a 75% or greater improvement (reduction) from baseline in PASI score.
The PASI measures the average redness (erythema), thickness (induration), and scaliness (each graded on a 0 to 4 scale) of psoriasis lesions, weighted by the area of involvement in the four main body areas (i.e., head and neck, trunk, upper extremities, and lower extremities). PASI scores can range from 0.0 to 72.0, with higher scores indicating greater severity and/or more extensive psoriasis.
This analysis was performed in the re-randomized analysis set.

End point type	Secondary

End point timeframe:

Baseline and Week 50

End point values	Part 2: ABP 501/ABP 501	Part 2: Adalimumab/Adalimumab	Part 2: Adalimumab/ABP 501	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	134[9]	70[10]	69[11]	
Units: percentage of participants				
number (not applicable)	85.1	87.1	81.2	

Notes:

[9] - Re-randomized analysis set with available data

[10] - Re-randomized analysis set with available data

[11] - Re-randomized analysis set with available data

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Improvement From Baseline in PASI at Week 32

End point title	Percent Improvement From Baseline in PASI at Week 32

End point description:

The PASI measures the average redness (erythema), thickness (induration), and scaliness (each graded on a 0 to 4 scale) of psoriasis lesions, weighted by the area of involvement in the four main body areas (i.e., head and neck, trunk, upper extremities, and lower extremities). PASI scores can range from 0.0 to 72.0, with higher scores indicating greater severity and/or more extensive psoriasis.
Percent improvement from baseline is calculated as (value at baseline – value at post-baseline visit) X 100 / (value at baseline).
This analysis was performed in the re-randomized analysis set.

End point type	Secondary

End point timeframe:

Baseline and Week 32

End point values	Part 2: ABP 501/ABP 501	Part 2: Adalimumab/Adalimumab	Part 2: Adalimumab/ABP 501	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	143[12]	72[13]	71[14]	
Units: percent change				
arithmetic mean (standard deviation)	87.62 (± 18.387)	88.16 (± 18.181)	86.98 (± 16.637)	

Notes:

[12] - Re-randomized analysis set with available data

[13] - Re-randomized analysis set with available data

[14] - Re-randomized analysis set with available data

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Improvement From Baseline in PASI at Week 50

End point title	Percent Improvement From Baseline in PASI at Week 50

End point description:

The PASI measures the average redness (erythema), thickness (induration), and scaliness (each graded on a 0 to 4 scale) of psoriasis lesions, weighted by the area of involvement in the four main body areas (i.e., head and neck, trunk, upper extremities, and lower extremities). PASI scores can range from 0.0

to 72.0, with higher scores indicating greater severity and/or more extensive psoriasis.
Percent improvement from baseline is calculated as (value at baseline – value at post-baseline visit) X 100 / (value at baseline).
This analysis was performed in the re-randomized analysis set.

End point type	Secondary

End point timeframe:

Baseline and Week 50

End point values	Part 2: ABP 501/ABP 501	Part 2: Adalimumab/Adalimumab	Part 2: Adalimumab/ABP 501	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	134[15]	70[16]	69[17]	
Units: percent change				
arithmetic mean (standard deviation)	87.16 (± 19.559)	88.11 (± 20.957)	85.82 (± 21.864)	

Notes:

[15] - Re-randomized analysis set with available data

[16] - Re-randomized analysis set with available data

[17] - Re-randomized analysis set with available data

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with a Static Physician’s Global Assessment (sPGA) Response at Week 16

End point title	Percentage of Participants with a Static Physician’s Global Assessment (sPGA) Response at Week 16

End point description:

The sPGA is a 6-point scale ranging from 0 (clear) to 5 (very severe) used to measure the severity of disease (induration, scaling, and erythema). A sPGA response is defined as a sPGA value of clear (score 0) or almost clear (score 1).
This analysis was performed using the full analysis set; LOCF imputation was used.

End point type	Secondary

End point timeframe:

Week 16

End point values	Part 1: ABP 501	Part 1: Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	172[18]	173[19]		
Units: percentage of participants				
number (not applicable)	58.7	65.3		

Notes:

[18] - Full analysis set with at least 1 post-baseline value

[19] - Full analysis set with at least 1 post-baseline value

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with a sPGA Response at Week 32

End point title	Percentage of Participants with a sPGA Response at Week 32

End point description:

The sPGA is a 6-point scale ranging from 0 (clear) to 5 (very severe) used to measure the severity of disease (induration, scaling, and erythema). A sPGA response is defined as a sPGA value of clear (score 0) or almost clear (score 1).
This analysis was performed in the re-randomized analysis set.

End point type	Secondary

End point timeframe:

Week 32

End point values	Part 2: ABP 501/ABP 501	Part 2: Adalimumab/Adalimumab	Part 2: Adalimumab/ABP 501	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	143[20]	72[21]	71[22]	
Units: percentage of participants				
number (not applicable)	66.4	72.2	70.4	

Notes:

[20] - Re-randomized analysis set with available data

[21] - Re-randomized analysis set with available data

[22] - Re-randomized analysis set with available data

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with a sPGA Response at Week 50

End point title	Percentage of Participants with a sPGA Response at Week 50

End point description:

The sPGA is a 6-point scale ranging from 0 (clear) to 5 (very severe) used to measure the severity of disease (induration, scaling, and erythema). A sPGA response is defined as a sPGA value of clear (score 0) or almost clear (score 1).
This analysis was performed in the re-randomized analysis set.

End point type	Secondary

End point timeframe:

Week 50

End point values	Part 2: ABP 501/ABP 501	Part 2: Adalimumab/Adalimumab	Part 2: Adalimumab/ABP 501	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	134[23]	70[24]	69[25]	
Units: percentage of participants				
number (not applicable)	68.7	74.3	69.6	

Notes:

[23] - Re-randomized analysis set with available data

[24] - Re-randomized analysis set with available data

[25] - Re-randomized analysis set with available data

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Percentage of Body Surface Area (BSA) Involved With Psoriasis at Week 16

End point title	Change From Baseline in the Percentage of Body Surface Area (BSA) Involved With Psoriasis at Week 16

End point description:

A measurement of psoriasis involvement, given as the physician's assessment of the percentage of the participant's total body surface area (BSA) involved with psoriasis. The percent of BSA affected was estimated by assuming that the subject's palm, excluding the fingers and thumb, represented roughly 1% of the body's surface. A decrease from Baseline (negative value) indicates improvement.
This analysis was performed in the full analysis set; LOCF imputation was used.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Part 1: ABP 501	Part 1: Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	172[26]	173[27]		
Units: Percentage of BSA				
arithmetic mean (standard deviation)	-18 (± 13.57)	-22.1 (± 17.11)		

Notes:

[26] - Full analysis set with at least 1 post-baseline value

[27] - Full analysis set with at least 1 post-baseline value

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Percentage of BSA Involved With Psoriasis at Week 32

End point title	Change From Baseline in the Percentage of BSA Involved With Psoriasis at Week 32

End point description:

A measurement of psoriasis involvement, given as the physician's assessment of the percentage of the participant's total body surface area (BSA) involved with psoriasis. The percent of BSA affected was estimated by assuming that the subject's palm, excluding the fingers and thumb, represented roughly 1% of the body's surface. A decrease from Baseline (negative value) indicates improvement.
This analysis was performed in the re-randomized analysis set for participants with available data.

End point type	Secondary

End point timeframe:

Baseline and Week 32

End point values	Part 2: ABP 501/ABP 501	Part 2: Adalimumab/Adalimumab	Part 2: Adalimumab/ABP 501	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	143[28]	72[29]	71[30]	
Units: percentage of BSA				
arithmetic mean (standard deviation)	-20.6 (± 13.87)	-25.3 (± 15.94)	-23.8 (± 16.17)	

Notes:

[28] - Re-randomized analysis set with available data

[29] - Re-randomized analysis set with available data

[30] - Re-randomized analysis set with available data

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Percentage of BSA Involved With Psoriasis at Week 50

End point title	Change From Baseline in the Percentage of BSA Involved With Psoriasis at Week 50

End point description:

A measurement of psoriasis involvement, given as the physician's assessment of the percentage of the participant's total body surface area (BSA) involved with psoriasis. The percent of BSA affected was estimated by assuming that the subject's palm, excluding the fingers and thumb, represented roughly 1% of the body's surface. A decrease from Baseline (negative value) indicates improvement.
This analysis was performed in the re-randomized analysis set for participants with available data.

End point type	Secondary

End point timeframe:

Baseline and Week 50

End point values	Part 2: ABP 501/ABP 501	Part 2: Adalimumab/Adalimumab	Part 2: Adalimumab/ABP 501	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	134[31]	70[32]	69[33]	
Units: percentage of BSA				
arithmetic mean (standard deviation)	-20.7 (± 13.58)	-25.5 (± 16.14)	-25.1 (± 17.43)	

Notes:

[31] - Re-randomized anlaysis set with available data

[32] - Re-randomized anlaysis set with available data

[33] - Re-randomized anlaysis set with available data

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Adverse Events

End point title	Number of Participants with Adverse Events

End point description:

The Investigator assessed whether each adverse event (AE) was possibly related to the investigational product (TRAE).
AEs were graded for severity according to the Common Toxicity Criteria for Adverse Events (CTCAE) version 4.03.
A serious AE is defined as an AE that meets at least 1 of the following serious criteria:
- fatal
- life threatening (places the subject at immediate risk of death)
- requires inpatient hospitalization or prolongation of existing hospitalization
- results in persistent or significant disability/incapacity
- congenital anomaly/birth defect
- other medically important serious event.

Results are reported from Day 1 to Week 16 for the ABP 501 and Adalimumab groups, and from post Week 16 to the end of study (Week 52) for the ABP 501/ABP 501, Adalimumab/Adalimumab and Adalimumab/ABP 501 groups.
The safety analysis set includes all randomized participants who received at least 1 dose of study drug, based on actual treatment received.

End point type	Secondary

End point timeframe:

From first dose of study drug until 28 days after the last dose. Treatment was for 16 weeks in Part 1 and 32 weeks in Part 2.

End point values	Part 1: ABP 501	Part 1: Adalimumab	Part 2: ABP 501/ABP 501	Part 2: Adalimumab/Adalimumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	174[34]	173[35]	152[36]	79[37]
Units: participants				
Any adverse event	117	110	108	52
Grade ≥ 3 adverse event	8	5	7	2
Treatment-related adverse event	43	43	28	18
Grade ≥ 3 treatment-related adverse event	4	2	3	1
Serious adverse event	6	5	4	4
Treatment-related serious adverse event	4	0	2	1
AE leading to discontinuation of study drug	7	5	7	1
TRAE leading to discontinuation of study drug	4	3	3	1
AE leading to discontinuation from study	7	5	4	1
TRAE leading to discontinuation from study	4	3	2	1

Notes:

[34] - Safety analysis set

[35] - Safety analysis set

[36] - Safety analysis set

[37] - Safety analysis set

End point values	Part 2: Adalimumab/ABP 501			
Subject group type	Reporting group			
Number of subjects analysed	77[38]			
Units: participants				

Any adverse event	54			
Grade ≥ 3 adverse event	3			
Treatment-related adverse event	20			
Grade ≥ 3 treatment-related adverse event	1			
Serious adverse event	4			
Treatment-related serious adverse event	1			
AE leading to discontinuation of study drug	3			
TRAE leading to discontinuation of study drug	2			
AE leading to discontinuation from study	2			
TRAE leading to discontinuation from study	1			

Notes:

[38] - Safety analysis set

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Developing Antibodies to ABP 501 or Adalimumab

End point title	Percentage of Participants Developing Antibodies to ABP 501 or Adalimumab

End point description:

Two validated assays were used to detect the presence of anti-drug antibodies. Samples were first tested in an electrochemiluminescence (ECL)-based bridging immunoassay to detect anti-drug antibodies (ADA) against ABP 501 and adalimumab (Binding Antibody Assay). Samples confirmed to be positive for binding antibodies were subsequently tested in a non-cell based bioassay to determine neutralizing activity against ABP 501 or adalimumab (Neutralizing Antibody Assay).
Developing antibody incidence is defined as a negative or no antibody result at baseline and a positive antibody result at a post-baseline time point.
Results are reported for the anti-drug antibody analysis set (defined as the subset of participants in the Safety Analysis Set who had at least 1 evaluable antibody test) from Baseline to Week 16 for all randomized participants, and from baseline to Week 52 for participants who were re-randomized.

End point type	Secondary

End point timeframe:

For 16 weeks in Part 1 and for 52 weeks for participants who were re-randomized in Part 2.

End point values	Part 1: ABP 501	Part 1: Adalimumab	Part 2: ABP 501/ABP 501	Part 2: Adalimumab/Adalimumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	174[39]	173[40]	152[41]	79[42]
Units: percentage of participants				
number (not applicable)				
Binding Antibody Positive	55.2	63.6	68.4	74.7
Neutralizing Antibody Positive	9.8	13.9	13.8	20.3

Notes:

[39] - Anti-drug antibody analysis set

[40] - Anti-drug antibody analysis set

[41] - Anti-drug antibody analysis set; re-randomized participants

[42] - Anti-drug antibody analysis set; re-randomized participants

End point values	Part 2: Adalimumab/ABP 501			
Subject group type	Reporting group			
Number of subjects analysed	77[43]			
Units: percentage of participants				
number (not applicable)				
Binding Antibody Positive	72.7			
Neutralizing Antibody Positive	24.7			

Notes:

[43] - Anti-drug antibody analysis set; re-randomized participants

Statistical analyses

No statistical analyses for this end point

Post-hoc: Percentage of Participants With a PASI 90 Response at Week 16

End point title	Percentage of Participants With a PASI 90 Response at Week 16

End point description:

A PASI 90 response is a 90% or greater improvement (reduction) from baseline in PASI score.
The PASI measures the average redness (erythema), thickness (induration), and scaliness (each graded on a 0 to 4 scale) of psoriasis lesions, weighted by the area of involvement in the four main body areas (i.e., head and neck, trunk, upper extremities, and lower extremities). PASI scores can range from 0.0 to 72.0, with higher scores indicating greater severity and/or more extensive psoriasis.
This analysis was performed in the full analysis set using LOCF imputation.

End point type	Post-hoc

End point timeframe:

Baseline and Week 16

End point values	Part 1: ABP 501	Part 1: Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	172[44]	173[45]		
Units: percentage of participants				
number (not applicable)	47.1	47.4		

Notes:

[44] - Full analysis set with at least 1 post-baseline value

[45] - Full analysis set with at least 1 post-baseline value

Statistical analyses

No statistical analyses for this end point

Post-hoc: Percentage of Participants With a PASI 90 Response at Week 32

End point title	Percentage of Participants With a PASI 90 Response at Week 32

End point description:

A PASI 90 response is a 90% or greater improvement (reduction) from baseline in PASI score.
The PASI measures the average redness (erythema), thickness (induration), and scaliness (each graded on a 0 to 4 scale) of psoriasis lesions, weighted by the area of involvement in the four main body areas (i.e., head and neck, trunk, upper extremities, and lower extremities). PASI scores can range from 0.0 to 72.0, with higher scores indicating greater severity and/or more extensive psoriasis.
This analysis was performed in the re-randomized analysis set.

End point type	Post-hoc

End point timeframe:

Baseline and Week 32

End point values	Part 2: ABP 501/ABP 501	Part 2: Adalimumab/Adalimumab	Part 2: Adalimumab/ABP 501	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	143[46]	72[47]	71[48]	
Units: percentage of participants				
number (not applicable)	62.2	65.3	57.7	

Notes:

[46] - Re-randomized analysis set with available data

[47] - Re-randomized analysis set with available data

[48] - Re-randomized analysis set with available data

Statistical analyses

No statistical analyses for this end point

Post-hoc: Percentage of Participants With a PASI 90 Response at Week 50

End point title	Percentage of Participants With a PASI 90 Response at Week 50

End point description:

A PASI 90 response is a 90% or greater improvement (reduction) from baseline in PASI score.
The PASI measures the average redness (erythema), thickness (induration), and scaliness (each graded on a 0 to 4 scale) of psoriasis lesions, weighted by the area of involvement in the four main body areas (i.e., head and neck, trunk, upper extremities, and lower extremities). PASI scores can range from 0.0 to 72.0, with higher scores indicating greater severity and/or more extensive psoriasis.
This analysis was performed in the re-randomized analysis set.

End point type	Post-hoc

End point timeframe:

Baseline and Week 50

End point values	Part 2: ABP 501/ABP 501	Part 2: Adalimumab/Adalimumab	Part 2: Adalimumab/ABP 501	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	134[49]	70[50]	69[51]	
Units: percentage of participants				
number (not applicable)	59	64.3	66.7	

Notes:

[49] - Re-randomized analysis set with available data

[50] - Re-randomized analysis set with available data

[51] - Re-randomized analysis set with available data

Statistical analyses

No statistical analyses for this end point

Post-hoc: Percentage of Participants With a PASI 100 Response at Week 16

End point title	Percentage of Participants With a PASI 100 Response at Week 16

End point description:

A PASI 100 response is a 100% improvement (reduction) from baseline in PASI score.
The PASI measures the average redness (erythema), thickness (induration), and scaliness (each graded on a 0 to 4 scale) of psoriasis lesions, weighted by the area of involvement in the four main body areas (i.e., head and neck, trunk, upper extremities, and lower extremities). PASI scores can range from 0.0 to 72.0, with higher scores indicating greater severity and/or more extensive psoriasis.
This analysis was performed in the full analysis set using LOCF imputation.

End point type	Post-hoc

End point timeframe:

Baseline and Week 16

End point values	Part 1: ABP 501	Part 1: Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	172[52]	173[53]		
Units: percentage of participants				
number (not applicable)	16.9	19.7		

Notes:

[52] - Full analysis set with at least 1 post-baseline value

[53] - Full analysis set with at least 1 post-baseline value

Statistical analyses

No statistical analyses for this end point

Post-hoc: Percentage of Participants With a PASI 100 Response at Week 32

End point title	Percentage of Participants With a PASI 100 Response at Week 32

End point description:

A PASI 100 response is a 100% improvement (reduction) from baseline in PASI score.
The PASI measures the average redness (erythema), thickness (induration), and scaliness (each graded on a 0 to 4 scale) of psoriasis lesions, weighted by the area of involvement in the four main body areas (i.e., head and neck, trunk, upper extremities, and lower extremities). PASI scores can range from 0.0 to 72.0, with higher scores indicating greater severity and/or more extensive psoriasis.
This analysis was performed in the re-randomized analysis set.

End point type	Post-hoc

End point timeframe:

Baseline and Week 32

End point values	Part 2: ABP 501/ABP 501	Part 2: Adalimumab/Adalimumab	Part 2: Adalimumab/ABP 501	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	143[54]	72[55]	71[56]	
Units: percentage of participants				
number (not applicable)	32.9	33.3	25.4	

Notes:

[54] - Re-randomized analysis set with available data

[55] - Re-randomized analysis set with available data

[56] - Re-randomized analysis set with available data

Statistical analyses

No statistical analyses for this end point

Post-hoc: Percentage of Participants With a PASI 100 Response at Week 50

End point title	Percentage of Participants With a PASI 100 Response at Week 50

End point description:

A PASI 100 response is a 100% improvement (reduction) from baseline in PASI score.
The PASI measures the average redness (erythema), thickness (induration), and scaliness (each graded on a 0 to 4 scale) of psoriasis lesions, weighted by the area of involvement in the four main body areas (i.e., head and neck, trunk, upper extremities, and lower extremities). PASI scores can range from 0.0 to 72.0, with higher scores indicating greater severity and/or more extensive psoriasis.
This analysis was performed in the re-randomized analysis set.

End point type	Post-hoc

End point timeframe:

Baseline and Week 50

End point values	Part 2: ABP 501/ABP 501	Part 2: Adalimumab/Adalimumab	Part 2: Adalimumab/ABP 501	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	134[57]	70[58]	69[59]	
Units: percentage of participants				
number (not applicable)	32.8	35.7	34.8	

Notes:

[57] - Re-randomized analysis set with available data

[58] - Re-randomized analysis set with available data

[59] - Re-randomized analysis set with available data

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first dose of study drug until 28 days after the last dose. Treatment was for 16 weeks in Part 1 and 32 weeks in Part 2.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.1

Reporting groups

Reporting group title	Part 1: ABP 501

Reporting group description:

In Part 1 (Weeks 1-16) participants received ABP 501 80 mg subcutaneously on Week 1/Day 1 (initial loading dose) and 40 mg at Week 2 and every 2 weeks thereafter until Week 16.

Reporting group title	Part 1: Adalimumab

Reporting group description:

In Part 1 (Weeks 1-16) participants received adalimumab 80 mg subcutaneously on Week 1/Day 1 (initial loading dose) and 40 mg at Week 2 and every 2 weeks thereafter until Week 16.

Reporting group title	Part 2: ABP 501/ABP 501

Reporting group description:

In Part 2 participants who received ABP 501 in Part 1 with a PASI50 response at Week 16 continued to receive ABP 501, 40 mg every 2 weeks until Week 48.

Reporting group title	Part 2: Adalimumab/Adalimumab

Reporting group description:

In Part 2 participants who received adalimumab in Part 1 with a PASI50 response at Week 16 continued to receive adalimumab, 40 mg every 2 weeks until Week 48.

Reporting group title	Part 2: Adalimumab/ABP 501

Reporting group description:

In Part 2 participants who received adalimumab in Part 1 with a PASI50 response at Week 16 were transitioned to receive ABP 501, 40 mg every 2 weeks until Week 48.

Serious adverse events	Part 1: ABP 501	Part 1: Adalimumab	Part 2: ABP 501/ABP 501
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 174 (3.45%)	5 / 173 (2.89%)	4 / 152 (2.63%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lentigo maligna			
subjects affected / exposed	1 / 174 (0.57%)	0 / 173 (0.00%)	0 / 152 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			

subjects affected / exposed	1 / 174 (0.57%)	0 / 173 (0.00%)	0 / 152 (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
Arrhythmia			
subjects affected / exposed	1 / 174 (0.57%)	0 / 173 (0.00%)	0 / 152 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 174 (0.00%)	0 / 173 (0.00%)	1 / 152 (0.66%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral ischaemia			
subjects affected / exposed	0 / 174 (0.00%)	0 / 173 (0.00%)	1 / 152 (0.66%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 174 (0.00%)	0 / 173 (0.00%)	0 / 152 (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
Migraine			
subjects affected / exposed	0 / 174 (0.00%)	0 / 173 (0.00%)	0 / 152 (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
Syncope			
subjects affected / exposed	0 / 174 (0.00%)	1 / 173 (0.58%)	0 / 152 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 174 (0.00%)	0 / 173 (0.00%)	0 / 152 (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
Immune system disorders			

Hypersensitivity			
subjects affected / exposed	1 / 174 (0.57%)	0 / 173 (0.00%)	0 / 152 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Metrorrhagia			
subjects affected / exposed	0 / 174 (0.00%)	1 / 173 (0.58%)	0 / 152 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
subjects affected / exposed	0 / 174 (0.00%)	0 / 173 (0.00%)	0 / 152 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Drug-induced liver injury			
subjects affected / exposed	0 / 174 (0.00%)	0 / 173 (0.00%)	1 / 152 (0.66%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 174 (0.57%)	0 / 173 (0.00%)	0 / 152 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 174 (0.00%)	0 / 173 (0.00%)	0 / 152 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 174 (0.00%)	0 / 173 (0.00%)	0 / 152 (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
Osteoarthritis			

subjects affected / exposed	0 / 174 (0.00%)	1 / 173 (0.58%)	0 / 152 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Patellofemoral pain syndrome			
subjects affected / exposed	0 / 174 (0.00%)	1 / 173 (0.58%)	0 / 152 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 174 (0.00%)	0 / 173 (0.00%)	1 / 152 (0.66%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	1 / 174 (0.57%)	0 / 173 (0.00%)	0 / 152 (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
Bronchitis			
subjects affected / exposed	0 / 174 (0.00%)	1 / 173 (0.58%)	0 / 152 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 173 (0.00%)	1 / 152 (0.66%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 174 (0.00%)	0 / 173 (0.00%)	0 / 152 (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
Postoperative abscess			
subjects affected / exposed	1 / 174 (0.57%)	0 / 173 (0.00%)	0 / 152 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	0 / 174 (0.00%)	0 / 173 (0.00%)	0 / 152 (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
Metabolism and nutrition disorders			
Dyslipidaemia			
subjects affected / exposed	0 / 174 (0.00%)	0 / 173 (0.00%)	1 / 152 (0.66%)
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	Part 2: Adalimumab/Adalimumab	Part 2: Adalimumab/ABP 501	
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 79 (5.06%)	4 / 77 (5.19%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lentigo maligna			
subjects affected / exposed	0 / 79 (0.00%)	0 / 77 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 79 (0.00%)	0 / 77 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			
subjects affected / exposed	0 / 79 (0.00%)	0 / 77 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	0 / 79 (0.00%)	0 / 77 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebral ischaemia			

subjects affected / exposed	0 / 79 (0.00%)	0 / 77 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	1 / 79 (1.27%)	0 / 77 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Migraine			
subjects affected / exposed	1 / 79 (1.27%)	0 / 77 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	0 / 79 (0.00%)	0 / 77 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	0 / 79 (0.00%)	1 / 77 (1.30%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 79 (0.00%)	0 / 77 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Metrorrhagia			
subjects affected / exposed	0 / 79 (0.00%)	0 / 77 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cyst			
subjects affected / exposed	0 / 79 (0.00%)	1 / 77 (1.30%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Hepatobiliary disorders			
Drug-induced liver injury			
subjects affected / exposed	0 / 79 (0.00%)	0 / 77 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 79 (0.00%)	0 / 77 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 79 (1.27%)	0 / 77 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	1 / 79 (1.27%)	0 / 77 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 77 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patellofemoral pain syndrome			
subjects affected / exposed	0 / 79 (0.00%)	0 / 77 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff syndrome			
subjects affected / exposed	0 / 79 (0.00%)	0 / 77 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			

Appendicitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 77 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 77 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 77 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 79 (0.00%)	1 / 77 (1.30%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative abscess			
subjects affected / exposed	0 / 79 (0.00%)	0 / 77 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 79 (0.00%)	1 / 77 (1.30%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dyslipidaemia			
subjects affected / exposed	0 / 79 (0.00%)	0 / 77 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Part 1: ABP 501	Part 1: Adalimumab	Part 2: ABP 501/ABP 501
Total subjects affected by non-serious adverse events			
subjects affected / exposed	50 / 174 (28.74%)	60 / 173 (34.68%)	48 / 152 (31.58%)
Nervous system disorders			
Headache			
subjects affected / exposed	12 / 174 (6.90%)	18 / 173 (10.40%)	5 / 152 (3.29%)
occurrences (all)	13	22	9
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	2 / 174 (1.15%)	3 / 173 (1.73%)	3 / 152 (1.97%)
occurrences (all)	2	3	3
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	2 / 174 (1.15%)	2 / 173 (1.16%)	10 / 152 (6.58%)
occurrences (all)	2	2	12
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	5 / 174 (2.87%)	7 / 173 (4.05%)	4 / 152 (2.63%)
occurrences (all)	5	10	5
Back pain			
subjects affected / exposed	7 / 174 (4.02%)	1 / 173 (0.58%)	5 / 152 (3.29%)
occurrences (all)	7	1	6
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	25 / 174 (14.37%)	27 / 173 (15.61%)	25 / 152 (16.45%)
occurrences (all)	30	29	30
Upper respiratory tract infection			
subjects affected / exposed	9 / 174 (5.17%)	9 / 173 (5.20%)	9 / 152 (5.92%)
occurrences (all)	9	10	10

Non-serious adverse events	Part 2: Adalimumab/Adalimumab	Part 2: Adalimumab/ABP 501	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	31 / 79 (39.24%)	34 / 77 (44.16%)	
Nervous system disorders			
Headache			
subjects affected / exposed	8 / 79 (10.13%)	2 / 77 (2.60%)	
occurrences (all)	10	11	

Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	 4 / 79 (5.06%) 4	 8 / 77 (10.39%) 8	
Skin and subcutaneous tissue disorders Psoriasis subjects affected / exposed occurrences (all)	 5 / 79 (6.33%) 6	 4 / 77 (5.19%) 4	
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) Back pain subjects affected / exposed occurrences (all)	 5 / 79 (6.33%) 5 5 / 79 (6.33%) 5	 2 / 77 (2.60%) 2 1 / 77 (1.30%) 1	
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all) Upper respiratory tract infection subjects affected / exposed occurrences (all)	 14 / 79 (17.72%) 18 6 / 79 (7.59%) 6	 18 / 77 (23.38%) 22 7 / 77 (9.09%) 11	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
03 December 2013	The following are the substantive changes covered by this amendment: - deleted PASI percent change as a secondary efficacy parameter - narrowed the equivalence margin used to assess clinical equivalence of PASI percent improvement to ± 15 - added additional efficacy assessments at the week 32 visit - clarified specific entry criteria - no evidence of active tuberculosis on chest radiograph was allowed within 3 months before screening - the presence or absence of active substance abuse was based on the investigator's opinion - contraception was required until 5 months after the last dose of study medication (not the end of study) - clarified that change in vital signs from baseline was a safety assessment rather than clinically significant changes in vital signs - specified that the primary analysis would be based on randomized treatment assignment - reduced the allowable window for day 8 treatment to days 8 to 11 after the first dose of investigational product and specified that no fewer than 7 days must elapse between any 2 doses of study medication - modified the prohibited concomitant medications to allow, if needed, live attenuated vaccines after the week 16 visit provided there was a treatment interruption of at least 28 days before and after vaccination - defined the determination of BSA as based on measurement of the subject's palm, excluding fingers and thumb - specified that the primary analysis would occur after all subjects completed week 20 - deleted the planned interim analysis - clarified that concomitant were to be reported from 4 weeks before screening

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported