Clinical trial results:
An Open-label, Single-arm Extension Study to Evaluate the Long-term Safety and Efficacy of ABP 501 in Subjects with Moderate to Severe Rheumatoid Arthritis

Summary

EudraCT number	2013-004654-13
Trial protocol	CZ HU GB ES DE BG PL RO
Global end of trial date	11 April 2016

Results information

Result version number	v1 (current)
This version publication date	01 April 2017
First version publication date	01 April 2017

Trial information

Trial identification

Sponsor protocol code	20130258

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02114931
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Amgen Inc.
Sponsor organisation address	One Agen 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	11 April 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	11 April 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective was to evaluate the long-term safety and efficacy of ABP 501 in subjects with moderate to severe rheumatoid arthritis (RA).

Protection of trial subjects:

This study was conducted in accordance with International Council for Harmonisation (ICH) Good Clinical Practice (GCP) regulations/guidelines, the general guidelines indicated in the Declaration of Helsinki, and all applicable regulatory requirements.
All subjects provided written informed consent before undergoing any study-related procedures, including screening procedures.
The study protocol, amendments, and the informed consent form (ICF) were reviewed by the Institutional Review Boards (IRBs) and Independent Ethics Committees (IECs). No subjects were recruited into the study and no investigational product (IP) was shipped until the IRB/IEC gave written approval of the protocol and ICF and Amgen received copies of these approvals.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	23 April 2014
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	Poland: 181
Country: Number of subjects enrolled	Czech Republic: 55
Country: Number of subjects enrolled	Hungary: 52
Country: Number of subjects enrolled	Bulgaria: 17
Country: Number of subjects enrolled	Romania: 3
Country: Number of subjects enrolled	Russian Federation: 1
Country: Number of subjects enrolled	United States: 121
Country: Number of subjects enrolled	Canada: 6
Country: Number of subjects enrolled	Germany: 19
Country: Number of subjects enrolled	Spain: 11
Country: Number of subjects enrolled	United Kingdom: 1
Worldwide total number of subjects	467
EEA total number of subjects	339

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)	364
From 65 to 84 years	103
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This study was conducted at 83 centers in 11 countries in Eastern Europe, North America and Western Europe.

Pre-assignment

Screening details:

Study 20130258 was a single-arm, open-label extension of the parent Study 20120262 (2013-000525-31). Results are reported according to treatment in the parent Study 20120262.

Period 1

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

Blinding implementation details:

This was an open-label study.

Arms

Are arms mutually exclusive?	Yes
Arm title	ABP 501/ABP 501

Arm description:

Participants who received ABP 501 in the parent study continued to receive ABP 501 40 mg subcutaneously (SC) every other week for an additional 18 months (total of 24-months treatment).

Arm type	Experimental
Investigational medicinal product name	ABP-501
Investigational medicinal product code	ABP 501
Other name	AMJEVITA™, Adalimumab-atto
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Solution for SC injection in a syringe containing 40 mg/0.8 mL ABP 501.

Arm title	Adalimumab/ABP 501

Arm description:

Participants who received adalimumab in the parent study transitioned to receive ABP 501 40 mg subcutaneously every other week for 18 months.

Arm type	Experimental
Investigational medicinal product name	ABP-501
Investigational medicinal product code	ABP 501
Other name	AMJEVITA™, Adalimumab-atto
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Solution for SC injection in a syringe containing 40 mg/0.8 mL ABP 501.

Number of subjects in period 1	ABP 501/ABP 501	Adalimumab/ABP 501
Started	230	237
Received Treatment	229	237
Completed	205	207
Not completed	25	30
Consent withdrawn by subject	15	18
Physician decision	1	2
Adverse event, non-fatal	4	6
Other	2	1
Lost to follow-up	3	3

Baseline characteristics

Reporting groups	
Reporting group title	ABP 501/ABP 501
Reporting group description:	
Participants who received ABP 501 in the parent study continued to receive ABP 501 40 mg subcutaneously (SC) every other week for an additional 18 months (total of 24-months treatment).	
Reporting group title	Adalimumab/ABP 501
Reporting group description:	
Participants who received adalimumab in the parent study transitioned to receive ABP 501 40 mg subcutaneously every other week for 18 months.	

Reporting group values	ABP 501/ABP 501	Adalimumab/ABP 501	Total
Number of subjects	230	237	467
Age Categorical			
Age at baseline of parent study			
Units: Subjects			
Between 18 and 65 years	183	181	364
≥ 65 years	47	56	103
Age Continuous			
Age at baseline of parent study			
Units: years			
arithmetic mean	54.7	56.1	
standard deviation	± 11.71	± 11.4	-
Gender, Male/Female			
Units: Subjects			
Female	188	191	379
Male	42	46	88
Race/Ethnicity, Customized			
Units: Subjects			
White	218	224	442
Black or African American	8	12	20
Asian	3	0	3
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Mixed Race	0	0	0
Other	1	1	2
Race/Ethnicity, Customized			
Units: Subjects			
Hispanic or Latino	27	19	46
Not Hispanic or Latino	202	217	419
Not Allowed to Collect	1	1	2
Geographic Region			
Units: Subjects			
Eastern Europe	153	156	309
Western Europe	12	19	31
North America	65	62	127
Latin America	0	0	0

End points

End points reporting groups

Reporting group title	ABP 501/ABP 501
Reporting group description:	
Participants who received ABP 501 in the parent study continued to receive ABP 501 40 mg subcutaneously (SC) every other week for an additional 18 months (total of 24-months treatment).	
Reporting group title	Adalimumab/ABP 501
Reporting group description:	
Participants who received adalimumab in the parent study transitioned to receive ABP 501 40 mg subcutaneously every other week for 18 months.	

Primary: Number of Participants with Adverse Events

End point title	Number of Participants with Adverse Events[1]

End point description:

Adverse events (AEs) were graded for severity according to the Common Terminology Criteria for Adverse Events (CTCAE) version 4.03 according to the following scale: 1 = mild; 2 = moderate; 3 = severe; 4 = life-threatening; 5 = fatal.
A treatment-related AE is defined as an event where the answer to the question "is there a reasonable possibility that the event may have been caused by the Investigational Medicinal Product" was yes. A serious adverse event 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.

End point type	Primary

End point timeframe:

From the first dose of study drug in the extension study to 28 days following the last dose; 72 weeks

Notes:

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

End point values	ABP 501/ABP 501	Adalimumab/ABP 501		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	229	237		
Units: participants				
Any adverse event (AE)	143	154		
Any grade ≥ 3 adverse event	26	16		
Any treatment-related adverse event (TRAE)	37	43		
Any grade ≥ 3 treatment-related adverse event	3	4		
Any adverse event with outcome of death	0	0		
Any TRAE with an outcome of death	0	0		
Any serious adverse event (SAE)	25	21		
Any treatment-related serious adverse event	2	1		
Any AE leading to discontinuation of ABP 501	7	10		

Any TRAE leading to discontinuation of ABP 501	4	5		
Any AE leading to discontinuation from study	3	5		
Any TRAE leading to discontinuation from study	1	3		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Grade ≥ 3 Hematology and Chemistry Laboratory Results

End point title	Number of Participants with Grade ≥ 3 Hematology and Chemistry Laboratory Results[2]

End point description:

Laboratory results were graded according to the Common Terminology Criteria for Adverse Events (CTCAE) version 4.03 according to the following scale: 1 = mild; 2 = moderate; 3 = severe; 4 = life-threatening; 5 = fatal.

End point type	Primary

End point timeframe:

From the first dose of study drug in the extension study to 28 days following the last dose; 72 weeks

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No inferential analyses were performed.

End point values	ABP 501/ABP 501	Adalimumab/ABP 501		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	229	237		
Units: participants				
Hemoglobin (anemia)	1	0		
Alanine aminotransferase (ALT)	1	0		
Aspartate aminotransferase (AST)	1	0		
Bilirubin	1	0		
Gamma glutamyl transferase	7	3		
Potassium (hyperkalemia)	1	1		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants Who Developed Antibodies to ABP 501

End point title	Percentage of Participants Who Developed Antibodies to ABP 501[3]

End point description:

Two validated assays were used to detect the presence of anti-drug antibodies. All samples were first tested in an electrochemiluminescence (ECL)-based bridging immunoassay to detect anti-drug antibodies against ABP 501 (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. If a sample was positive for binding antibodies and demonstrated neutralizing activity at the same time point, the sample was defined as positive for neutralizing antibodies. Preexisting antibody positive indicates participants with a positive result at baseline of the extension study. Developing antibody positive indicates participants with a negative or no result at baseline of the extension study who were positive at any time point post-baseline during the extension study.

End point type	Primary

End point timeframe:

Up to week 72

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No inferential analyses were performed.

End point values	ABP 501/ABP 501	Adalimumab/ABP 501		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	229	237		
Units: percentage of participants				
number (not applicable)				
Preexisting Binding Antibody Positive	32.3	34.2		
Preexisting Neutralizing Antibody Positive	5.7	8.9		
Developing Binding Antibody Positive	21.8	14.8		
Developing Neutralizing Antibody Positive	8.7	5.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With an American College of Rheumatology (ACR) 20 Response

End point title	Percentage of Participants With an American College of Rheumatology (ACR) 20 Response

End point description:

A participant was a responder if the following 3 criteria for improvement from Baseline of the parent study were met:
- ≥ 20% improvement in tender joint count;
- ≥ 20% improvement in swollen joint count; and
- ≥ 20% improvement in at least 3 of the 5 following parameters:
  - Patient's assessment of pain (measured on a 100 mm visual analog scale [VAS]);
  - Patient's global assessment of disease activity (measured on a likert scale from 0 to 10);
  - Physician's global assessment of disease activity (measured on a likert scale from 0 to 10);
  - Patient's self-assessment of physical function (Health Assessment Questionnaire - Disability Index [HAQ-DI]);
  - C-Reactive Protein level.

End point type	Secondary

End point timeframe:

Parent study baseline, extension study baseline and weeks 4, 24, 48, and 70

End point values	ABP 501/ABP 501	Adalimumab/ABP 501		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	230	237		
Units: percentage of participants				
number (not applicable)				
Extension study baseline (n = 228, 236)	73.2	73.3		
Week 4 (n = 228, 237)	77.6	77.6		
Week 24 (n = 223, 230)	74	74.3		
Week 48 (n = 216, 218)	76.9	78.4		
Week 70 (n = 206, 209)	79.6	78		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Parent Study Baseline in Disease Activity Score 28-C-reactive Protein (DAS28-CRP)

End point title	Change From Parent Study Baseline in Disease Activity Score 28-C-reactive Protein (DAS28-CRP)

End point description:

The DAS28-CRP is a composite score to measure disease activity in patients with rheumatoid arthritis, derived from the following variables:
- The number of swollen and tender joints assessed using the 28-joint count;
- C-reactive protein (CRP) level;
- Patient's global assessment of disease activity assessed on a score from 0 to 100 transformed from the result measured on a horizontal scale from 0 (no RA activity at all) to 10 (worst RA activity imaginable).

The DAS28-CRP score ranges from approximately zero to ten. Higher DAS28-CRP scores indicate higher disease activity.

End point type	Secondary

End point timeframe:

Parent study baseline, extension study baseline and weeks 4, 24, 48 and 70

End point values	ABP 501/ABP 501	Adalimumab/ABP 501		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	230	237		
Units: units on a scale				
arithmetic mean (standard deviation)				
Extension Study Baseline (n = 219, 221)	-2.26 (± 1.255)	-2.25 (± 1.289)		
Week 4 (n = 228, 235)	-2.4 (± 1.322)	-2.32 (± 1.257)		
Week 24 (n = 223, 227)	-2.49 (± 1.272)	-2.33 (± 1.316)		
Week 48 (n = 216, 217)	-2.59 (± 1.433)	-2.51 (± 1.414)		
Week 70 (n = 205, 207)	-2.7 (± 1.389)	-2.51 (± 1.445)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
From the first dose of study drug in the extension study to 28 days following the last dose; 72 weeks	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	17.1

Reporting groups	
Reporting group title	ABP 501/ABP 501
Reporting group description:	
Participants who received ABP 501 in the parent study continued to receive ABP 501 40 mg subcutaneously (SC) every other week for an additional 18 months (total of 24-months treatment).	
Reporting group title	Adalimumab/ABP 501
Reporting group description:	
Participants who received adalimumab in the parent study transitioned to receive ABP 501 40 mg subcutaneously every other week for 18 months.	

Serious adverse events	ABP 501/ABP 501	Adalimumab/ABP 501	
Total subjects affected by serious adverse events			
subjects affected / exposed	25 / 229 (10.92%)	21 / 237 (8.86%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder cancer			
subjects affected / exposed	0 / 229 (0.00%)	1 / 237 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer			
subjects affected / exposed	1 / 229 (0.44%)	0 / 237 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diffuse large B-cell lymphoma			
subjects affected / exposed	1 / 229 (0.44%)	0 / 237 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial adenocarcinoma			

subjects affected / exposed	1 / 229 (0.44%)	0 / 237 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Accelerated hypertension			
subjects affected / exposed	0 / 229 (0.00%)	1 / 237 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive crisis			
subjects affected / exposed	0 / 229 (0.00%)	1 / 237 (0.42%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Raynaud's phenomenon			
subjects affected / exposed	0 / 229 (0.00%)	1 / 237 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Bunion operation			
subjects affected / exposed	0 / 229 (0.00%)	1 / 237 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prosthesis implantation			
subjects affected / exposed	1 / 229 (0.44%)	0 / 237 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	1 / 229 (0.44%)	0 / 237 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Device failure			

subjects affected / exposed	0 / 229 (0.00%)	1 / 237 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Uterine cervical erosion			
subjects affected / exposed	1 / 229 (0.44%)	0 / 237 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polyp			
subjects affected / exposed	1 / 229 (0.44%)	0 / 237 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine prolapse			
subjects affected / exposed	1 / 229 (0.44%)	0 / 237 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 229 (0.44%)	0 / 237 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	1 / 229 (0.44%)	0 / 237 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 229 (0.00%)	1 / 237 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Foot fracture			

subjects affected / exposed	1 / 229 (0.44%)	0 / 237 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pubis fracture			
subjects affected / exposed	0 / 229 (0.00%)	1 / 237 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulna fracture			
subjects affected / exposed	0 / 229 (0.00%)	1 / 237 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Aortic valve stenosis			
subjects affected / exposed	1 / 229 (0.44%)	0 / 237 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis coronary artery			
subjects affected / exposed	1 / 229 (0.44%)	0 / 237 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	1 / 229 (0.44%)	0 / 237 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	2 / 229 (0.87%)	0 / 237 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial ischaemia			
subjects affected / exposed	1 / 229 (0.44%)	0 / 237 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			

Carotid artery stenosis			
subjects affected / exposed	0 / 229 (0.00%)	1 / 237 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	1 / 229 (0.44%)	0 / 237 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Cataract			
subjects affected / exposed	1 / 229 (0.44%)	2 / 237 (0.84%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular degeneration			
subjects affected / exposed	0 / 229 (0.00%)	1 / 237 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal tear			
subjects affected / exposed	0 / 229 (0.00%)	1 / 237 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Duodenal ulcer haemorrhage			
subjects affected / exposed	1 / 229 (0.44%)	0 / 237 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer			
subjects affected / exposed	0 / 229 (0.00%)	1 / 237 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 229 (0.00%)	1 / 237 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Haematochezia			
subjects affected / exposed	0 / 229 (0.00%)	1 / 237 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	1 / 229 (0.44%)	0 / 237 (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			
Arthralgia			
subjects affected / exposed	0 / 229 (0.00%)	1 / 237 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc degeneration			
subjects affected / exposed	0 / 229 (0.00%)	1 / 237 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint swelling			
subjects affected / exposed	0 / 229 (0.00%)	1 / 237 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neck pain			
subjects affected / exposed	1 / 229 (0.44%)	0 / 237 (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	2 / 229 (0.87%)	3 / 237 (1.27%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoporotic fracture			
subjects affected / exposed	0 / 229 (0.00%)	1 / 237 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Rheumatoid arthritis			
subjects affected / exposed	2 / 229 (0.87%)	0 / 237 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal column stenosis			
subjects affected / exposed	0 / 229 (0.00%)	1 / 237 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal osteoarthritis			
subjects affected / exposed	0 / 229 (0.00%)	1 / 237 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 229 (0.00%)	1 / 237 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	1 / 229 (0.44%)	0 / 237 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis			
subjects affected / exposed	1 / 229 (0.44%)	0 / 237 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	0 / 229 (0.00%)	1 / 237 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngitis			
subjects affected / exposed	1 / 229 (0.44%)	0 / 237 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salpingitis			

subjects affected / exposed	1 / 229 (0.44%)	0 / 237 (0.00%)	
occurrences causally related to treatment / all	0 / 1	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	ABP 501/ABP 501	Adalimumab/ABP 501	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	72 / 229 (31.44%)	71 / 237 (29.96%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	16 / 229 (6.99%)	6 / 237 (2.53%)	
occurrences (all)	16	6	
Musculoskeletal and connective tissue disorders			
Rheumatoid arthritis			
subjects affected / exposed	11 / 229 (4.80%)	17 / 237 (7.17%)	
occurrences (all)	15	21	
Infections and infestations			
Bronchitis			
subjects affected / exposed	16 / 229 (6.99%)	13 / 237 (5.49%)	
occurrences (all)	16	14	
Nasopharyngitis			
subjects affected / exposed	18 / 229 (7.86%)	25 / 237 (10.55%)	
occurrences (all)	26	34	
Pharyngitis			
subjects affected / exposed	12 / 229 (5.24%)	7 / 237 (2.95%)	
occurrences (all)	14	10	
Upper respiratory tract infection			
subjects affected / exposed	18 / 229 (7.86%)	22 / 237 (9.28%)	
occurrences (all)	21	29	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported