Clinical trial results:
MULTICENTER, OPEN-LABEL (PART A) FOLLOWED BY A RANDOMIZED, DOUBLE-BLIND, PARALLEL-GROUP, PLACEBO-CONTROLLED STUDY (PART B) TO EVALUATE MAINTENANCE OF REMISSION IN SUBJECTS WITH ACTIVE AXIAL SPONDYLOARTHRITIS (AXSPA) RECEIVING EITHER CERTOLIZUMAB PEGOL 200MG Q2W OR 200MG Q4W AS COMPARED TO PLACEBO

Summary

EudraCT number	2015-000339-34
Trial protocol	HU BE CZ DE GB ES NL FR RO PL BG
Global end of trial date	23 April 2019

Results information

Result version number	v1 (current)
This version publication date	08 May 2020
First version publication date	08 May 2020

Trial information

Trial identification

Sponsor protocol code	AS0005

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02505542
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	UCB BIOSCIENCES GmbH
Sponsor organisation address	Alfred-Nobel-Strasse 10, Monheim, Germany, 40789
Public contact	Clin Trial Reg & Results Disclosure, UCB BIOSCIENCES GmbH, clinicaltrials@ucb.com
Scientific contact	Clin Trial Reg & Results Disclosure, UCB BIOSCIENCES GmbH, clinicaltrials@ucb.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	09 May 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	23 April 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the percentage of subjects who do not experience a flare on CZP 200 mg Q2W (full dose) or 200 mg Q4W (half-dose) as compared to placebo (CZP withdrawal) during Part B

Protection of trial subjects:

During the conduct of the study all study participants were closely monitored.

Background therapy:

Background therapy as permitted and stated in the protocol.

Evidence for comparator:

Not Applicable

Actual start date of recruitment	31 July 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	Belgium: 25
Country: Number of subjects enrolled	Bulgaria: 59
Country: Number of subjects enrolled	Czech Republic: 214
Country: Number of subjects enrolled	France: 9
Country: Number of subjects enrolled	Germany: 40
Country: Number of subjects enrolled	Hungary: 46
Country: Number of subjects enrolled	Netherlands: 6
Country: Number of subjects enrolled	Poland: 184
Country: Number of subjects enrolled	Romania: 34
Country: Number of subjects enrolled	Spain: 5
Country: Number of subjects enrolled	Taiwan: 34
Country: Number of subjects enrolled	Turkey: 41
Country: Number of subjects enrolled	United Kingdom: 6
Country: Number of subjects enrolled	United States: 33
Worldwide total number of subjects	736
EEA total number of subjects	628

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)	736
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study started to enroll patients in July 2015 and concluded in April 2019.

Pre-assignment

Screening details:

The study included 2 parts: Part A with a Screening Period (up to 5 Weeks) and an Open-Label Period (Week 0 to Week 48) and Part B with a Double-Blind Period (Week 48 to Week 96) and a Safety Follow-Up Period (10 weeks after the last dose of study medication).
Participant Flow refers to the Open-Label Set.

Period 1

Period 1 title	Part A: Open-Label Period
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Certolizumab pegol Open-Label

Arm description:

Participants in this arm received certolizumab pegol (CZP) 400 mg subcutaneous (sc) on Weeks 0, 2 and 4, followed by 200 mg CZP sc every 2 weeks (Q2W) from Week 6 to Week 48 (Part A). Participants in sustained remission at Week 48 were eligible for randomization into Part B.

Arm type	Experimental
Investigational medicinal product name	Certolizumab pegol
Investigational medicinal product code	CZP
Other name	Cimzia
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Certolizumab pegol (CZP) 400 mg or 200 mg were administered as subcutaneous (sc) injections every 2 weeks (Q2W) (full-dose) or every 4 weeks (Q4W) (half-dose).
Suitable areas for administrations were the lateral abdominal wall and upper outer thigh. Study medication should have been administered with a minimum of 10 days between the CZP 200 mg Q2W administrations.

Number of subjects in period 1	Certolizumab pegol Open-Label
Started	736
Completed	659
Not completed	77
Participant did not attend week 48 visit	1
Consent withdrawn by subject	27
New medical history available	1
Adverse event, non-fatal	31
Screening failure (detected too late)	1
Sponsor directive	1

Pregnancy	2
Non-compliance	1
Medical monitor decision	1
Lost to follow-up	5
Lack of efficacy	5
Protocol deviation	1

Period 2

Period 2 title	Completed Part A, did not enter Part B
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Certolizumab pegol Open-Label

Arm description:

Participants in this arm received certolizumab pegol (CZP) 400 mg subcutaneous (sc) on Weeks 0, 2 and 4, followed by 200 mg CZP sc every 2 weeks (Q2W) from Week 6 to Week 48 (Part A). Participants in sustained remission at Week 48 were eligible for randomization into Part B.

Arm type	Experimental
Investigational medicinal product name	Certolizumab pegol
Investigational medicinal product code	CZP
Other name	Cimzia
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Certolizumab pegol (CZP) 400 mg or 200 mg were administered as subcutaneous (sc) injections every 2 weeks (Q2W) (full-dose) or every 4 weeks (Q4W) (half-dose).
Suitable areas for administrations were the lateral abdominal wall and upper outer thigh. Study medication should have been administered with a minimum of 10 days between the CZP 200 mg Q2W administrations.

Number of subjects in period 2	Certolizumab pegol Open-Label
Started	659
Completed	313
Not completed	346
Consent withdrawn by subject	3
The subject was not eligible for Part B	341
Lack of efficacy	2

Period 3

Period 3 title	Part B: Double-Blind Period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Carer, Assessor, Subject

Blinding implementation details:

Subjects who flared were given escape treatment until the end of the study.

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo Double-Blind

Arm description:

Participants in this arm received Placebo subcutaneous (sc) every 2 weeks from Week 48 onwards.

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

Dosage and administration details:

Matching Placebo was administered as subcutaneous (sc) injections every 2 weeks (Q2W) or to maintain the study blind.

Arm title	Certolizumab pegol 200 mg Q2W Double-Blind

Arm description:

Participants in this arm received certolizumab pegol (CZP) 200 mg subcutaneous (sc) every 2 weeks (Q2W) from Week 48 onwards.

Arm type	Experimental
Investigational medicinal product name	Certolizumab pegol
Investigational medicinal product code	CZP
Other name	Cimzia
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Certolizumab pegol (CZP) 400 mg or 200 mg were administered as subcutaneous (sc) injections every 2 weeks (Q2W) (full-dose) or every 4 weeks (Q4W) (half-dose).
Suitable areas for administrations were the lateral abdominal wall and upper outer thigh. Study medication should have been administered with a minimum of 10 days between the CZP 200 mg Q2W administrations.

Arm title	Certolizumab pegol 200 mg Q4W Double-Blind

Arm description:

Participants in this arm received certolizumab pegol (CZP) 200 mg subcutaneous (sc) every 4 weeks (Q4W) from Week 48 onwards. At visits where CZP was not received, subjects received one injection of Placebo to maintain the study blind.

Arm type	Experimental

Investigational medicinal product name	Certolizumab pegol
Investigational medicinal product code	CZP
Other name	Cimzia
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Certolizumab pegol (CZP) 400 mg or 200 mg were administered as subcutaneous (sc) injections every 2 weeks (Q2W) (full-dose) or every 4 weeks (Q4W) (half-dose).
Suitable areas for administrations were the lateral abdominal wall and upper outer thigh. Study medication should have been administered with a minimum of 10 days between the CZP 200 mg Q2W administrations.

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

Dosage and administration details:

Matching Placebo was administered as subcutaneous (sc) injections every 2 weeks (Q2W) or to maintain the study blind.

Number of subjects in period 3	Placebo Double-Blind	Certolizumab pegol 200 mg Q2W Double-Blind	Certolizumab pegol 200 mg Q4W Double-Blind
Started	104	104	105
Started Escape Period	73 [1]	7 [2]	15 [3]
Completed	92	95	98
Not completed	12	9	7
Consent withdrawn by subject	8	7	2
Miscalculation	1	-	-
Adverse event, non-fatal	-	1	3
Patient was moved from the country	-	-	1
Subject did not complete all visits	1	-	-
Lost to follow-up	-	-	1
Week 94 missed	-	1	-
Planning pregnancy	1	-	-
Lack of efficacy	1	-	-

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Number of participants at the milestones reflects those who experienced a flare during the Double-Blind Period and escaped to full-dose treatment until the end of that period or for at least 12 weeks, whichever is longer.
[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Number of participants at the milestones reflects those who experienced a flare during the Double-Blind Period and escaped to full-dose treatment until the end of that period or for at least 12 weeks, whichever is longer.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Number of participants at the milestones reflects those who experienced a flare during the Double-Blind Period and escaped to full-dose treatment until the end of that period or for at least 12 weeks, whichever is longer.

Baseline characteristics

Reporting groups	
Reporting group title	Certolizumab pegol Open-Label
Reporting group description:	
Participants in this arm received certolizumab pegol (CZP) 400 mg subcutaneous (sc) on Weeks 0, 2 and 4, followed by 200 mg CZP sc every 2 weeks (Q2W) from Week 6 to Week 48 (Part A). Participants in sustained remission at Week 48 were eligible for randomization into Part B.	

Reporting group values	Certolizumab pegol Open-Label	Total	
Number of subjects	736	736	
Age categorical Units: Subjects			
<=18 years	7	7	
Between 18 and 65 years	729	729	
>=65 years	0	0	
Age continuous Units: years			
arithmetic mean	32.9		
standard deviation	± 7.0	-	
Gender categorical Units: Subjects			
Male	514	514	
Female	222	222	

End points

End points reporting groups

Reporting group title	Certolizumab pegol Open-Label
Reporting group description:	
Participants in this arm received certolizumab pegol (CZP) 400 mg subcutaneous (sc) on Weeks 0, 2 and 4, followed by 200 mg CZP sc every 2 weeks (Q2W) from Week 6 to Week 48 (Part A). Participants in sustained remission at Week 48 were eligible for randomization into Part B.	
Reporting group title	Certolizumab pegol Open-Label
Reporting group description:	
Participants in this arm received certolizumab pegol (CZP) 400 mg subcutaneous (sc) on Weeks 0, 2 and 4, followed by 200 mg CZP sc every 2 weeks (Q2W) from Week 6 to Week 48 (Part A). Participants in sustained remission at Week 48 were eligible for randomization into Part B.	
Reporting group title	Placebo Double-Blind
Reporting group description:	
Participants in this arm received Placebo subcutaneous (sc) every 2 weeks from Week 48 onwards.	
Reporting group title	Certolizumab pegol 200 mg Q2W Double-Blind
Reporting group description:	
Participants in this arm received certolizumab pegol (CZP) 200 mg subcutaneous (sc) every 2 weeks (Q2W) from Week 48 onwards.	
Reporting group title	Certolizumab pegol 200 mg Q4W Double-Blind
Reporting group description:	
Participants in this arm received certolizumab pegol (CZP) 200 mg subcutaneous (sc) every 4 weeks (Q4W) from Week 48 onwards. At visits where CZP was not received, subjects received one injection of Placebo to maintain the study blind.	
Subject analysis set title	Placebo Double-Blind (RS)
Subject analysis set type	Full analysis
Subject analysis set description:	
Participants in this arm received Placebo subcutaneous (sc) every 2 weeks from Week 48 onwards. Participants formed the Randomized Set (RS).	
Subject analysis set title	Certolizumab pegol 200 mg Q2W Double-Blind (RS)
Subject analysis set type	Full analysis
Subject analysis set description:	
Participants in this arm received certolizumab pegol (CZP) 200 mg subcutaneous (sc) every 2 weeks (Q2W) from Week 48 onwards. Participants formed the RS.	
Subject analysis set title	Certolizumab pegol 200 mg Q4W Double-Blind (RS)
Subject analysis set type	Full analysis
Subject analysis set description:	
Participants in this arm received certolizumab pegol (CZP) 200 mg subcutaneous (sc) every 4 weeks (Q4W) from Week 48 onwards. At visits where CZP was not received, subjects received one injection of Placebo to maintain the study blind. Participants formed the RS.	
Subject analysis set title	Certolizumab pegol Open-Label (OLS)
Subject analysis set type	Full analysis
Subject analysis set description:	
Participants in this arm received certolizumab pegol (CZP) 400 mg subcutaneous (sc) on Weeks 0, 2 and 4, followed by 200 mg CZP sc every 2 weeks (Q2W) from Week 6 to Week 48 (Part A). Participants in sustained remission at Week 48 were eligible for randomization into Part B. Participants formed the Open-Label Set (OLS).	
Subject analysis set title	Placebo DB/CZP 200 mg Q2W Escape (FS)
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants randomized to Placebo who met flare criteria received CZP 400 mg subcutaneous (sc) every 2 weeks (Q2W) for the first 3 visits after flare has been confirmed. After that, CZP 200 mg was given every 2 weeks in open-label fashion. The duration was from starting escape treatment after flare until	

Week 96 with a minimum of 12 weeks.
Participants formed the Flared Set (FS).

Subject analysis set title	CZP 200 mg Q2W DB/CZP 200 mg Q2W Escape (FS)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants randomized to CZP 200 mg Q2W who meet flare criteria received CZP 200 mg subcutaneous (sc) every 2 weeks (Q2W) for all visits after flare has been confirmed. At the first 3 visits after flare has been confirmed, participants received one injection of 200 mg CZP and one injection of Placebo to maintain the study blind. The duration was from starting escape treatment after flare until Week 96 with a minimum of 12 weeks.
Participants formed the FS.

Subject analysis set title	CZP 200 mg Q4W DB/CZP 200 mg Q2W Escape (FS)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants randomized to CZP 200 mg Q4W who meet flare criteria received CZP 200 mg subcutaneous (sc) every 2 weeks (Q2W) for all visits after flare has been confirmed. At the first 3 visits after flare has been confirmed, participants received one injection of 200 mg CZP and one injection of Placebo to maintain the study blind. The duration was from starting escape treatment after flare until Week 96 with a minimum of 12 weeks.
Participants formed the FS.

Subject analysis set title	Certolizumab pegol Open-Label (SS) Wk 0-48
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants in this arm received certolizumab pegol (CZP) 400 mg subcutaneous (sc) on Weeks 0, 2 and 4, followed by 200 mg CZP sc every 2 weeks (Q2W) from Week 6 to Week 48 (Part A). Participants in sustained remission at Week 48 were eligible for randomization into Part B.
Participants formed the Safety Set (SS).

Subject analysis set title	Placebo Double-Blind (SSB) Wk 48–96
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants in this arm received Placebo subcutaneous (sc) every 2 weeks from Week 48 onwards.
Participants formed the Safety Set Part B (SSB).

Subject analysis set title	Certolizumab pegol 200 mg Q2W Double-Blind (SSB) Wk 48–96
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants in this arm received certolizumab pegol (CZP) 200 mg subcutaneous (sc) every 2 weeks (Q2W) from Week 48 onwards.
Participants formed the SSB.

Subject analysis set title	Certolizumab pegol 200 mg Q4W Double-Blind (SSB) Wk 48–96
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants in this arm received certolizumab pegol (CZP) 200 mg subcutaneous (sc) every 4 weeks (Q4W) from Week 48 onwards. At visits where CZP was not received, subjects received one injection of Placebo to maintain the study blind.
Participants formed the SSB.

Subject analysis set title	Placebo DB/CZP 200 mg Q2W Escape (ETS) Escape Wk 0–>=12
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants randomized to Placebo who met flare criteria received CZP 400 mg subcutaneous (sc) every 2 weeks (Q2W) for the first 3 visits after flare has been confirmed. After that, CZP 200 mg was given every 2 weeks in open-label fashion. The duration was from starting escape treatment after flare until Week 96 with a minimum of 12 weeks.
Participants formed the Escape Therapy Set (ETS).

Subject analysis set title	CZP 200 mg Q2W DB/CZP 200 mg Q2W Escape (ETS) Escape Wk 0–>=12
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants randomized to CZP 200 mg Q2W who meet flare criteria received CZP 200 mg subcutaneous (sc) every 2 weeks (Q2W) for all visits after flare has been confirmed. At the first 3 visits after flare has been confirmed, participants received one injection of 200 mg CZP and one injection of Placebo to maintain the study blind. The duration was from starting escape treatment after flare until Week 96 with a minimum of 12 weeks.
Participants formed the ETS.

Subject analysis set title	CZP 200 mg Q4W DB/CZP 200 mg Q2W Escape (ETS) Escape Wk 0–>=12
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants randomized to CZP 200 mg Q4W who meet flare criteria received CZP 200 mg subcutaneous (sc) every 2 weeks (Q2W) for all visits after flare has been confirmed. At the first 3 visits after flare has been confirmed, participants received one injection of 200 mg CZP and one injection of Placebo to maintain the study blind. The duration was from starting escape treatment after flare until Week 96 with a minimum of 12 weeks.
Participants formed the ETS.

Subject analysis set title	Placebo Double-Blind (PKSB)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in this arm received Placebo subcutaneous (sc) every 2 weeks from Week 48 onwards.
Participants formed the Pharmacokinetic Set B (PKSB).

Subject analysis set title	Certolizumab pegol 200 mg Q2W Double-Blind (PKSB)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in this arm received certolizumab pegol (CZP) 200 mg subcutaneous (sc) every 2 weeks (Q2W) from Week 48 onwards.
Participants formed the PKSB.

Subject analysis set title	Certolizumab pegol 200 mg Q4W Double-Blind (PKSB)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in this arm received certolizumab pegol (CZP) 200 mg subcutaneous (sc) every 4 weeks (Q4W) from Week 48 onwards. At visits where CZP was not received, subjects received one injection of Placebo to maintain the study blind.
Participants formed the PKSB.

Primary: Percentage of participants in Part B who did not experienced a flare

End point title	Percentage of participants in Part B who did not experienced a flare

End point description:

A participant was considered to have experienced a flare if the participant had an Ankylosing spondylitis disease activity score (ASDAS) greater or equal to (≥) 2.1 at 2 consecutive visits or an ASDAS greater than (>) 3.5 at any visit during Part B up until Week 96.
A participant qualified for Part B only if he achieved sustained remission after 48 weeks of Open-Label certolizumab pegol (CZP) treatment. Sustained remission was achieved when a participant had an ASDAS less than (<) 1.3 at Week 32 or Week 36 (if ASDAS < 1.3 at Week 32, it must have been < 2.1 at Week 36; if ASDAS < 2.1 at Week 32, it must have been < 1.3 at Week 36) and an ASDAS < 1.3 at Week 48.
Missing data were handled using non-response imputation (NRI) methods.

End point type	Primary

End point timeframe:

From Week 48 to Week 96

End point values	Placebo Double-Blind (RS)	Certolizumab pegol 200 mg Q2W Double-Blind (RS)	Certolizumab pegol 200 mg Q4W Double-Blind (RS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	104	104	105	
Units: percentage of participants				
number (confidence interval 95%)	20.2 (13.0 to 29.2)	83.7 (75.1 to 90.2)	79.0 (70.0 to 86.4)	

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Odds ratio (and corresponding p-value) resulted from a logistic regression model with factors for treatment, geographic region, and modified New York (mNY) classification for study participants who did not experience a flare. An odds ratio > 1 indicates a study participant on CZP was more likely not to experience a flare than a study participant on placebo. Penalized maximum likelihood approach was used for logistic regression.

Comparison groups	Placebo Double-Blind (RS) v Certolizumab pegol 200 mg Q2W Double-Blind (RS)
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [1]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	18.822
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.605
upper limit	38.864

Notes:

[1] - A fixed sequence testing procedure was used whereby the second test (CZP 200 mg Q4W vs PBO) was interpreted as statistically significant only if the first test (CZP 200 mg Q2W vs PBO) was significant at the 0.05 level as well.

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

Odds ratio (and corresponding p-value) resulted from a logistic regression model with factors for treatment, geographic region, and modified New York (mNY) classification for study participants who did not experience a flare. An odds ratio > 1 indicates a study participant on CZP was more likely not to experience a flare than a study participant on placebo. Penalized maximum likelihood approach was used for logistic regression.

Comparison groups	Placebo Double-Blind (RS) v Certolizumab pegol 200 mg Q4W Double-Blind (RS)
Number of subjects included in analysis	209
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [2]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	14.069

Confidence interval	
level	95 %
sides	2-sided
lower limit	7.395
upper limit	27.955

Notes:

[2] - A fixed sequence testing procedure was used whereby the second test (CZP 200 mg Q4W vs PBO) was interpreted as statistically significant only if the first test (CZP 200 mg Q2W vs PBO) was significant at the 0.05 level as well.

Secondary: Percentage of participants achieving sustained remission at Week 48 in Part A

End point title	Percentage of participants achieving sustained remission at Week 48 in Part A

End point description:

Sustained remission was achieved when a participant had an ASDAS less than (<) 1.3 at Week 32 or Week 36 (if ASDAS < 1.3 at Week 32, it must have been < 2.1 at Week 36; if ASDAS < 2.1 at Week 32, it must have been < 1.3 at Week 36) and an ASDAS < 1.3 at Week 48.
Missing data were handled using non-response imputation (NRI) methods.

End point type	Secondary

End point timeframe:

Week 48

End point values	Certolizumab pegol Open-Label (OLS)			
Subject group type	Subject analysis set			
Number of subjects analysed	736			
Units: percentage of participants				
number (confidence interval 95%)	43.9 (40.3 to 47.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants in Ankylosing Spondylitis Disease Activity Score (ASDAS) disease activity categories at Week 48 in Part A

End point title	Percentage of participants in Ankylosing Spondylitis Disease Activity Score (ASDAS) disease activity categories at Week 48 in Part A

End point description:

The ASDAS was calculated as the sum of the following components:
0.121 x Back pain (BASDAI Q2 result)
0.058 x Duration of morning stiffness (BASDAI Q6 result)
0.110 x PGADA (Patient's Global Assessment of Disease Activity)
0.073 x Peripheral pain/swelling (BASDAI Q3 result)
0.579 × (natural logarithm [ln] of the (CRP [mg/L] + 1))
Back pain, PGADA, duration of morning stiffness, peripheral pain/swelling and fatigue were all assessed on a numerical scale (0 to 10 units).

Disease activity was measured by categorical response variables:
• ASDAS-Inactive Disease (ASDAS-ID): ASDAS < 1.3

• ASDAS-Moderate Disease (ASDAS-MD): ASDAS ≥ 1.3, < 2.1
• ASDAS-High Disease activity (ASDAS-HD): ASDAS ≥ 2.1, ≤ 3.5
• ASDAS-very High Disease activity (ASDAS-vHD): ASDAS > 3.5

Missing data were handled using last observation carried forward (LOCF) methods.

End point type	Secondary

End point timeframe:

Week 48

End point values	Certolizumab pegol Open-Label (OLS)			
Subject group type	Subject analysis set			
Number of subjects analysed	736			
Units: percentage of participants				
number (not applicable)				
ASDAS-ID	52.5			
ASDAS-MD	22.8			
ASDAS-HD	18.9			
ASDAS-vHD	5.9			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants in Ankylosing Spondylitis Disease Activity Score (ASDAS) clinical improvement categories at Week 48 in Part A

End point title	Percentage of participants in Ankylosing Spondylitis Disease Activity Score (ASDAS) clinical improvement categories at Week 48 in Part A

End point description:

The ASDAS was calculated as the sum of the following components:
0.121 x Back pain (BASDAI Q2 result)
0.058 x Duration of morning stiffness (BASDAI Q6 result)
0.110 x PGADA (Patient’s Global Assessment of Disease Activity)
0.073 x Peripheral pain/swelling (BASDAI Q3 result)
0.579 × (natural logarithm [ln] of the (CRP [mg/L] + 1))
Back pain, PGADA, duration of morning stiffness, peripheral pain/swelling and fatigue were all assessed on a numerical scale (0 to 10 units).

ASDAS improvement was measured by binary response variables:
• ASDAS-CII: ASDAS reduction (improvement) of ≥ 1.1 relative to Baseline
• ASDAS-MI: ASDAS reduction (improvement) of ≥ 2.0 relative to Baseline

Missing data were handled using non-response imputation (NRI) methods.

End point type	Secondary

End point timeframe:

Week 48

End point values	Certolizumab pegol Open-Label (OLS)			
Subject group type	Subject analysis set			
Number of subjects analysed	736			
Units: percentage of participants				
number (not applicable)				
ASDAS-CII	76.6			
ASDAS-MI	56.1			

Statistical analyses

No statistical analyses for this end point

Secondary: Time to flare in Part B

End point title	Time to flare in Part B

End point description:

For those who met the criteria for flare (see primary efficacy variable), the time to flare was the length in days from randomization in Part B until the visit at which the criteria for flare were met. Participants who discontinued the study without meeting the criteria for flare were counted as experiencing a flare at the time of their last study visit.

The time to flare was analyzed using Kaplan-Meier methods. If Kaplan-Meier Estimate was NA for all estimates then more than 75 % failed to meet the flare condition.

Missing data were handled using non-response imputation (NRI) methods.

Note: 999 was used as a placeholder for values that were not calculated since more than 75 % failed to meet the flare condition.

End point type	Secondary

End point timeframe:

From Week 48 to Week 96

End point values	Placebo Double-Blind (RS)	Certolizumab pegol 200 mg Q2W Double-Blind (RS)	Certolizumab pegol 200 mg Q4W Double-Blind (RS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	104	104	105	
Units: days				
median (inter-quartile range (Q1-Q3))	113 (84 to 257)	371 (371 to 371)	999 (999 to 999)	

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

P-values were from stratified log-rank test comparing the Certolizumab pegol 200 mg Q2W Double-Blind (RS) group with the Placebo Double-Blind (RS) group (Geographic region and modified New York (mNY)

classification were used as stratification factors).

Comparison groups	Placebo Double-Blind (RS) v Certolizumab pegol 200 mg Q2W Double-Blind (RS)
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Logrank

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

P-values were from stratified log-rank test comparing the Certolizumab pegol 200 mg Q4W Double-Blind (RS) group with the Placebo Double-Blind (RS) group (Geographic region and modified New York (mNY) classification were used as stratification factors).

Comparison groups	Placebo Double-Blind (RS) v Certolizumab pegol 200 mg Q4W Double-Blind (RS)
Number of subjects included in analysis	209
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Logrank

Secondary: Percentage of participants in Ankylosing Spondylitis Disease Activity Score (ASDAS) disease activity categories at Week 96 in Part B

End point title	Percentage of participants in Ankylosing Spondylitis Disease Activity Score (ASDAS) disease activity categories at Week 96 in Part B

End point description:

The ASDAS was calculated as the sum of the following components:
0.121 x Back pain (BASDAI Q2 result)
0.058 x Duration of morning stiffness (BASDAI Q6 result)
0.110 x PGADA (Patient's Global Assessment of Disease Activity)
0.073 x Peripheral pain/swelling (BASDAI Q3 result)
0.579 × (natural logarithm [ln] of the (CRP [mg/L] + 1))
Back pain, PGADA, duration of morning stiffness, peripheral pain/swelling and fatigue were all assessed on a numerical scale (0 to 10 units).

Disease activity was measured by categorical response variables:
• ASDAS-Inactive Disease (ASDAS-ID): ASDAS < 1.3
• ASDAS-Moderate Disease (ASDAS-MD): ASDAS ≥ 1.3, < 2.1
• ASDAS-High Disease activity (ASDAS-HD): ASDAS ≥ 2.1, ≤ 3.5
• ASDAS-very High Disease activity (ASDAS-vHD): ASDAS > 3.5

End point type	Secondary

End point timeframe:

Week 96

End point values	Placebo Double-Blind (RS)	Certolizumab pegol 200 mg Q2W Double-Blind (RS)	Certolizumab pegol 200 mg Q4W Double-Blind (RS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	104	104	105	
Units: percentage of participants				
number (not applicable)				
ASDAS-ID	58.3	86.2	69.9	
ASDAS-MD	25.0	13.8	22.9	
ASDAS-HD	16.7	0	7.2	
ASDAS-vHD	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants in Ankylosing Spondylitis Disease Activity Score (ASDAS) clinical improvement categories at Week 96 in Part B

End point title	Percentage of participants in Ankylosing Spondylitis Disease Activity Score (ASDAS) clinical improvement categories at Week 96 in Part B

End point description:

The ASDAS was calculated as the sum of the following components:
0.121 x Back pain (BASDAI Q2 result)
0.058 x Duration of morning stiffness (BASDAI Q6 result)
0.110 x PGADA (Patient’s Global Assessment of Disease Activity)
0.073 x Peripheral pain/swelling (BASDAI Q3 result)
0.579 × (natural logarithm [ln] of the (CRP [mg/L] + 1))
Back pain, PGADA, duration of morning stiffness, peripheral pain/swelling and fatigue were all assessed on a numerical scale (0 to 10 units).

ASDAS improvement was measured by binary response variables:
• ASDAS-CII: ASDAS reduction (improvement) of ≥ 1.1 relative to Baseline
• ASDAS-MI: ASDAS reduction (improvement) of ≥ 2.0 relative to Baseline

Missing data were handled using non-response imputation (NRI) methods.

End point type	Secondary

End point timeframe:

Week 96

End point values	Placebo Double-Blind (RS)	Certolizumab pegol 200 mg Q2W Double-Blind (RS)	Certolizumab pegol 200 mg Q4W Double-Blind (RS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	104	104	105	
Units: percentage of participants				
number (not applicable)				
ASDAS-CII	21.2	82.7	75.2	
ASDAS-MI	10.6	67.3	58.1	

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description: Odds ratios (and corresponding p-values) were from a logistic regression model with factors for treatment group, geographical region, and modified New York (mNY) classification.	
Comparison groups	Placebo Double-Blind (RS) v Certolizumab pegol 200 mg Q2W Double-Blind (RS)
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	17.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.95
upper limit	35.961

Statistical analysis title	Statistical analysis 2
Statistical analysis description: Odds ratios (and corresponding p-values) were from a logistic regression model with factors for treatment group, geographical region, and modified New York (mNY) classification.	
Comparison groups	Placebo Double-Blind (RS) v Certolizumab pegol 200 mg Q4W Double-Blind (RS)
Number of subjects included in analysis	209
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	11.385
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.952
upper limit	21.778

Statistical analysis title	Statistical analysis 3

Statistical analysis description:	
Odds ratios (and corresponding p-values) were from a logistic regression model with factors for treatment group, geographical region, and modified New York (mNY) classification.	
Comparison groups	Placebo Double-Blind (RS) v Certolizumab pegol 200 mg Q2W Double-Blind (RS)
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	17.653
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.333
upper limit	37.399

Statistical analysis title	Statistical analysis 4
Statistical analysis description:	
Odds ratios (and corresponding p-values) were from a logistic regression model with factors for treatment group, geographical region, and modified New York (mNY) classification.	
Comparison groups	Placebo Double-Blind (RS) v Certolizumab pegol 200 mg Q4W Double-Blind (RS)
Number of subjects included in analysis	209
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	11.863
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.67
upper limit	24.822

Secondary: Percentage of participants with Axial SpondyloArthritis International Society 20 % response criteria (ASAS20) response at Week 96 in Part B

End point title	Percentage of participants with Axial SpondyloArthritis International Society 20 % response criteria (ASAS20) response at Week 96 in Part B

End point description:

The ASAS20 response was defined as an improvement of at least 20 % and absolute improvement of at least 1 unit on a 0 to 10 Numeric Rating Scale (NRS) in at least 3 of the 4 domains: Patient's Global Assessment of Disease Activity (PGADA), Pain assessment (total spinal pain NRS scores), Function (Bath Ankylosing Spondylitis Functional Index (BASFI)), Inflammation (mean of Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) questions 5 and 6 concerning morning stiffness intensity and duration) and absence of deterioration in the potential remaining domain [deterioration was defined as a relative worsening of at least 20 % and an absolute worsening of at least 1 unit].

Missing data were handled using non-response imputation (NRI) methods.

End point type	Secondary

End point timeframe:

Week 96

End point values	Placebo Double-Blind (RS)	Certolizumab pegol 200 mg Q2W Double-Blind (RS)	Certolizumab pegol 200 mg Q4W Double-Blind (RS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	104	104	105	
Units: percentage of participants				
number (not applicable)	23.1	85.6	78.1	

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Odds ratios (and corresponding p-values) were from a logistic regression model with factors for treatment group, geographical region, and mNY classification.

Comparison groups	Placebo Double-Blind (RS) v Certolizumab pegol 200 mg Q2W Double-Blind (RS)
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	20.205
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.851
upper limit	41.439

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

Odds ratios (and corresponding p-values) were from a logistic regression model with factors for treatment group, geographical region, and mNY classification.

Comparison groups	Placebo Double-Blind (RS) v Certolizumab pegol 200 mg Q4W Double-Blind (RS)

Number of subjects included in analysis	209
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	12.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.275
upper limit	23.218

Secondary: Percentage of participants with Axial SpondyloArthritis International Society 40 % response criteria (ASAS40) response at Week 96 in Part B

End point title	Percentage of participants with Axial SpondyloArthritis International Society 40 % response criteria (ASAS40) response at Week 96 in Part B

End point description:

The ASAS40 response was defined as a relative improvement of at least 40 % and absolute improvement of at least 2 units on a 0 to 10 Numeric Rating Scale (NRS) in at least 3 of the 4 domains: Patient's Global Assessment of Disease Activity (PGADA), Pain assessment (total spinal pain NRS scores), Function (Bath Ankylosing Spondylitis Functional Index (BASFI)), Inflammation (mean of Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) questions 5 and 6 concerning morning stiffness intensity and duration) and no worsening at all in the remaining domain.

Missing data were handled using non-response imputation (NRI) methods.

End point type	Secondary

End point timeframe:

Week 96

End point values	Placebo Double-Blind (RS)	Certolizumab pegol 200 mg Q2W Double-Blind (RS)	Certolizumab pegol 200 mg Q4W Double-Blind (RS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	104	104	105	
Units: percentage of participants				
number (not applicable)	21.2	84.6	73.3	

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Odds ratios (and corresponding p-values) were from a logistic regression model with factors for treatment group, geographical region, and mNY classification.

Comparison groups	Placebo Double-Blind (RS) v Certolizumab pegol 200 mg Q2W Double-Blind (RS)

Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	20.891
Confidence interval	
level	95 %
sides	2-sided
lower limit	10.21
upper limit	42.744

Statistical analysis title	Statistical analysis 2
Statistical analysis description:	
Odds ratios (and corresponding p-values) were from a logistic regression model with factors for treatment group, geographical region, and mNY classification.	
Comparison groups	Placebo Double-Blind (RS) v Certolizumab pegol 200 mg Q4W Double-Blind (RS)
Number of subjects included in analysis	209
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	10.377
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.456
upper limit	19.738

Secondary: Percentage of participants with Axial SpondyloArthritis International Society (ASAS) 5/6 response criteria response at Week 96 in Part B

End point title	Percentage of participants with Axial SpondyloArthritis International Society (ASAS) 5/6 response criteria response at Week 96 in Part B

End point description:

The ASAS 5/6 response was defined as achieving at least 20 % improvement in 5 of 6 domains, including the 4 domains defined for ASAS20 as well as spinal mobility (lateral spinal flexion) and C-reactive Protein (CRP).

Missing data were handled using non-response imputation (NRI) methods.

End point type	Secondary

End point timeframe:

Week 96

End point values	Placebo Double-Blind (RS)	Certolizumab pegol 200 mg Q2W Double-Blind (RS)	Certolizumab pegol 200 mg Q4W Double-Blind (RS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	104	104	105	
Units: percentage of participants				
number (not applicable)	12.5	70.2	62.9	

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description:	
Odds ratios (and corresponding p-values) were from a logistic regression model with factors for treatment group, geographical region, and mNY classification.	
Comparison groups	Placebo Double-Blind (RS) v Certolizumab pegol 200 mg Q2W Double-Blind (RS)
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	16.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.211
upper limit	34.785

Statistical analysis title	Statistical analysis 2
Statistical analysis description:	
Odds ratios (and corresponding p-values) were from a logistic regression model with factors for treatment group, geographical region, and mNY classification.	
Comparison groups	Placebo Double-Blind (RS) v Certolizumab pegol 200 mg Q4W Double-Blind (RS)
Number of subjects included in analysis	209
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	12.072

Confidence interval	
level	95 %
sides	2-sided
lower limit	5.954
upper limit	24.476

Secondary: Percentage of participants with Axial SpondyloArthritis International Society (ASAS) partial remission (PR) response criteria response at Week 96 in Part B

End point title	Percentage of participants with Axial SpondyloArthritis International Society (ASAS) partial remission (PR) response criteria response at Week 96 in Part B

End point description:

The ASAS partial remission (PR) response was defined as a score of ≤ 2 units on a 0 to 10 unit scale in all 4 domains listed for ASAS20.

Missing data were handled using non-response imputation (NRI) methods.

End point type	Secondary

End point timeframe:

Week 96

End point values	Placebo Double-Blind (RS)	Certolizumab pegol 200 mg Q2W Double-Blind (RS)	Certolizumab pegol 200 mg Q4W Double-Blind (RS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	104	104	105	
Units: percentage of participants				
number (not applicable)	17.3	77.9	70.5	

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Odds ratios (and corresponding p-values) were from a logistic regression model with factors for treatment group, geographical region, and mNY classification.

Comparison groups	Placebo Double-Blind (RS) v Certolizumab pegol 200 mg Q2W Double-Blind (RS)
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	17.082

Confidence interval	
level	95 %
sides	2-sided
lower limit	8.561
upper limit	34.085

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

Odds ratios (and corresponding p-values) were from a logistic regression model with factors for treatment group, geographical region, and mNY classification.

Comparison groups	Placebo Double-Blind (RS) v Certolizumab pegol 200 mg Q4W Double-Blind (RS)
Number of subjects included in analysis	209
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	11.503
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.939
upper limit	22.278

Secondary: Change from Baseline in Ankylosing Spondylitis Disease Activity Score (ASDAS) at Week 96 in Part B

End point title	Change from Baseline in Ankylosing Spondylitis Disease Activity Score (ASDAS) at Week 96 in Part B

End point description:

The ASDAS was calculated as the sum of the following components:
0.121 x Back pain (BASDAI Q2 result)
0.058 x Duration of morning stiffness (BASDAI Q6 result)
0.110 x PGADA (Patient's Global Assessment of Disease Activity)
0.073 x Peripheral pain/swelling (BASDAI Q3 result)
0.579 × (natural logarithm [ln] of the (CRP [mg/L] + 1))
Back pain, PGADA, duration of morning stiffness, peripheral pain/swelling and fatigue were all assessed on a numerical scale (0 to 10 units).
There is a minimum score of 0.636 for the total ASDAS score, but no defined upper score. Based on the formula even in the situation that the CRP is normal, any value below 4 is recorded as "below the limit of quantification" (BLQ) and a value of BLQ/2=2 was prespecified. This assumption is triggering the lowest possible value of 0.636.
The change from Part B Baseline is calculated, a negative value indicating improvement and a positive value worsening.

End point type	Secondary

End point timeframe:

From Week 48 to Week 96

End point values	Placebo Double-Blind (RS)	Certolizumab pegol 200 mg Q2W Double-Blind (RS)	Certolizumab pegol 200 mg Q4W Double-Blind (RS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	104	104	105	
Units: scores on a scale				
least squares mean (standard error)	1.66 (± 0.110)	0.24 (± 0.077)	0.45 (± 0.077)	

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

An mixed model with repeated measures (MMRM) analysis on all observed post-baseline data with the following fixed-effect covariates was used: treatment, geographical region, mNY classification, Part B Baseline value, and visit as fixed-effect factors, as well as treatment group by visit interaction and Part B Baseline value by visit interaction.

Comparison groups	Placebo Double-Blind (RS) v Certolizumab pegol 200 mg Q2W Double-Blind (RS)
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LS Mean Difference vs Placebo
Point estimate	-1.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.66
upper limit	-1.17
Variability estimate	Standard error of the mean
Dispersion value	0.126

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

An mixed model with repeated measures (MMRM) analysis on all observed post-baseline data with the following fixed-effect covariates was used: treatment, geographical region, mNY classification, Part B Baseline value, and visit as fixed-effect factors, as well as treatment group by visit interaction and Part B Baseline value by visit interaction.

Comparison groups	Placebo Double-Blind (RS) v Certolizumab pegol 200 mg Q4W Double-Blind (RS)
Number of subjects included in analysis	209
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LS Mean Difference vs Placebo
Point estimate	-1.21

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.45
upper limit	-0.96
Variability estimate	Standard error of the mean
Dispersion value	0.126

Secondary: Change from Baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) at Week 96 in Part B

End point title	Change from Baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) at Week 96 in Part B

End point description:

The BASDAI is a validated self-reported instrument, which consists of six 10 unit horizontal Numeric Rating Scales (NRS) to measure the disease activity of ankylosing spondylitis (AS) from the subject's perspective. It measures the severity of fatigue, spinal and peripheral joint pain and swelling, enthesitis, and morning stiffness (both severity and duration) over the last week. The final BASDAI scores ranges from 0 to 10, with lower scores indicating lower disease activity.
The change from Part B Baseline is calculated, a negative value indicating improvement and a positive value worsening.

End point type	Secondary

End point timeframe:

From Week 48 to Week 96

End point values	Placebo Double-Blind (RS)	Certolizumab pegol 200 mg Q2W Double-Blind (RS)	Certolizumab pegol 200 mg Q4W Double-Blind (RS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	104	104	105	
Units: scores on a scale				
least squares mean (standard error)	3.02 (± 0.226)	0.56 (± 0.176)	0.78 (± 0.176)	

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

An mixed model with repeated measures (MMRM) analysis on all observed post-baseline data with the following fixed-effect covariates was used: treatment, geographical region, mNY classification, Part B Baseline value, and visit as fixed-effect factors, as well as treatment group by visit interaction and Part B Baseline value by visit interaction.

Comparison groups	Placebo Double-Blind (RS) v Certolizumab pegol 200 mg Q2W Double-Blind (RS)

Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LS Mean Difference vs Placebo
Point estimate	-2.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.99
upper limit	-1.94
Variability estimate	Standard error of the mean
Dispersion value	0.268

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

An mixed model with repeated measures (MMRM) analysis on all observed post-baseline data with the following fixed-effect covariates was used: treatment, geographical region, mNY classification, Part B Baseline value, and visit as fixed-effect factors, as well as treatment group by visit interaction and Part B Baseline value by visit interaction.

Comparison groups	Placebo Double-Blind (RS) v Certolizumab pegol 200 mg Q4W Double-Blind (RS)
Number of subjects included in analysis	209
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LS Mean Difference vs Placebo
Point estimate	-2.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.77
upper limit	-1.72
Variability estimate	Standard error of the mean
Dispersion value	0.267

Secondary: Change from Baseline in Bath Ankylosing Spondylitis Functional Index (BASFI) at Week 96 in Part B

End point title	Change from Baseline in Bath Ankylosing Spondylitis Functional Index (BASFI) at Week 96 in Part B

End point description:

The BASFI is a validated disease-specific instrument for assessing physical function. The BASFI comprises 10 items relating to the past week. The BASFI is the mean of the 10 scores such that the total score ranges from 0 (Easy) to 10 (Impossible), with lower scores indicating better physical function. The change from Part B Baseline is calculated, a negative value indicating improvement and a positive value worsening.

End point type	Secondary

End point timeframe:

From Week 48 to Week 96

End point values	Placebo Double-Blind (RS)	Certolizumab pegol 200 mg Q2W Double-Blind (RS)	Certolizumab pegol 200 mg Q4W Double-Blind (RS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	104	104	105	
Units: scores on a scale				
least squares mean (standard error)	1.90 (± 0.233)	0.32 (± 0.198)	0.46 (± 0.205)	

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

An mixed model with repeated measures (MMRM) analysis on all observed post-baseline data with the following fixed-effect covariates was used: treatment, geographical region, mNY classification, Part B Baseline value, and visit as fixed-effect factors, as well as treatment group by visit interaction and Part B Baseline value by visit interaction.

Comparison groups	Placebo Double-Blind (RS) v Certolizumab pegol 200 mg Q2W Double-Blind (RS)
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LS Mean Difference vs Placebo
Point estimate	-1.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.04
upper limit	-1.11
Variability estimate	Standard error of the mean
Dispersion value	0.238

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

An mixed model with repeated measures (MMRM) analysis on all observed post-baseline data with the following fixed-effect covariates was used: treatment, geographical region, mNY classification, Part B Baseline value, and visit as fixed-effect factors, as well as treatment group by visit interaction and Part B Baseline value by visit interaction.

Comparison groups	Placebo Double-Blind (RS) v Certolizumab pegol 200 mg Q4W Double-Blind (RS)

Number of subjects included in analysis	209
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LS Mean Difference vs Placebo
Point estimate	-1.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	-0.96
Variability estimate	Standard error of the mean
Dispersion value	0.238

Secondary: Change from Baseline in Bath Ankylosing Spondylitis Metrology Index (BASMI) at Week 96 in Part B

End point title	Change from Baseline in Bath Ankylosing Spondylitis Metrology Index (BASMI) at Week 96 in Part B

End point description:

The BASMI is a disease-specific measure consisting of 5 clinical measures to reflect subject axial status: cervical rotation; tragus to wall distance; lateral lumbar flexion; lumbar flexion (modified Schober test); intermalleolar distance. According to the linear definition of the BASMI a score of 0 to 10 was calculated for each item based on the measurement. The mean of the sum of the 5 scores provided the total BASMI score, ranging from 0 to 10. The higher the BASMI score the more severe the patient's limitation of movement due to their axial spondyloarthritis (axSpA).
The change from Part B Baseline is calculated, a negative value indicating improvement and a positive value worsening.

End point type	Secondary

End point timeframe:

From Week 48 to Week 96

End point values	Placebo Double-Blind (RS)	Certolizumab pegol 200 mg Q2W Double-Blind (RS)	Certolizumab pegol 200 mg Q4W Double-Blind (RS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	104	104	105	
Units: scores on a scale				
least squares mean (standard error)	0.21 (± 0.105)	0.00 (± 0.065)	-0.03 (± 0.068)	

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

An mixed model with repeated measures (MMRM) analysis on all observed post-baseline data with the following fixed-effect covariates was used: treatment, geographical region, mNY classification, Part B

Baseline value, and visit as fixed-effect factors, as well as treatment group by visit interaction and Part B Baseline value by visit interaction.

Comparison groups	Placebo Double-Blind (RS) v Certolizumab pegol 200 mg Q2W Double-Blind (RS)
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.074
Method	Mixed models analysis
Parameter estimate	LS Mean Difference vs Placebo
Point estimate	-0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.42
upper limit	0.02
Variability estimate	Standard error of the mean
Dispersion value	0.112

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

An mixed model with repeated measures (MMRM) analysis on all observed post-baseline data with the following fixed-effect covariates was used: treatment, geographical region, mNY classification, Part B Baseline value, and visit as fixed-effect factors, as well as treatment group by visit interaction and Part B Baseline value by visit interaction.

Comparison groups	Placebo Double-Blind (RS) v Certolizumab pegol 200 mg Q4W Double-Blind (RS)
Number of subjects included in analysis	209
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.036
Method	Mixed models analysis
Parameter estimate	LS Mean Difference vs Placebo
Point estimate	-0.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.46
upper limit	-0.02
Variability estimate	Standard error of the mean
Dispersion value	0.113

Secondary: Percentage of participants with Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) 50 response criteria response at Week 96 in Part B

End point title	Percentage of participants with Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) 50 response criteria response at Week 96 in Part B

End point description:

The BASDAI50 response was defined as an improvement of at least 50 % in the BASDAI score relative

to Baseline.

Missing data were handled using non-response imputation (NRI) methods.

End point type	Secondary

End point timeframe:

Week 96

End point values	Placebo Double-Blind (RS)	Certolizumab pegol 200 mg Q2W Double-Blind (RS)	Certolizumab pegol 200 mg Q4W Double-Blind (RS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	104	104	105	
Units: percentage of participants				
number (not applicable)	22.1	83.7	77.1	

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Odds ratios (and corresponding p-values) were from a logistic regression model with factors for treatment group, geographical region, and mNY classification.

Comparison groups	Placebo Double-Blind (RS) v Certolizumab pegol 200 mg Q2W Double-Blind (RS)
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	18.308
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.084
upper limit	36.898

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

Odds ratios (and corresponding p-values) were from a logistic regression model with factors for treatment group, geographical region, and mNY classification.

Comparison groups	Placebo Double-Blind (RS) v Certolizumab pegol 200 mg Q4W Double-Blind (RS)

Number of subjects included in analysis	209
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	12.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.255
upper limit	23.098

Secondary: Change from Baseline in sacroiliac Spondyloarthritis Research Consortium of Canada (SPARCC) score at Week 96 in Part B

End point title	Change from Baseline in sacroiliac Spondyloarthritis Research Consortium of Canada (SPARCC) score at Week 96 in Part B

End point description:

The SPARCC scoring method for lesions found on the Magnetic Resonance Imaging (MRI) is based on an abnormal increased signal on the Short-Tau-Inversion Recovery (STIR) sequence, representing bone marrow edema. Total Sacroiliac (SI) joint SPARCC score can range from 0 to 72 with higher scores indicating higher joint inflammation.
The change from Part B Baseline is calculated, a negative value indicating improvement and a positive value worsening.

End point type	Secondary

End point timeframe:

From Week 48 to Week 96

End point values	Placebo Double-Blind (RS)	Certolizumab pegol 200 mg Q2W Double-Blind (RS)	Certolizumab pegol 200 mg Q4W Double-Blind (RS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	24	79	77	
Units: scores on a scale				
arithmetic mean (standard deviation)	1.1 (± 3.6)	0.2 (± 2.4)	0.6 (± 3.8)	

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Only MRIs performed ± 2 weeks around the Week 96 or Early Withdrawal Visit were assigned to Week 96 or Early Withdrawal.
Only results of the double-read assessments of the central MRI review were included. The analysis used the average of the scores from the 2 independent reviewers. Whenever an adjudication was present, the average score across all 3 reviewers was used.
ANCOVA model with treatment, geographical region, mNY classification, and Part B Baseline as covariates.

Comparison groups	Placebo Double-Blind (RS) v Certolizumab pegol 200 mg Q2W Double-Blind (RS)
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.195
Method	ANCOVA
Parameter estimate	LS Mean Difference vs Placebo
Point estimate	-1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	0.51
Variability estimate	Standard error of the mean
Dispersion value	0.76

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

Only MRIs performed ± 2 weeks around the Week 96 or Early Withdrawal Visit were assigned to Week 96 or Early Withdrawal.
Only results of the double-read assessments of the central MRI review were included. The analysis used the average of the scores from the 2 independent reviewers. Whenever an adjudication was present, the average score across all 3 reviewers was used.
ANCOVA model with treatment, geographical region, mNY classification, and Part B Baseline as covariates.

Comparison groups	Placebo Double-Blind (RS) v Certolizumab pegol 200 mg Q4W Double-Blind (RS)
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.432
Method	ANCOVA
Parameter estimate	LS Mean Difference vs Placebo
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.11
upper limit	0.91
Variability estimate	Standard error of the mean
Dispersion value	0.76

Secondary: Change from Baseline in spine Ankylosing Spondylitis spine Magnetic Resonance Imaging Score for Disease activity (ASspIMRI-a) in the Berlin modification score at Week 96 in Part B

End point title	Change from Baseline in spine Ankylosing Spondylitis spine Magnetic Resonance Imaging Score for Disease activity (ASspIMRI-a) in the Berlin modification score at Week 96 in Part B

End point description:

The Berlin modification of the ASspiMRI-a is a scoring system with a concentration on Short-Tau-Inversion Recovery (STIR) sequences without other fat saturation techniques. It quantifies changes in 23 Vertebral Units (VU) of the spine. Active inflammation was scored by grading the degree of bone marrow edema from 0 to 3 in 1 dimension on 1 or more consecutive slices that represent the highest level of inflammation in a particular VU.
The change from Part B Baseline is calculated, a negative value indicating improvement and a positive value worsening.

End point type	Secondary

End point timeframe:

From Week 48 to Week 96

End point values	Placebo Double-Blind (RS)	Certolizumab pegol 200 mg Q2W Double-Blind (RS)	Certolizumab pegol 200 mg Q4W Double-Blind (RS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	24	79	78	
Units: scores on a scale				
arithmetic mean (standard deviation)	0.4 (± 0.9)	0.0 (± 0.8)	0.0 (± 0.8)	

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Only MRIs performed ± 2 weeks around the Week 96 or Early Withdrawal Visit were assigned to Week 96 or Early Withdrawal.
Only results of the double-read assessments of the central MRI review were included. The analysis used the average of the scores from the 2 independent reviewers. Whenever an adjudication was present, the average score across all 3 reviewers was used.
ANCOVA model with treatment, geographical region, mNY classification, and Part B Baseline as covariates.

Comparison groups	Placebo Double-Blind (RS) v Certolizumab pegol 200 mg Q2W Double-Blind (RS)
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.04
Method	ANCOVA
Parameter estimate	LS Mean Difference vs Placebo
Point estimate	-0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.78
upper limit	-0.02
Variability estimate	Standard error of the mean
Dispersion value	0.19

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

Only MRIs performed ± 2 weeks around the Week 96 or Early Withdrawal Visit were assigned to Week 96 or Early Withdrawal.
Only results of the double-read assessments of the central MRI review were included. The analysis used the average of the scores from the 2 independent reviewers. Whenever an adjudication was present, the average score across all 3 reviewers was used.
ANCOVA model with treatment, geographical region, mNY classification, and Part B Baseline as covariates.

Comparison groups	Placebo Double-Blind (RS) v Certolizumab pegol 200 mg Q4W Double-Blind (RS)
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.074
Method	ANCOVA
Parameter estimate	LS Mean Difference vs Placebo
Point estimate	-0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.73
upper limit	0.03
Variability estimate	Standard error of the mean
Dispersion value	0.19

Secondary: Percentage of participants in Ankylosing Spondylitis Disease Activity Score (ASDAS) disease activity categories at Escape Week 12 for participants who experienced a flare in Part B

End point title	Percentage of participants in Ankylosing Spondylitis Disease Activity Score (ASDAS) disease activity categories at Escape Week 12 for participants who experienced a flare in Part B

End point description:

The ASDAS was calculated as the sum of the following components:
0.121 x Back pain (BASDAI Q2 result)
0.058 x Duration of morning stiffness (BASDAI Q6 result)
0.110 x PGADA (Patient’s Global Assessment of Disease Activity)
0.073 x Peripheral pain/swelling (BASDAI Q3 result)
0.579 × (natural logarithm [ln] of the (CRP [mg/L] + 1))
Back pain, PGADA, duration of morning stiffness, peripheral pain/swelling and fatigue were all assessed on a numerical scale (0 to 10 units).

Disease activity was measured by categorical response variables:
• ASDAS-Inactive Disease (ASDAS-ID): ASDAS < 1.3
• ASDAS-Moderate Disease (ASDAS-MD): ASDAS ≥ 1.3, < 2.1
• ASDAS-High Disease activity (ASDAS-HD): ASDAS ≥ 2.1, ≤ 3.5
• ASDAS-very High Disease activity (ASDAS-vHD): ASDAS > 3.5

End point type	Secondary

End point timeframe:

Escape Week 12

End point values	Placebo DB/CZP 200 mg Q2W Escape (FS)	CZP 200 mg Q2W DB/CZP 200 mg Q2W Escape (FS)	CZP 200 mg Q4W DB/CZP 200 mg Q2W Escape (FS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	73	7	15	
Units: percentage of participants				
number (not applicable)				
ASDAS-ID	63.4	16.7	60.0	
ASDAS-MD	26.8	50.0	20.0	
ASDAS-HD	8.5	33.3	20.0	
ASDAS-vHD	1.4	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants in Ankylosing Spondylitis Disease Activity Score (ASDAS) clinical improvement categories at Escape Week 12 for participants who experienced a flare in Part B

End point title	Percentage of participants in Ankylosing Spondylitis Disease Activity Score (ASDAS) clinical improvement categories at Escape Week 12 for participants who experienced a flare in Part B

End point description:

The ASDAS was calculated as the sum of the following components:
0.121 x Back pain (BASDAI Q2 result)
0.058 x Duration of morning stiffness (BASDAI Q6 result)
0.110 x PGADA (Patient's Global Assessment of Disease Activity)
0.073 x Peripheral pain/swelling (BASDAI Q3 result)
0.579 × (natural logarithm [ln] of the (CRP [mg/L] + 1))
Back pain, PGADA, duration of morning stiffness, peripheral pain/swelling and fatigue were all assessed on a numerical scale (0 to 10 units).

ASDAS improvement was measured by binary response variables:
• ASDAS-CII: ASDAS reduction (improvement) of ≥ 1.1 relative to Baseline
• ASDAS-MI: ASDAS reduction (improvement) of ≥ 2.0 relative to Baseline

End point type	Secondary

End point timeframe:

Escape Week 12

End point values	Placebo DB/CZP 200 mg Q2W Escape (FS)	CZP 200 mg Q2W DB/CZP 200 mg Q2W Escape (FS)	CZP 200 mg Q4W DB/CZP 200 mg Q2W Escape (FS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	73	7	15	
Units: percentage of participants				
number (not applicable)				
ASDAS-CII	84.5	16.7	46.7	
ASDAS-MI	49.3	0	13.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with Axial SpondyloArthritis International Society 20 % response criteria (ASAS20) response at Escape Week 12 for participants who experienced a flare in Part B

End point title	Percentage of participants with Axial SpondyloArthritis International Society 20 % response criteria (ASAS20) response at Escape Week 12 for participants who experienced a flare in Part B

End point description:

The ASAS20 response was defined as an improvement of at least 20 % and absolute improvement of at least 1 unit on a 0 to 10 Numeric Rating Scale (NRS) in at least 3 of the 4 domains: Patient's Global Assessment of Disease Activity (PGADA), Pain assessment (total spinal pain NRS scores), Function (Bath Ankylosing Spondylitis Functional Index (BASFI)), Inflammation (mean of Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) questions 5 and 6 concerning morning stiffness intensity and duration) and absence of deterioration in the potential remaining domain [deterioration was defined as a relative worsening of at least 20% and an absolute worsening of at least 1 unit].

End point type	Secondary

End point timeframe:

Escape Week 12

End point values	Placebo DB/CZP 200 mg Q2W Escape (FS)	CZP 200 mg Q2W DB/CZP 200 mg Q2W Escape (FS)	CZP 200 mg Q4W DB/CZP 200 mg Q2W Escape (FS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	73	7	15	
Units: percentage of participants				
number (not applicable)	83.3	50.0	64.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with Axial SpondyloArthritis International Society 40 % response criteria (ASAS40) response at Escape Week 12 for participants who experienced a flare in Part B

End point title	Percentage of participants with Axial SpondyloArthritis International Society 40 % response criteria (ASAS40) response at Escape Week 12 for participants who experienced a flare in Part B

End point description:

The ASAS40 response was defined as a relative improvement of at least 40 % and absolute

improvement of at least 2 units on a 0 to 10 Numeric Rating Scale (NRS) in at least 3 of the 4 domains: Patient's Global Assessment of Disease Activity (PGADA), Pain assessment (total spinal pain NRS scores), Function (Bath Ankylosing Spondylitis Functional Index (BASFI)), Inflammation (mean of Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) questions 5 and 6 concerning morning stiffness intensity and duration) and no worsening at all in the remaining domain.

End point type	Secondary

End point timeframe:

Escape Week 12

End point values	Placebo DB/CZP 200 mg Q2W Escape (FS)	CZP 200 mg Q2W DB/CZP 200 mg Q2W Escape (FS)	CZP 200 mg Q4W DB/CZP 200 mg Q2W Escape (FS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	73	7	15	
Units: percentage of participants				
number (not applicable)	69.4	16.7	50.0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with Axial SpondyloArthritis International Society (ASAS) 5/6 response criteria response at Escape Week 12 for participants who experienced a flare in Part B

End point title	Percentage of participants with Axial SpondyloArthritis International Society (ASAS) 5/6 response criteria response at Escape Week 12 for participants who experienced a flare in Part B

End point description:

The ASAS 5/6 response was defined as achieving at least 20 % improvement in 5 of 6 domains, including the 4 domains defined for ASAS20 as well as spinal mobility (lateral spinal flexion) and C-reactive Protein (CRP).

End point type	Secondary

End point timeframe:

Escape Week 12

End point values	Placebo DB/CZP 200 mg Q2W Escape (FS)	CZP 200 mg Q2W DB/CZP 200 mg Q2W Escape (FS)	CZP 200 mg Q4W DB/CZP 200 mg Q2W Escape (FS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	73	7	15	
Units: percentage of participants				
number (not applicable)	60.6	16.7	7.1	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with Axial SpondyloArthritis International Society (ASAS) partial remission (PR) response criteria response at Escape Week 12 for participants who experienced a flare in Part B

End point title	Percentage of participants with Axial SpondyloArthritis International Society (ASAS) partial remission (PR) response criteria response at Escape Week 12 for participants who experienced a flare in Part B

End point description:

The ASAS partial remission (PR) response was defined as a score of ≤ 2 units on a 0 to 10 unit scale in all 4 domains listed for ASAS20.

End point type	Secondary

End point timeframe:

Escape Week 12

End point values	Placebo DB/CZP 200 mg Q2W Escape (FS)	CZP 200 mg Q2W DB/CZP 200 mg Q2W Escape (FS)	CZP 200 mg Q4W DB/CZP 200 mg Q2W Escape (FS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	73	7	15	
Units: percentage of participants				
number (not applicable)	66.7	16.7	50.0	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Ankylosing Spondylitis Disease Activity Score (ASDAS) at Escape Week 12 for participants who experienced a flare in Part B

End point title	Change from Baseline in Ankylosing Spondylitis Disease Activity Score (ASDAS) at Escape Week 12 for participants who experienced a flare in Part B

End point description:

The ASDAS was calculated as the sum of the following components:
0.121 x Back pain (BASDAI Q2 result)
0.058 x Duration of morning stiffness (BASDAI Q6 result)
0.110 x PGADA (Patient's Global Assessment of Disease Activity)
0.073 x Peripheral pain/swelling (BASDAI Q3 result)
0.579 × (natural logarithm [ln] of the (CRP [mg/L] + 1))
Back pain, PGADA, duration of morning stiffness, peripheral pain/swelling and fatigue were all assessed on a numerical scale (0 to 10 units).
There is a minimum score of 0.636 for the total ASDAS score, but no defined upper score. Based on the formula even in the situation that the CRP is normal, any value below 4 is recorded as "below the limit of quantification" (BLQ) and a value of BLQ/2=2 was prespecified. This assumption is triggering the lowest possible value of 0.636.
The change from Part B Baseline is calculated, a negative value indicating improvement and a positive value worsening.

End point type	Secondary

End point timeframe:

From time of flare to Escape Week 12

End point values	Placebo DB/CZP 200 mg Q2W Escape (FS)	CZP 200 mg Q2W DB/CZP 200 mg Q2W Escape (FS)	CZP 200 mg Q4W DB/CZP 200 mg Q2W Escape (FS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	71	6	15	
Units: scores on a scale				
arithmetic mean (standard deviation)	-2.18 (± 1.13)	-0.56 (± 0.64)	-0.83 (± 0.94)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) at Escape Week 12 for participants who experienced a flare in Part B

End point title	Change from Baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) at Escape Week 12 for participants who experienced a flare in Part B

End point description:

The BASDAI is a validated self-reported instrument, which consists of six 10 unit horizontal Numeric Rating Scales (NRS) to measure the disease activity of ankylosing spondylitis (AS) from the subject's perspective. It measures the severity of fatigue, spinal and peripheral joint pain and swelling, enthesitis, and morning stiffness (both severity and duration) over the last week. The final BASDAI scores ranges from 0 to 10, with lower scores indicating lower disease activity.
The change from flare Baseline is calculated, a negative value indicating improvement and a positive value worsening.

End point type	Secondary

End point timeframe:

From time of flare to Escape Week 12

End point values	Placebo DB/CZP 200 mg Q2W Escape (FS)	CZP 200 mg Q2W DB/CZP 200 mg Q2W Escape (FS)	CZP 200 mg Q4W DB/CZP 200 mg Q2W Escape (FS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	72	6	15	
Units: scores on a scale				
arithmetic mean (standard deviation)	-3.75 (± 2.52)	-1.55 (± 1.05)	-2.29 (± 2.35)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Bath Ankylosing Spondylitis Functional Index (BASFI) at Escape Week 12 for participants who experienced a flare in Part B

End point title	Change from Baseline in Bath Ankylosing Spondylitis Functional Index (BASFI) at Escape Week 12 for participants who experienced a flare in Part B

End point description:

The BASFI is a validated disease-specific instrument for assessing physical function. The BASFI comprises 10 items relating to the past week. The BASFI is the mean of the 10 scores such that the total score ranges from 0 (Easy) to 10 (Impossible), with lower scores indicating better physical function.
The change from flare Baseline is calculated, a negative value indicating improvement and a positive value worsening.

End point type	Secondary

End point timeframe:

From time of flare to Escape Week 12

End point values	Placebo DB/CZP 200 mg Q2W Escape (FS)	CZP 200 mg Q2W DB/CZP 200 mg Q2W Escape (FS)	CZP 200 mg Q4W DB/CZP 200 mg Q2W Escape (FS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	72	6	14	
Units: scores on a scale				
arithmetic mean (standard deviation)	-2.52 (± 2.46)	-0.72 (± 0.70)	-1.83 (± 2.38)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Bath Ankylosing Spondylitis Metrology Index (BASMI) at Escape Week 12 for participants who experienced a flare in Part B

End point title	Change from Baseline in Bath Ankylosing Spondylitis Metrology Index (BASMI) at Escape Week 12 for participants who experienced a flare in Part B

End point description:

The BASMI is a disease-specific measure consisting of 5 clinical measures to reflect subject axial status: cervical rotation; tragus to wall distance; lateral lumbar flexion; lumbar flexion (modified Schober test); intermalleolar distance. According to the linear definition of the BASMI a score of 0 to 10 was calculated for each item based on the measurement. The mean of the sum of the 5 scores provided the total BASMI score, ranging from 0 to 10. The higher the BASMI score the more severe the patient's limitation of movement due to their axial spondyloarthritis (axSpA).
The change from flare Baseline is calculated, a negative value indicating improvement and a positive value worsening.

End point type	Secondary

End point timeframe:

From time of flare to Escape Week 12

End point values	Placebo DB/CZP 200 mg Q2W Escape (FS)	CZP 200 mg Q2W DB/CZP 200 mg Q2W Escape (FS)	CZP 200 mg Q4W DB/CZP 200 mg Q2W Escape (FS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	67	6	15	
Units: scores on a scale				
arithmetic mean (standard deviation)	-0.43 (± 0.58)	-0.27 (± 0.35)	-0.26 (± 0.30)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in sacroiliac Spondyloarthritis Research Consortium of Canada (SPARCC) score at Escape Week 12 for participants who experienced a flare in Part B

End point title	Change from Baseline in sacroiliac Spondyloarthritis Research Consortium of Canada (SPARCC) score at Escape Week 12 for participants who experienced a flare in Part B

End point description:

The SPARCC scoring method for lesions found on the Magnetic Resonance Imaging (MRI) is based on an abnormal increased signal on the Short-Tau-Inversion Recovery (STIR) sequence, representing bone marrow edema. Total Sacroiliac (SI) joint SPARCC score can range from 0 to 72 with higher scores indicating higher joint inflammation.
The change from flare Baseline is calculated, a negative value indicating improvement and a positive value worsening.

End point type	Secondary

End point timeframe:

From time of flare to Escape Week 12

End point values	Placebo DB/CZP 200 mg Q2W Escape (FS)	CZP 200 mg Q2W DB/CZP 200 mg Q2W Escape (FS)	CZP 200 mg Q4W DB/CZP 200 mg Q2W Escape (FS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	48	2	12	
Units: scores on a scale				
arithmetic mean (standard deviation)	-9.3 (± 13.2)	0.0 (± 0.0)	0.2 (± 3.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in spine Ankylosing Spondylitis spine Magnetic Resonance Imaging Score for activity (ASspIMRI-a) in the Berlin modification score at Escape Week 12 for participants who experienced a flare in Part B

End point title	Change from Baseline in spine Ankylosing Spondylitis spine Magnetic Resonance Imaging Score for activity (ASspIMRI-a) in the Berlin modification score at Escape Week 12 for

	participants who experienced a flare in Part B

End point description:

The Berlin modification of the ASspiMRI-a is a scoring system with a concentration on Short-Tau-Inversion Recovery (STIR) sequences without other fat saturation techniques. It quantifies changes in 23 Vertebral Units (VU) of the spine. Active inflammation was scored by grading the degree of bone marrow edema from 0 to 3 in 1 dimension on 1 or more consecutive slices that represent the highest level of inflammation in a particular VU.
The change from flare Baseline is calculated, a negative value indicating improvement and a positive value worsening.

End point type	Secondary

End point timeframe:

From time of flare to Escape Week 12

End point values	Placebo DB/CZP 200 mg Q2W Escape (FS)	CZP 200 mg Q2W DB/CZP 200 mg Q2W Escape (FS)	CZP 200 mg Q4W DB/CZP 200 mg Q2W Escape (FS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	48	2	12	
Units: scores on a scale				
arithmetic mean (standard deviation)	-2.3 (± 4.6)	0.0 (± 0.0)	-0.3 (± 1.0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Certolizumab pegol (CZP) Plasma Concentration during the study

End point title	Certolizumab pegol (CZP) Plasma Concentration during the study

End point description:

CZP plasma concentration was measured in micrograms per milliliter (µg/mL).
Blood sample measurements that were deemed to be below the level of quantification, were set to half the lower level of quantification (LLOQ) for analysis purposes. Summary statistics were only displayed if at least two-thirds of the values were above the LLOQ and if n was greater or equal to (>=) 4.
The primary purpose of the study was to evaluate treatment options for axSpA patients after being in sustained remission. Hence, one of the objectives was to evaluate the PK of these patients. The CZP plasma concentration of the patients that did not reach sustained remission were therefore not analysed, and the Pharmacokinetic Set A as described in the protocol was removed from the SAP.

Note: Number of participants analyzed each Week is presented in parentheses following the model: (PBO, CZP 200 mg Q2W, CZP 200 mg Q4W). 999 is used as a placeholder for values below the level of detection.

End point type	Secondary

End point timeframe:

From Week 0 until the Safety Follow-up Visit (10 weeks after the last dose of study medication)

End point values	Placebo Double-Blind (PKSB)	Certolizumab pegol 200 mg Q2W Double-Blind (PKSB)	Certolizumab pegol 200 mg Q4W Double-Blind (PKSB)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	101	102	105	
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
Part A Baseline (99, 101, 105)	999 (± 999)	999 (± 999)	999 (± 999)	
Week 4 (101, 100, 104)	48.71 (± 85.76)	53.39 (± 30.93)	48.92 (± 43.17)	
Week 12 (100, 101, 105)	30.91 (± 89.23)	31.74 (± 50.79)	30.69 (± 56.82)	
Week 24 (100, 101, 104)	26.31 (± 135.58)	30.23 (± 46.57)	28.96 (± 58.38)	
Week 48/Part B Baseline (98, 100, 104)	36.28 (± 74.18)	36.59 (± 84.36)	31.11 (± 138.29)	
Week 60 (98, 100, 105)	999 (± 999)	27.76 (± 49.47)	6.95 (± 178.27)	
Week 72 (76, 95, 99)	999 (± 999)	26.36 (± 105.58)	7.61 (± 176.39)	
Week 84 (38, 91, 90)	999 (± 999)	26.57 (± 44.90)	8.00 (± 113.48)	
Week 96 (27, 86, 85)	999 (± 999)	24.76 (± 97.60)	7.16 (± 131.76)	
Withdrawal Visit (4, 3, 5)	0.81 (± 1802.40)	999 (± 999)	0.30 (± 2621.06)	
Escape Week 0/Flare Baseline (72, 6, 14)	999 (± 999)	30.77 (± 19.78)	12.70 (± 98.45)	
Escape Week 2 (71, 6, 15)	18.27 (± 488.45)	33.50 (± 21.17)	15.43 (± 124.10)	
Escape Week 4 (71, 6, 15)	37.32 (± 151.18)	32.94 (± 30.48)	18.43 (± 79.93)	
Escape Week 12 (69, 6, 15)	23.89 (± 232.36)	23.76 (± 65.42)	19.14 (± 136.22)	
Escape Week 24 (54, 3, 8)	27.47 (± 45.31)	999 (± 999)	19.23 (± 66.68)	
Escape Week 36 (14, 3, 3)	24.88 (± 77.53)	999 (± 999)	999 (± 999)	
Last Visit (Week 96) (66, 6, 14)	24.64 (± 112.75)	26.19 (± 54.74)	18.59 (± 95.75)	
Withdrawal Escape Visit (4, 1, 0)	4.71 (± 133329.3)	999 (± 999)	0 (± 0)	
Safety Follow-up (92, 92, 98)	999 (± 999)	0.52 (± 1158.85)	0.14 (± 772.54)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with positive anti-certolizumab pegol-antibody levels in plasma during the study

End point title	Percentage of participants with positive anti-certolizumab pegol-antibody levels in plasma during the study

End point description:

Treatment emergent ADAb status positive was defined as either baseline ADAb negative subjects having

at least one ADAb confirmed positive sample post baseline or baseline ADAb positive subjects with at least one post baseline sample with >= minimum significant ratio (MSR) increase from baseline on CZP treatment. Once determined positive, the highest titer during Part A and Part B (including Escape and Safety Follow up) was used to categorize the subject.
The primary purpose of the study was to evaluate treatment options for axSpA patients after being in sustained remission. Hence, one of the objectives was to evaluate the immunogenicity of these patients. The ADAb titer of the patients that did not reach sustained remission were therefore not analysed, and the Pharmacokinetic Set A as described in the protocol was removed from the SAP.

End point type	Secondary

End point timeframe:

From Week 0 until the Safety Follow-up Visit (10 weeks after the last dose of study medication)

End point values	Placebo Double-Blind (PKSB)	Certolizumab pegol 200 mg Q2W Double-Blind (PKSB)	Certolizumab pegol 200 mg Q4W Double-Blind (PKSB)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	101	102	105	
Units: percentage of participants				
number (not applicable)	100	96.1	100	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with at least one Adverse Event (AE) during Part A of the study

End point title	Percentage of participants with at least one Adverse Event (AE) during Part A of the study

End point description:

An AE was any untoward medical occurrence in a patient or clinical investigation study participant administered a pharmaceutical product that did not necessarily have a causal relationship with this treatment. An AE could therefore have been any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

End point type	Secondary

End point timeframe:

From Screening Period (Week -5 to Week -1) until Week 48

End point values	Certolizumab pegol Open-Label (SS) Wk 0-48			
Subject group type	Subject analysis set			
Number of subjects analysed	736			
Units: percentage of participants				
number (not applicable)				
Screening Period (Week -5 to Week -1)	7.3			
Open-Label Period (Week 0 to Week 48)	67.9			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with at least one Adverse Event (AE) during Part B of the study

End point title	Percentage of participants with at least one Adverse Event (AE) during Part B of the study

End point description:

An AE was any untoward medical occurrence in a patient or clinical investigation study participant administered a pharmaceutical product that did not necessarily have a causal relationship with this treatment. An AE could therefore have been any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.
For subjects with flare in Part B and do escape to CZP full-dose therapy, only TEAEs with an onset date prior to the start date of escape CZP full-dose therapy were included.

End point type	Secondary

End point timeframe:

From Week 0 until the Safety Follow-up Visit (10 weeks after the last dose of study medication)

End point values	Placebo Double-Blind (SSB) Wk 48–96	Certolizumab pegol 200 mg Q2W Double-Blind (SSB) Wk 48–96	Certolizumab pegol 200 mg Q4W Double-Blind (SSB) Wk 48–96	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	103	104	105	
Units: percentage of participants				
number (not applicable)	54.4	57.7	61.0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with at least one Adverse Event (AE) and who experienced a flare during Part B of the study

End point title	Percentage of participants with at least one Adverse Event (AE) and who experienced a flare during Part B of the study

End point description:

An AE was any untoward medical occurrence in a patient or clinical investigation study participant administered a pharmaceutical product that did not necessarily have a causal relationship with this treatment. An AE could therefore have been any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.
For subjects with flare in Part B and do escape to CZP full-dose therapy, only TEAEs with an onset date

after or on the start date of escape CZP full-dose therapy were included.

End point type	Secondary

End point timeframe:

From time of flare to Escape Week 12

End point values	Placebo DB/CZP 200 mg Q2W Escape (ETS) Escape Wk 0–>=12	CZP 200 mg Q2W DB/CZP 200 mg Q2W Escape (ETS) Escape Wk 0–>=12	CZP 200 mg Q4W DB/CZP 200 mg Q2W Escape (ETS) Escape Wk 0–>=12	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	72	6	15	
Units: percentage of participants				
number (not applicable)	51.4	83.3	46.7	

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Adverse events were collected from Week 0 (Baseline) until the Safety Follow-Up Period (10 weeks after the last dose of study medication).

Adverse event reporting additional description:

TEAEs counts are for each study period: Open-Label (Wk0-48), Double-Blind (Wk48-96) and Escape (Wk0-12). During Escape (last 3 columns) all participants received CZP 200 mg Q2W at time of TEAEs, although they were coming from 3 arms of the double-blind phase. Participants randomized or who entered escape but received no treatment are not included.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups

Reporting group title	Certolizumab pegol Open-Label (SS) Wk 0-48

Reporting group description:

Participants in this arm received certolizumab pegol (CZP) 400 mg subcutaneous (sc) on Weeks 0, 2 and 4, followed by 200 mg CZP sc every 2 weeks (Q2W) from Week 6 to Week 48 (Part A). Participants in sustained remission at Week 48 were eligible for randomization into Part B.
Participants formed the Safety Set (SS).

Reporting group title	Placebo Double-Blind (SSB) Wk 48–96

Reporting group description:

Participants in this arm received Placebo subcutaneous (sc) every 2 weeks from Week 48 onwards.
Participants formed the Safety Set Part B (SSB).

Reporting group title	Certolizumab pegol 200 mg Q2W Double-Blind (SSB) Wk 48–96

Reporting group description:

Participants in this arm received certolizumab pegol (CZP) 200 mg subcutaneous (sc) every 2 weeks (Q2W) from Week 48 onwards.
Participants formed the SSB.

Reporting group title	Certolizumab pegol 200 mg Q4W Double-Blind (SSB) Wk 48–96

Reporting group description:

Participants in this arm received certolizumab pegol (CZP) 200 mg subcutaneous (sc) every 4 weeks (Q4W) from Week 48 onwards. At visits where CZP was not received, subjects received one injection of Placebo to maintain the study blind.
Participants formed the SSB.

Reporting group title	Placebo DB/CZP 200 mg Q2W Escape (ETS) Escape Wk 0–>=12

Reporting group description:

Participants randomized to Placebo who met flare criteria received CZP 400 mg subcutaneous (sc) every 2 weeks (Q2W) for the first 3 visits after flare has been confirmed. After that, CZP 200 mg was given every 2 weeks in open-label fashion. The duration was from starting escape treatment after flare until Week 96 with a minimum of 12 weeks.
Participants formed the Escape Therapy Set (ETS).

Reporting group title	CZP 200 mg Q2W DB/CZP 200 mg Q2W Escape (ETS) Escape Wk 0–>=12

Reporting group description:

Participants randomized to CZP 200 mg Q2W who meet flare criteria received CZP 200 mg subcutaneous (sc) every 2 weeks (Q2W) for all visits after flare has been confirmed. At the first 3 visits after flare has been confirmed, participants received one injection of 200 mg CZP and one injection of Placebo to maintain the study blind. The duration was from starting escape treatment after flare until Week 96 with a minimum of 12 weeks.
Participants formed the ETS.

Reporting group title	CZP 200 mg Q4W DB/CZP 200 mg Q2W Escape (ETS) Escape Wk 0–>=12

Reporting group description:

Participants randomized to CZP 200 mg Q4W who meet flare criteria received CZP 200 mg subcutaneous (sc) every 2 weeks (Q2W) for all visits after flare has been confirmed. At the first 3 visits after flare has been confirmed, participants received one injection of 200 mg CZP and one injection of Placebo to maintain the study blind. The duration was from starting escape treatment after flare until Week 96 with a minimum of 12 weeks.
Participants formed the ETS.

Serious adverse events	Certolizumab pegol Open-Label (SS) Wk 0-48	Placebo Double-Blind (SSB) Wk 48–96	Certolizumab pegol 200 mg Q2W Double-Blind (SSB) Wk 48–96
Total subjects affected by serious adverse events			
subjects affected / exposed	44 / 736 (5.98%)	0 / 103 (0.00%)	5 / 104 (4.81%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Pregnancy on contraceptive			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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			
Endometrial hyperplasia			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			

subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Nasal septum deviation			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Schizophrenia			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Investigations			
False positive tuberculosis test			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Injury, poisoning and procedural complications			
Meniscus injury			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Foot fracture			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Epicondylitis			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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

Ligament rupture			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Tendon rupture			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Limb injury			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Cardiac disorders			
Tachycardia			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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			
Migraine			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Optic neuritis			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Eye disorders			
Retinal vein occlusion			

subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Gastrointestinal disorders			
Pancreatitis acute			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	1 / 104 (0.96%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	2 / 736 (0.27%)	0 / 103 (0.00%)	0 / 104 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dental caries			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Glossitis			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Crohn's disease			
subjects affected / exposed	0 / 736 (0.00%)	0 / 103 (0.00%)	1 / 104 (0.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 736 (0.00%)	0 / 103 (0.00%)	1 / 104 (0.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Irritable bowel syndrome			
subjects affected / exposed	0 / 736 (0.00%)	0 / 103 (0.00%)	0 / 104 (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
Skin and subcutaneous tissue disorders			

Dermatitis atopic			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Dyshidrotic eczema			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Pustular psoriasis			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Urticaria			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Renal and urinary disorders			
Ureterolithiasis			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Axial spondyloarthritis			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Infections and infestations			
Appendicitis			

subjects affected / exposed	2 / 736 (0.27%)	0 / 103 (0.00%)	0 / 104 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perirectal abscess			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Meningitis aseptic			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Pulpitis dental			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Hepatitis E			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Abscess limb			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Wound infection			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Pneumonia			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Pneumonia mycoplasmal			

subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Pulmonary tuberculosis			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Tuberculous pleurisy			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Peritonsillar abscess			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Pyelonephritis			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (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
Anal abscess			
subjects affected / exposed	0 / 736 (0.00%)	0 / 103 (0.00%)	1 / 104 (0.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Latent tuberculosis			
subjects affected / exposed	0 / 736 (0.00%)	0 / 103 (0.00%)	1 / 104 (0.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Certolizumab pegol 200 mg Q4W Double-Blind (SSB) Wk 48–96	Placebo DB/CZP 200 mg Q2W Escape (ETS) Escape Wk 0–>=12	CZP 200 mg Q2W DB/CZP 200 mg Q2W Escape (ETS) Escape Wk 0–>=12
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	1 / 6 (16.67%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Pregnancy on contraceptive			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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			
Drug hypersensitivity			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Reproductive system and breast disorders			
Endometrial hyperplasia			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Nasal septum deviation			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Schizophrenia			

subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Investigations			
False positive tuberculosis test			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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			
Meniscus injury			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Foot fracture			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Epicondylitis			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Ligament rupture			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Tendon rupture			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Limb injury			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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

Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Nervous system disorders			
Migraine			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Optic neuritis			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Eye disorders			
Retinal vein occlusion			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Gastrointestinal disorders			
Pancreatitis acute			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Colitis ulcerative			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Dental caries			

subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Glossitis			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Crohn's disease			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Intestinal obstruction			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Irritable bowel syndrome			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Dyshidrotic eczema			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Pustular psoriasis			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Urticaria			

subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Renal and urinary disorders			
Ureterolithiasis			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Axial spondyloarthritis			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Perirectal abscess			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Meningitis aseptic			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Pulpitis dental			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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

Hepatitis E			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Abscess limb			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Wound infection			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Pneumonia			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Pneumonia mycoplasmal			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Pulmonary tuberculosis			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Tuberculous pleurisy			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Peritonsillar abscess			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Pyelonephritis			

subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Anal abscess			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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
Latent tuberculosis			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (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	CZP 200 mg Q4W DB/CZP 200 mg Q2W Escape (ETS) Escape Wk 0–>=12		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 15 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pregnancy on contraceptive			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Endometrial hyperplasia			

subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nasal septum deviation			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Schizophrenia			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
False positive tuberculosis test			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Meniscus injury			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foot fracture			

subjects affected / exposed	0 / 15 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Epicondylitis				
subjects affected / exposed	0 / 15 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ligament rupture				
subjects affected / exposed	0 / 15 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tendon rupture				
subjects affected / exposed	0 / 15 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Limb injury				
subjects affected / exposed	0 / 15 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Tachycardia				
subjects affected / exposed	0 / 15 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Migraine				
subjects affected / exposed	0 / 15 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Optic neuritis				
subjects affected / exposed	0 / 15 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				

Lymphadenopathy				
subjects affected / exposed	0 / 15 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eye disorders				
Retinal vein occlusion				
subjects affected / exposed	0 / 15 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Pancreatitis acute				
subjects affected / exposed	0 / 15 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colitis ulcerative				
subjects affected / exposed	0 / 15 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dental caries				
subjects affected / exposed	0 / 15 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Glossitis				
subjects affected / exposed	0 / 15 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Crohn's disease				
subjects affected / exposed	0 / 15 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal obstruction				
subjects affected / exposed	0 / 15 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Irritable bowel syndrome			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dyshidrotic eczema			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pustular psoriasis			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urticaria			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Ureterolithiasis			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Axial spondyloarthritis			

subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Perirectal abscess			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meningitis aseptic			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulpitis dental			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatitis E			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abscess limb			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound infection			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia			

subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia mycoplasmal			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary tuberculosis			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tuberculous pleurisy			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peritonsillar abscess			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anal abscess			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Latent tuberculosis			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Certolizumab pegol Open-Label (SS) Wk 0-48	Placebo Double-Blind (SSB) Wk 48–96	Certolizumab pegol 200 mg Q2W Double-Blind (SSB) Wk 48–96
Total subjects affected by non-serious adverse events			
subjects affected / exposed	188 / 736 (25.54%)	25 / 103 (24.27%)	31 / 104 (29.81%)
Investigations			
Antinuclear antibody increased			
subjects affected / exposed	0 / 736 (0.00%)	0 / 103 (0.00%)	0 / 104 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Cervicogenic vertigo			
subjects affected / exposed	0 / 736 (0.00%)	0 / 103 (0.00%)	0 / 104 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	0 / 736 (0.00%)	0 / 103 (0.00%)	0 / 104 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Influenza like illness			
subjects affected / exposed	8 / 736 (1.09%)	1 / 103 (0.97%)	0 / 104 (0.00%)
occurrences (all)	9	1	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	4 / 736 (0.54%)	0 / 103 (0.00%)	0 / 104 (0.00%)
occurrences (all)	4	0	0
Eye disorders			
Iritis			
subjects affected / exposed	0 / 736 (0.00%)	0 / 103 (0.00%)	0 / 104 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Irritable bowel syndrome			
subjects affected / exposed	2 / 736 (0.27%)	0 / 103 (0.00%)	0 / 104 (0.00%)
occurrences (all)	2	0	0

Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	12 / 736 (1.63%)	0 / 103 (0.00%)	3 / 104 (2.88%)
occurrences (all)	14	0	3
Musculoskeletal and connective tissue disorders			
Axial spondyloarthritis			
subjects affected / exposed	8 / 736 (1.09%)	8 / 103 (7.77%)	6 / 104 (5.77%)
occurrences (all)	8	8	6
Joint stiffness			
subjects affected / exposed	0 / 736 (0.00%)	0 / 103 (0.00%)	0 / 104 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	117 / 736 (15.90%)	8 / 103 (7.77%)	12 / 104 (11.54%)
occurrences (all)	156	8	17
Upper respiratory tract infection			
subjects affected / exposed	63 / 736 (8.56%)	10 / 103 (9.71%)	12 / 104 (11.54%)
occurrences (all)	88	12	14
Pharyngitis			
subjects affected / exposed	22 / 736 (2.99%)	3 / 103 (2.91%)	2 / 104 (1.92%)
occurrences (all)	24	3	2
Oral herpes			
subjects affected / exposed	13 / 736 (1.77%)	2 / 103 (1.94%)	1 / 104 (0.96%)
occurrences (all)	21	3	3
Hordeolum			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	9 / 736 (1.22%)	1 / 103 (0.97%)	3 / 104 (2.88%)
occurrences (all)	9	1	3
Bronchitis			
subjects affected / exposed	24 / 736 (3.26%)	3 / 103 (2.91%)	0 / 104 (0.00%)
occurrences (all)	25	3	0
Conjunctivitis			
subjects affected / exposed	6 / 736 (0.82%)	1 / 103 (0.97%)	0 / 104 (0.00%)
occurrences (all)	6	1	0

Furuncle			
subjects affected / exposed	1 / 736 (0.14%)	0 / 103 (0.00%)	0 / 104 (0.00%)
occurrences (all)	1	0	0
Laryngitis			
subjects affected / exposed	0 / 736 (0.00%)	0 / 103 (0.00%)	0 / 104 (0.00%)
occurrences (all)	0	0	0
Latent tuberculosis			
subjects affected / exposed	5 / 736 (0.68%)	0 / 103 (0.00%)	3 / 104 (2.88%)
occurrences (all)	5	0	3
Sinusitis			
subjects affected / exposed	12 / 736 (1.63%)	1 / 103 (0.97%)	0 / 104 (0.00%)
occurrences (all)	12	1	0

Non-serious adverse events	Certolizumab pegol 200 mg Q4W Double-Blind (SSB) Wk 48–96	Placebo DB/CZP 200 mg Q2W Escape (ETS) Escape Wk 0–>=12	CZP 200 mg Q2W DB/CZP 200 mg Q2W Escape (ETS) Escape Wk 0–>=12
Total subjects affected by non-serious adverse events			
subjects affected / exposed	26 / 105 (24.76%)	20 / 72 (27.78%)	5 / 6 (83.33%)
Investigations			
Antinuclear antibody increased			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Nervous system disorders			
Cervicogenic vertigo			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Sciatica			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Influenza like illness			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Immune system disorders			

Drug hypersensitivity			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Eye disorders			
Iritis			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Irritable bowel syndrome			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	2 / 105 (1.90%)	0 / 72 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal and connective tissue disorders			
Axial spondyloarthritis			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Joint stiffness			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	13 / 105 (12.38%)	8 / 72 (11.11%)	2 / 6 (33.33%)
occurrences (all)	18	9	2
Upper respiratory tract infection			
subjects affected / exposed	11 / 105 (10.48%)	5 / 72 (6.94%)	1 / 6 (16.67%)
occurrences (all)	12	7	1
Pharyngitis			
subjects affected / exposed	6 / 105 (5.71%)	2 / 72 (2.78%)	0 / 6 (0.00%)
occurrences (all)	6	2	0
Oral herpes			
subjects affected / exposed	2 / 105 (1.90%)	1 / 72 (1.39%)	1 / 6 (16.67%)
occurrences (all)	2	1	3
Hordeolum			

subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	1 / 105 (0.95%)	2 / 72 (2.78%)	1 / 6 (16.67%)
occurrences (all)	1	3	1
Bronchitis			
subjects affected / exposed	3 / 105 (2.86%)	1 / 72 (1.39%)	0 / 6 (0.00%)
occurrences (all)	3	1	0
Conjunctivitis			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Furuncle			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Latent tuberculosis			
subjects affected / exposed	2 / 105 (1.90%)	1 / 72 (1.39%)	0 / 6 (0.00%)
occurrences (all)	2	1	0
Sinusitis			
subjects affected / exposed	2 / 105 (1.90%)	0 / 72 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0

Non-serious adverse events	CZP 200 mg Q4W DB/CZP 200 mg Q2W Escape (ETS) Escape Wk 0–>=12		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 15 (46.67%)		
Investigations			
Antinuclear antibody increased			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Cervicogenic vertigo			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Sciatica			

subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0		
Blood and lymphatic system disorders Iron deficiency anaemia subjects affected / exposed occurrences (all)	 1 / 15 (6.67%) 1		
General disorders and administration site conditions Influenza like illness subjects affected / exposed occurrences (all)	 0 / 15 (0.00%) 0		
Immune system disorders Drug hypersensitivity subjects affected / exposed occurrences (all)	 0 / 15 (0.00%) 0		
Eye disorders Iritis subjects affected / exposed occurrences (all)	 1 / 15 (6.67%) 1		
Gastrointestinal disorders Irritable bowel syndrome subjects affected / exposed occurrences (all)	 0 / 15 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders Oropharyngeal pain subjects affected / exposed occurrences (all)	 1 / 15 (6.67%) 1		
Musculoskeletal and connective tissue disorders Axial spondyloarthritis subjects affected / exposed occurrences (all) Joint stiffness subjects affected / exposed occurrences (all)	 0 / 15 (0.00%) 0 1 / 15 (6.67%) 1		
Infections and infestations Nasopharyngitis			

subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Upper respiratory tract infection			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Pharyngitis			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Oral herpes			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Hordeolum			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Influenza			
subjects affected / exposed	0 / 15 (0.00%)		
occurrences (all)	0		
Bronchitis			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Conjunctivitis			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Furuncle			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Laryngitis			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Latent tuberculosis			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Sinusitis			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
24 November 2015	Global Protocol Amendment 1 (dated 24 Nov 2015) was a substantial protocol amendment implemented to include additional efficacy variables for study participants who entered Part A and Part B of the study, as well as a completely new list of other efficacy variables for those study participants who experienced a flare in Part B. For the purposes of analysis, 4 new analysis sets were defined, 2 of which were to be used in the pharmacokinetic (PK) analysis, 1 which was to be used in the efficacy analysis of study participants who experienced a flare in Part B, and 1 which was to be used to evaluate safety in study participants who ever received treatment with full-dose CZP during Part B of the study. Several clarifications were made including the time point for the assessment of the secondary efficacy variables for study participants who experienced a flare in Part B, human leukocyte antigen B27 (HLA-B27) as a Screening laboratory assessment, and the assessments to be performed 3 to 5 days prior to Week 48. Inconsistencies in the naming of Week 96 Visit and assessments were corrected, study personnel information was updated, and minor editorial changes were made.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported