



Clinical trial results:

A Golimumab Phase 3b, Multicenter, Switch Assessment of Subcutaneous and Intravenous Efficacy in Rheumatoid Arthritis Patients Who Have Inadequate Disease Control Despite Treatment with Etanercept (ENBREL®) or Adalimumab (HUMIRA®)

Due to a system error, the data reported in v1 is not correct and has been removed from public view.

Summary

EudraCT number	2009-010582-23
Trial protocol	DE BE AT SE GR IT GB
Global end of trial date	03 October 2013

Results information

Result version number	v2 (current)
This version publication date	16 July 2016
First version publication date	30 July 2015
Version creation reason	• Correction of full data set Review of data

Trial information

Trial identification

Sponsor protocol code	CNT0148ART3002
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01004432
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Biologics B.V.
Sponsor organisation address	Archimedesweg 29, Leiden, Netherlands, 2333 CM
Public contact	Clinical Registry Group, Janssen Biologics B.V., clinicaltrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen Biologics B.V., clinicaltrialsEU@its.jnj.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	03 October 2013
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	03 October 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to evaluate the efficacy of Golimumab + Methotrexate (MTX) in reducing signs and symptoms of Rheumatoid Arthritis (RA) (as assessed by the American College of Rheumatology [ACR] 20) at Week 14 in Participants with inadequate disease control despite treatment with etanercept + MTX or adalimumab + MTX.

Protection of trial subjects:

Safety evaluations included physical examinations, vital sign measurements, chest x-ray, tuberculosis (TB) testing, pregnancy tests, urinalysis, routine laboratory tests, and tests for hepatitis B virus (HBV) infection, as well as monitoring concomitant medications and adverse events (including injection-site reactions and infusion reactions).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	29 October 2009
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 1
Country: Number of subjects enrolled	Belgium: 9
Country: Number of subjects enrolled	Canada: 37
Country: Number of subjects enrolled	Germany: 7
Country: Number of subjects enrolled	United Kingdom: 9
Country: Number of subjects enrolled	Greece: 8
Country: Number of subjects enrolled	Italy: 12
Country: Number of subjects enrolled	Sweden: 1
Country: Number of subjects enrolled	United States: 349
Worldwide total number of subjects	433
EEA total number of subjects	47

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)	339
From 65 to 84 years	94
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Approximately 400 participants were planned. A total of 696 Participants entered the screening run-in period, 433 enrolled in the open-label treatment period of the study at Week 0, and 350 entered the continued open-label/double-blind treatment period at Week 16.

Period 1

Period 1 title	Open-label (OL) Period (Week 0 – 16)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Open-label (OL) Overall Group: Golimumab 50 mg SC + MTX
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Arm description:

All Participants received golimumab 50 mg SC injection every 4 weeks + MTX from Week 0 to Week 12.

Arm type	Experimental
Investigational medicinal product name	Golimumab
Investigational medicinal product code	CNTO 148
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

All Participants receive golimumab 50 milligram (mg) subcutaneous (SC) injection every 4 weeks+Methotrexate (MTX) from Week 0 to Week 12.

Number of subjects in period 1	Open-label (OL) Overall Group: Golimumab 50 mg SC + MTX
Started	433
Completed	350
Not completed	83
Consent withdrawn by subject	17
Adverse event, non-fatal	20
Lost to follow-up	2
Protocol deviation	29
Lack of efficacy	15

Period 2

Period 2 title	OL/Double-Blind (DB) Period (Week 16-52)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Carer, Assessor, Subject

Arms

Are arms mutually exclusive?	Yes
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Arm title	OL Group 1: Golimumab 50 mg SC + MTX
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Arm description:

Participants, who achieved Disease Activity Score in 28 joints (DAS28) good response at Week 16, received Golimumab 50 milligram (mg) subcutaneous (SC) injection every 4 weeks + Methotrexate (MTX) from Week 16 to Week 48.

Arm type	Experimental
Investigational medicinal product name	Golimumab
Investigational medicinal product code	CNTO 148
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants, who achieved Disease Activity Score in 28 joints (DAS28) good response at Week 16, received Golimumab 50 milligram (mg) subcutaneous (SC) injection every 4 weeks + Methotrexate (MTX) from Week 16 to Week 48.

Arm title	Double Blind (DB) Group 2a: Golimumab 50mg SC & Placebo IV+M
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Arm description:

Participants, who did not achieve DAS28 good response at Week 16, were randomly assigned to receive golimumab 50 mg SC injection every 4 weeks + MTX from Week 16 to Week 48, along with placebo matched to golimumab intravenous infusion (IV) at Week 16, 20, 28, 36, and 44.

Arm type	Experimental
Investigational medicinal product name	Golimumab
Investigational medicinal product code	CNTO 148
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants, who did not achieve Disease Activity Score in 28 joints (DAS28) good response at Week 16, were randomly assigned to receive golimumab 50 mg SC injection every 4 weeks + MTX from Week 16 to Week 48, along with placebo matched to golimumab intravenous infusion (IV) at Week 16, 20, 28, 36, and 44.

Arm title	DB Group 2b: Golimumab 2mg/kg IV & Placebo SC + MTX
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Arm description:

Participants, who did not achieve Disease Activity Score in 28 joints (DAS28) good response at Week 16, were randomly assigned to receive golimumab 2 milligram per kilogram (mg/kg) intravenous infusion (IV) + MTX, at Week 16, 20, 28, 36 and 44, along with placebo matched to golimumab SC injection every 4 weeks from Week 16 to Week 48.

Arm type	Experimental
Investigational medicinal product name	Golimumab
Investigational medicinal product code	CNTO 148
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants, who did not achieve Disease Activity Score in 28 joints (DAS28) good response at Week 16,

were randomly assigned to receive golimumab 2 milligram per kilogram (mg/kg) intravenous infusion (IV) + MTX, at Week 16, 20, 28, 36 and 44, along with placebo matched to golimumab SC injection every 4 weeks from Week 16 to Week 48.

Number of subjects in period 2	OL Group 1: Golimumab 50 mg SC + MTX	Double Blind (DB) Group 2a: Golimumab 50mg SC & Placebo IV+M	DB Group 2b: Golimumab 2mg/kg IV & Placebo SC + MTX
Started	75	91	184
Completed	65	54	126
Not completed	10	37	58
Consent withdrawn by subject	1	4	7
Adverse event, non-fatal	1	5	6
Death	-	-	1
Lost to follow-up	3	1	3
Protocol deviation	3	3	4
Lack of efficacy	2	24	37

Period 3

Period 3 title	OL Study Extension (Week 52 - 76)
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	OL Study Extension Group: Golimumab 50 mg SC + MTX
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Arm description:

Participants who completed the main study (Week 0 to Week 52), not met lack of efficacy criteria, and participated in the OL study extension, received golimumab 50 mg SC injection every 4 weeks + MTX from Week 52 to Week 72.

Arm type	Experimental
Investigational medicinal product name	Golimumab
Investigational medicinal product code	CNTO 148
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants not met lack of efficacy criteria, and participated in the OL study extension, received golimumab 50 mg SC injection every 4 weeks + MTX from Week 52 to Week 72.

Number of subjects in period 3^[1]	OL Study Extension Group: Golimumab 50 mg SC + MTX
Started	212
Completed	194
Not completed	18
Consent withdrawn by subject	2
Adverse event, non-fatal	2
Protocol deviation	4
Lack of efficacy	10

Notes:

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

Justification: Participants who completed the main study and did not meet lack of efficacy criteria, participated in the OL study extension.

Baseline characteristics

Reporting groups

Reporting group title	Open-label (OL) Period (Week 0 – 16)
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Reporting group description: -

Reporting group values	Open-label (OL) Period (Week 0 – 16)	Total	
Number of subjects	433	433	
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	339	339	
From 65 to 84 years	94	94	
85 years and over	0	0	
Title for AgeContinuous Units: years			
arithmetic mean	55.7		
standard deviation	± 11.52	-	
Title for Gender Units: subjects			
Female	358	358	
Male	75	75	

End points

End points reporting groups

Reporting group title	Open-label (OL) Overall Group: Golimumab 50 mg SC + MTX
Reporting group description: All Participants received golimumab 50 mg SC injection every 4 weeks + MTX from Week 0 to Week 12.	
Reporting group title	OL Group 1: Golimumab 50 mg SC + MTX
Reporting group description: Participants, who achieved Disease Activity Score in 28 joints (DAS28) good response at Week 16, received Golimumab 50 milligram (mg) subcutaneous (SC) injection every 4 weeks + Methotrexate (MTX) from Week 16 to Week 48.	
Reporting group title	Double Blind (DB) Group 2a: Golimumab 50mg SC & Placebo IV+M
Reporting group description: Participants, who did not achieve DAS28 good response at Week 16, were randomly assigned to receive golimumab 50 mg SC injection every 4 weeks + MTX from Week 16 to Week 48, along with placebo matched to golimumab intravenous infusion (IV) at Week 16, 20, 28, 36, and 44.	
Reporting group title	DB Group 2b: Golimumab 2mg/kg IV & Placebo SC + MTX
Reporting group description: Participants, who did not achieve Disease Activity Score in 28 joints (DAS28) good response at Week 16, were randomly assigned to receive golimumab 2 milligram per kilogram (mg/kg) intravenous infusion (IV) + MTX, at Week 16, 20, 28, 36 and 44, along with placebo matched to golimumab SC injection every 4 weeks from Week 16 to Week 48.	
Reporting group title	OL Study Extension Group: Golimumab 50 mg SC + MTX
Reporting group description: Participants who completed the main study (Week 0 to Week 52), not met lack of efficacy criteria, and participated in the OL study extension, received golimumab 50 mg SC injection every 4 weeks + MTX from Week 52 to Week 72.	
Subject analysis set title	Modified Intent To Treat (mITT)
Subject analysis set type	Modified intention-to-treat
Subject analysis set description: Modified Intent To Treat (mITT) Population included all enrolled participants who had Week 0 measurements and received at least 1 dose of study drug.	
Subject analysis set title	Open-label modified Intent To Treat (mITT)
Subject analysis set type	Modified intention-to-treat
Subject analysis set description: Open-label modified Intent To Treat (mITT) population included all participants, who received at least 1 open-label Golimumab 50 milligram (mg) subcutaneous (SC) injection during the continued open-label/double-blind treatment period.	
Subject analysis set title	Double-blind modified Intent To Treat (mITT)
Subject analysis set type	Modified intention-to-treat
Subject analysis set description: Double-blind modified Intent To Treat (mITT) population included Participants who were randomized at Week 16 to subcutaneous (SC) or IV Golimumab (Groups 2a and 2b) and received at least 1 dose of study drug after randomization.	

Primary: Percentage of Participants Achieving Erythrocyte Sedimentation Rate Based ACR 20 Response at Week 14

End point title	Percentage of Participants Achieving Erythrocyte Sedimentation Rate Based ACR 20 Response at Week 14 ^[1]
End point description: Erythrocyte Sedimentation Rate (ESR)-based ACR 20 response: greater than or equal to (\geq) 20 percent (%) improvement from Baseline in tender (68 joints assessed) and swollen (66 joints assessed) joint counts and \geq 20% improvement from Baseline in 3 of the following 5 assessments: 1- Participant's assessment of pain using Visual Analog Scale (VAS) (0 to 10 centimeters [cm]), 2- Participant's global assessment of disease activity using VAS (0 to 10 cm), 3- Physician's global assessment of disease	

activity using VAS (0 to 10 cm), 4- Participant's assessment of physical function as measured by the Disability Index of the Health Assessment Questionnaire (HAQ-DI) (score of 0-3 in 8 functional areas), 5- ESR.

End point type	Primary
End point timeframe:	
week 14	

Notes:

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

Justification: No statistical analysis were performed for this endpoint.

End point values	Open-label (OL) Overall Group: Golimumab 50 mg SC + MTX			
Subject group type	Reporting group			
Number of subjects analysed	433			
Units: Percentage of Participants				
number (confidence interval 95%)	34.9 (30.4 to 39.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved Erythrocyte Sedimentation rate Based ACR20 Response at Week 2

End point title	Percentage of Participants Who Achieved Erythrocyte Sedimentation rate Based ACR20 Response at Week 2
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End point description:

Erythrocyte Sedimentation Rate (ESR)-based ACR 20 response: greater than or equal to (\geq) 20 percent (%) improvement from Baseline in tender (68 joints assessed) and swollen (66 joints assessed) joint counts and \geq 20% improvement from Baseline in 3 of the following 5 assessments: 1- Participant's assessment of pain using Visual Analog Scale (VAS) (0 to 10 centimeters [cm]), 2- Participant's global assessment of disease activity using VAS (0 to 10 cm), 3- Physician's global assessment of disease activity using VAS (0 to 10 cm), 4- Participant's assessment of physical function as measured by the Disability Index of the Health Assessment Questionnaire (HAQ-DI) (score of 0-3 in 8 functional areas),

End point type	Secondary
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End point timeframe:

Within 2 weeks of initiating therapy

End point values	Open-label (OL) Overall Group: Golimumab 50 mg SC + MTX			
Subject group type	Reporting group			
Number of subjects analysed	433			
Units: Percentage of Participants				
number (confidence interval 95%)	24.5 (20.4 to			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved Erythrocyte Sedimentation Rate based DAS28 Response at Week 16 and Through Week 52

End point title	Percentage of Participants Who Achieved Erythrocyte Sedimentation Rate based DAS28 Response at Week 16 and Through Week 52
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End point description:

Erythrocyte Sedimentation Rate (ESR)-based disease activity score for 28-joints count (DAS28) as defined by European League Against Rheumatism (EULAR), response criteria was used to assess individual response as none, moderate, or good, depending on the extent of change from Baseline and the level of disease activity reached. A participant was classified as having achieved a DAS28 good response if, DAS28 was less than or equal to (\leq) 3.2 at a given visit and improvement from Baseline was >1.2 . Percentage of participants, who achieved ESR-based DAS 28 good response at Week 16 and maintained that response through Week 52, was reported.

End point type	Secondary
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End point timeframe:

Week 52

End point values	Double Blind (DB) Group 2a: Golimumab 50mg SC & Placebo IV+M	DB Group 2b: Golimumab 2mg/kg IV & Placebo SC + MTX		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	91	184		
Units: Percentage of Participants				
number (confidence interval 95%)	13.2 (6.2 to 20.1)	9.2 (5.1 to 13.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved Erythrocyte Sedimentation Rate - Based ACR20 Response at Week 52 Relative to Week 16

End point title	Percentage of Participants Who Achieved Erythrocyte Sedimentation Rate - Based ACR20 Response at Week 52 Relative to Week 16
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End point description:

Erythrocyte Sedimentation Rate (ESR)-based ACR 20 response: ≥ 20 % improvement from Week 16 in tender (68 joints assessed) and swollen (66 joints assessed) joint counts and ≥ 20 % improvement from Week 16 in 3 of the following 5 assessments: 1- Participant's assessment of pain using VAS (0 to

10 cm), 2- Participant's global assessment of disease activity using VAS (0 to 10 cm), 3- Physician's global assessment of disease activity using VAS (0 to 10 cm), 4- Participant's assessment of physical function as measured by the Disability Index of the Health Assessment Questionnaire (HAQ-DI) (score of 0-3 in 8 functional areas), 5- ESR. Percentage of participants, who achieved ESR-based ACR 20 responses at Week 52 relative to Week 16, was reported.

End point type	Secondary
End point timeframe:	
Week 52	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved ESR-based and C-Reactive Protein (CRP) - Based ACR20 Response at Week 76 Relative to Week 16

End point title	Percentage of Participants Who Achieved ESR-based and C-Reactive Protein (CRP) - Based ACR20 Response at Week 76 Relative to Week 16
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End point description:

Erythrocyte Sedimentation Rate (ESR)-based/ C Reactive Protein (CRP)-based ACR 20 response: $\geq 20\%$ improvement from Week 16 in tender (68 joints assessed) and swollen (66 joints assessed) joint counts and $\geq 20\%$ improvement from Week 16 in 3 of the following 5 assessments: 1- Participant's assessment of pain using VAS (0 to 10 cm), 2- Participant's global assessment of disease activity using VAS (0 to 10 cm), 3- Physician's global assessment of disease activity using VAS (0 to 10 cm), 4- Participant's assessment of physical function as measured by the Disability Index of the Health Assessment Questionnaire (HAQ-DI) (score of 0-3 in 8 functional areas), 5- ESR or CRP. Percentage of participants, who achieved ESR/ CRP-based ACR 20 responses at Week 76 relative to Week 16, was reported.

End point type	Secondary
End point timeframe:	
Week 76	

End point values	OL Group 1: Golimumab 50 mg SC + MTX	OL Study Extension Group: Golimumab 50 mg SC + MTX	Double Blind (DB) Group 2a: Golimumab 50mg SC & Placebo IV+M	DB Group 2b: Golimumab 2mg/kg IV & Placebo SC + MTX
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	212	47	102
Units: Percentage of Participants				
number (confidence interval 95%)				
ESR-based ACR 20 Response	7.9 (1.3 to 14.6)	11.8 (7.5 to 16.1)	8.5 (0.5 to 16.5)	15.7 (8.6 to 22.7)
CRP-based ACR 20 Response	7.9 (1.3 to 14.6)	12.7 (8.2 to 17.2)	8.5 (0.5 to 16.5)	17.6 (10.2 to 25)

Statistical analyses

No statistical analyses for this end point

Secondary: Change in ESR-based DAS28 Score at Week 76 Relative to Week 52

End point title	Change in ESR-based DAS28 Score at Week 76 Relative to Week 52
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End point description:

Erythrocyte Sedimentation Rate (ESR)-based disease activity score for 28-joints count (DAS28) was calculated from number of swollen joint counts (SJC) and tender joint counts (TJC) using 28 joints count, ESR, and patient global assessment of disease activity (participant rated arthritis activity assessment with scores ranging 0 to 10; higher scores indicated greater disease activity). Total ESRbased DAS28 score range: 0 to 9.4, higher score=more disease activity.

End point type	Secondary
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End point timeframe:

Week 52, 76

End point values	OL Group 1: Golimumab 50 mg SC + MTX	OL Study Extension Group: Golimumab 50 mg SC + MTX	Double Blind (DB) Group 2a: Golimumab 50mg SC & Placebo IV+M	DB Group 2b: Golimumab 2mg/kg IV & Placebo SC + MTX
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	61	196	40	95
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 52 (n = 61, 40, 95, 196)	3.182 (± 1.1109)	3.95 (± 1.2379)	4.07 (± 0.8037)	4.394 (± 1.2389)
Change at Week 76 (n = 57, 33, 84,	-0.136 (± 1.2095)	-0.013 (± 1.1386)	0.209 (± 1.2253)	-0.017 (± 1.0518)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Week 0 to Week 52

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	16.0
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Reporting groups

Reporting group title	OL Overall Group: Golimumab 50 mg SC + MTX
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Reporting group description:

All participants received Golimumab 50 milligram (mg) subcutaneous (SC) injection every 4 weeks + Methotrexate (MTX) from Week 0 – 12. Where OL is used to abbreviate Open-Label.

Reporting group title	DB Group 2a: Golimumab 50 mg SC & Placebo IV + MTX
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Reporting group description:

Participants who did not achieved good Disease Activity Score in 28 joints (DAS28) response at Week 16. Randomized to receive Golimumab 50 milligram (mg) subcutaneous (SC) injection every 4 weeks + Methotrexate (MTX) from Week 16 – 48. Placebo IV at Weeks 16, 20, 28, 36, and 44. Where DB is used to abbreviate Double Blind.

Reporting group title	OL Group 1: Golimumab Open Label 50 mg + MTX
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Reporting group description:

Participants who achieved Disease Activity Score in 28 joints (DAS28) good response at Week 16. Golimumab 50 mg SC injection every 4 weeks + Methotrexate (MTX) from Week 16 – 48.

Reporting group title	DB Group 2b: Golimumab 2 mg/kg IV & Placebo SC + MTX
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Reporting group description:

Participants who did not achieve Disease Activity Score in 28 joints (DAS28) good response at Week 16. Randomized to receive Golimumab 2 milligram per kilogram (mg/kg) IV at Weeks 16, 20, 28, 36 and 44 + MTX. Placebo subcutaneous (SC) every 4 weeks from Week 16 – 48.

Reporting group title	Study Extension OL Group: Golimumab 50 mg SC + MTX
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Reporting group description:

Participants who completed Study Extension Open label received Golimumab 50 milligram (mg) subcutaneous (SC) injection every 4 weeks + Methotrexate (MTX) from Week 52-72.

Serious adverse events	OL Overall Group: Golimumab 50 mg SC + MTX	DB Group 2a: Golimumab 50 mg SC & Placebo IV + MTX	OL Group 1: Golimumab Open Label 50 mg + MTX
Total subjects affected by serious adverse events			
subjects affected / exposed	20 / 433 (4.62%)	4 / 91 (4.40%)	2 / 75 (2.67%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer			
subjects affected / exposed	0 / 433 (0.00%)	0 / 91 (0.00%)	0 / 75 (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

Breast cancer stage III			
subjects affected / exposed	0 / 433 (0.00%)	0 / 91 (0.00%)	0 / 75 (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
Essential thrombocythaemia			
subjects affected / exposed	0 / 433 (0.00%)	0 / 91 (0.00%)	0 / 75 (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			
Fall			
subjects affected / exposed	1 / 433 (0.23%)	0 / 91 (0.00%)	0 / 75 (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
Femur fracture			
subjects affected / exposed	0 / 433 (0.00%)	0 / 91 (0.00%)	0 / 75 (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
Intentional overdose			
subjects affected / exposed	0 / 433 (0.00%)	0 / 91 (0.00%)	1 / 75 (1.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	1 / 433 (0.23%)	0 / 91 (0.00%)	0 / 75 (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
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 433 (0.23%)	0 / 91 (0.00%)	0 / 75 (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
Hypotension			
subjects affected / exposed	0 / 433 (0.00%)	0 / 91 (0.00%)	0 / 75 (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			
Acute myocardial infarction			
subjects affected / exposed	0 / 433 (0.00%)	0 / 91 (0.00%)	0 / 75 (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
Bradycardia			
subjects affected / exposed	0 / 433 (0.00%)	0 / 91 (0.00%)	0 / 75 (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 failure congestive			
subjects affected / exposed	0 / 433 (0.00%)	0 / 91 (0.00%)	0 / 75 (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
Coronary artery disease			
subjects affected / exposed	0 / 433 (0.00%)	0 / 91 (0.00%)	0 / 75 (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			
Carotid artery occlusion			
subjects affected / exposed	0 / 433 (0.00%)	0 / 91 (0.00%)	0 / 75 (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
Cerebral haemorrhage			
subjects affected / exposed	1 / 433 (0.23%)	0 / 91 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Intracranial aneurysm			
subjects affected / exposed	0 / 433 (0.00%)	0 / 91 (0.00%)	0 / 75 (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
Polyneuropathy			
subjects affected / exposed	1 / 433 (0.23%)	0 / 91 (0.00%)	0 / 75 (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

General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	1 / 433 (0.23%)	0 / 91 (0.00%)	0 / 75 (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
Pyrexia			
subjects affected / exposed	0 / 433 (0.00%)	0 / 91 (0.00%)	0 / 75 (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			
Oesophagitis haemorrhagic			
subjects affected / exposed	0 / 433 (0.00%)	1 / 91 (1.10%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 433 (0.00%)	0 / 91 (0.00%)	0 / 75 (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
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 433 (0.00%)	0 / 91 (0.00%)	0 / 75 (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			
Acute respiratory failure			
subjects affected / exposed	0 / 433 (0.00%)	0 / 91 (0.00%)	0 / 75 (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
Asthma			
subjects affected / exposed	2 / 433 (0.46%)	1 / 91 (1.10%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Emphysema			

subjects affected / exposed	1 / 433 (0.23%)	0 / 91 (0.00%)	0 / 75 (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
Pneumothorax			
subjects affected / exposed	0 / 433 (0.00%)	0 / 91 (0.00%)	0 / 75 (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 embolism			
subjects affected / exposed	0 / 433 (0.00%)	1 / 91 (1.10%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	1 / 433 (0.23%)	0 / 91 (0.00%)	0 / 75 (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
Renal and urinary disorders			
Renal failure acute			
subjects affected / exposed	1 / 433 (0.23%)	0 / 91 (0.00%)	0 / 75 (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			
Arthralgia			
subjects affected / exposed	0 / 433 (0.00%)	0 / 91 (0.00%)	0 / 75 (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
Back pain			
subjects affected / exposed	2 / 433 (0.46%)	0 / 91 (0.00%)	0 / 75 (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
Joint effusion			
subjects affected / exposed	1 / 433 (0.23%)	0 / 91 (0.00%)	0 / 75 (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

Muscular weakness			
subjects affected / exposed	0 / 433 (0.00%)	0 / 91 (0.00%)	1 / 75 (1.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	1 / 433 (0.23%)	0 / 91 (0.00%)	0 / 75 (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
Pain in extremity			
subjects affected / exposed	0 / 433 (0.00%)	0 / 91 (0.00%)	1 / 75 (1.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polymyalgia rheumatica			
subjects affected / exposed	1 / 433 (0.23%)	0 / 91 (0.00%)	0 / 75 (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
Rheumatoid arthritis			
subjects affected / exposed	1 / 433 (0.23%)	0 / 91 (0.00%)	0 / 75 (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
Tenosynovitis			
subjects affected / exposed	0 / 433 (0.00%)	1 / 91 (1.10%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	1 / 433 (0.23%)	0 / 91 (0.00%)	0 / 75 (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
Cellulitis			
subjects affected / exposed	1 / 433 (0.23%)	0 / 91 (0.00%)	0 / 75 (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
Diverticulitis			

subjects affected / exposed	1 / 433 (0.23%)	0 / 91 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 433 (0.23%)	0 / 91 (0.00%)	0 / 75 (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
Gastroenteritis viral			
subjects affected / exposed	1 / 433 (0.23%)	0 / 91 (0.00%)	0 / 75 (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
Hepatitis C			
subjects affected / exposed	0 / 433 (0.00%)	0 / 91 (0.00%)	0 / 75 (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	1 / 433 (0.23%)	1 / 91 (1.10%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 433 (0.00%)	0 / 91 (0.00%)	0 / 75 (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
Urinary tract infection			
subjects affected / exposed	0 / 433 (0.00%)	0 / 91 (0.00%)	0 / 75 (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
Urosepsis			
subjects affected / exposed	1 / 433 (0.23%)	0 / 91 (0.00%)	0 / 75 (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 staphylococcal			

subjects affected / exposed	1 / 433 (0.23%)	0 / 91 (0.00%)	0 / 75 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 433 (0.00%)	0 / 91 (0.00%)	0 / 75 (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
Diabetic ketoacidosis			
subjects affected / exposed	1 / 433 (0.23%)	0 / 91 (0.00%)	0 / 75 (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
Hypokalaemia			
subjects affected / exposed	0 / 433 (0.00%)	0 / 91 (0.00%)	0 / 75 (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	DB Group 2b: Golimumab 2 mg/kg IV & Placebo SC + MTX	Study Extension OL Group: Golimumab 50 mg SC + MTX	
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 184 (5.43%)	10 / 212 (4.72%)	
number of deaths (all causes)	1	0	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer			
subjects affected / exposed	1 / 184 (0.54%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer stage III			
subjects affected / exposed	0 / 184 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Essential thrombocythaemia			

subjects affected / exposed	0 / 184 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 184 (0.00%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	0 / 184 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intentional overdose			
subjects affected / exposed	0 / 184 (0.00%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture			
subjects affected / exposed	0 / 184 (0.00%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	0 / 184 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 184 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Bradycardia			
subjects affected / exposed	1 / 184 (0.54%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure congestive			
subjects affected / exposed	1 / 184 (0.54%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	1 / 184 (0.54%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Nervous system disorders			
Carotid artery occlusion			
subjects affected / exposed	1 / 184 (0.54%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haemorrhage			
subjects affected / exposed	0 / 184 (0.00%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracranial aneurysm			
subjects affected / exposed	1 / 184 (0.54%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyneuropathy			
subjects affected / exposed	0 / 184 (0.00%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	3 / 184 (1.63%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pyrexia			
subjects affected / exposed	0 / 184 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Oesophagitis haemorrhagic			
subjects affected / exposed	0 / 184 (0.00%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	0 / 184 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 184 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	1 / 184 (0.54%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma			
subjects affected / exposed	1 / 184 (0.54%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Emphysema			
subjects affected / exposed	0 / 184 (0.00%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	0 / 184 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pulmonary embolism			
subjects affected / exposed	0 / 184 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory distress			
subjects affected / exposed	0 / 184 (0.00%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Renal failure acute			
subjects affected / exposed	0 / 184 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 184 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	0 / 184 (0.00%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint effusion			
subjects affected / exposed	0 / 184 (0.00%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular weakness			
subjects affected / exposed	0 / 184 (0.00%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pain in extremity			
subjects affected / exposed	0 / 184 (0.00%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polymyalgia rheumatica			
subjects affected / exposed	0 / 184 (0.00%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rheumatoid arthritis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tenosynovitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			

subjects affected / exposed	0 / 184 (0.00%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis C			
subjects affected / exposed	0 / 184 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	2 / 184 (1.09%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	1 / 184 (0.54%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	1 / 184 (0.54%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection staphylococcal			
subjects affected / exposed	0 / 184 (0.00%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 184 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ketoacidosis			

subjects affected / exposed	0 / 184 (0.00%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	0 / 184 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	OL Overall Group: Golimumab 50 mg SC + MTX	DB Group 2a: Golimumab 50 mg SC & Placebo IV + MTX	OL Group 1: Golimumab Open Label 50 mg + MTX
Total subjects affected by non-serious adverse events			
subjects affected / exposed	123 / 433 (28.41%)	30 / 91 (32.97%)	21 / 75 (28.00%)
Nervous system disorders			
Headache			
subjects affected / exposed	24 / 433 (5.54%)	1 / 91 (1.10%)	0 / 75 (0.00%)
occurrences (all)	28	1	0
Psychiatric disorders			
Depression			
subjects affected / exposed	7 / 433 (1.62%)	3 / 91 (3.30%)	4 / 75 (5.33%)
occurrences (all)	7	3	4
Musculoskeletal and connective tissue disorders			
Rheumatoid arthritis			
subjects affected / exposed	13 / 433 (3.00%)	9 / 91 (9.89%)	2 / 75 (2.67%)
occurrences (all)	13	9	2
Arthralgia			
subjects affected / exposed	20 / 433 (4.62%)	8 / 91 (8.79%)	2 / 75 (2.67%)
occurrences (all)	23	15	2
Infections and infestations			
Bronchitis			
subjects affected / exposed	12 / 433 (2.77%)	6 / 91 (6.59%)	2 / 75 (2.67%)
occurrences (all)	12	7	2
Sinusitis			

subjects affected / exposed	17 / 433 (3.93%)	4 / 91 (4.40%)	4 / 75 (5.33%)
occurrences (all)	18	4	5
Upper respiratory tract infection			
subjects affected / exposed	29 / 433 (6.70%)	5 / 91 (5.49%)	7 / 75 (9.33%)
occurrences (all)	31	5	7
Urinary tract infection			
subjects affected / exposed	24 / 433 (5.54%)	2 / 91 (2.20%)	3 / 75 (4.00%)
occurrences (all)	26	4	3

Non-serious adverse events	DB Group 2b: Golimumab 2 mg/kg IV & Placebo SC + MTX	Study Extension OL Group: Golimumab 50 mg SC + MTX	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	54 / 184 (29.35%)	61 / 212 (28.77%)	
Nervous system disorders			
Headache			
subjects affected / exposed	5 / 184 (2.72%)	3 / 212 (1.42%)	
occurrences (all)	8	3	
Psychiatric disorders			
Depression			
subjects affected / exposed	2 / 184 (1.09%)	5 / 212 (2.36%)	
occurrences (all)	2	5	
Musculoskeletal and connective tissue disorders			
Rheumatoid arthritis			
subjects affected / exposed	9 / 184 (4.89%)	11 / 212 (5.19%)	
occurrences (all)	11	11	
Arthralgia			
subjects affected / exposed	8 / 184 (4.35%)	11 / 212 (5.19%)	
occurrences (all)	13	12	
Infections and infestations			
Bronchitis			
subjects affected / exposed	11 / 184 (5.98%)	4 / 212 (1.89%)	
occurrences (all)	13	4	
Sinusitis			
subjects affected / exposed	13 / 184 (7.07%)	12 / 212 (5.66%)	
occurrences (all)	14	12	
Upper respiratory tract infection			

subjects affected / exposed	15 / 184 (8.15%)	13 / 212 (6.13%)	
occurrences (all)	15	15	
Urinary tract infection			
subjects affected / exposed	11 / 184 (5.98%)	13 / 212 (6.13%)	
occurrences (all)	11	16	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
31 July 2009	The overall reason for the amendment was to include the following changes: The open-label or double-blind treatment period was extended from Week 36 to Week 52. The Golimumab IV dose was changed from 4 milligram per kilogram (mg/kg) IV every 8 weeks with a loading dose to 2 mg/kg IV every 8 weeks with a loading dose. The disease flare Golimumab IV rescue treatment group was removed. The American College of Rheumatology (ACR) 50 response was replaced by a Disease Activity Score in 28 joints (DAS28) good response (as defined by European League Against Rheumatism (EULAR) criteria and calculated using ESR) requirement at Week 16 to determine whether a subject would continue open label treatment or be randomized to receive double-blind treatment. The TB inclusion criterion was also modified to allow for a chest radiograph at screening. Exclusion criteria related to drugs and investigational agents received before the first dose of study agent were modified. Instructions for reporting malfunctions or damage to the autoinjectors/prefilled pens were provided. Changes to the statistical analyses included an update to the treatment failure criteria for the primary analysis, a revision to the Cochran-Mantel-Haenszel (CMH) test to include stratification by ACR 20 criteria, an update to DAS28 response (EULAR response criteria) analyses using C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR), an addition of a summary of injection-site reactions for Golimumab by severity, deletion of subgroup analyses to evaluate consistency of safety over time, and a change to the significance level of the 2-sided binomial test from 0.05 to 0.049 to adjust for 1 interim analysis.
01 March 2010	The overall reason for the amendment was to include the following changes: Stopping rules were added for participants who had continued severe disease activity [Disease Activity Score in 28 joints (DAS28) greater than (>) 5.2] or diminished treatment effectiveness beginning at the Week 20 visit. The treatment regimen of etanercept or adalimumab for inclusion of participants in the study was clarified. Inclusion criteria for TB were modified. A Data Monitoring Committee (DMC) was added to monitor safety throughout the study. Information pertaining to the use of corticosteroids, Non-steroidal anti-inflammatory drugs (NSAIDs), analgesics, prohibited biologic agents, and prohibited DMARDs/systemic immunosuppressive agents were modified. The number of study sites was increased from 120 to 150 worldwide.
10 August 2010	The overall reason for the amendment was to include the following changes: A voluntary, open-label, 24 week study extension period was added. A definition for Disease Activity Score in 28 joints (DAS28) (ESR-based) low disease activity was added. Two additional secondary analyses related to DAS28 greater than or equal to (\geq) 3.2 were added and the use of CRP or ESR in the definition for DAS28 remission was clarified.

29 October 2010	The overall reason for the amendment was to include the following changes: Testing for HBV infection prior to receiving study agent was added. Evaluations for suspected Tuberculosis (TB) were clarified. Revised exclusion criteria, and other applicable protocol sections, related to treatment with disease modifying antirheumatic drugs (DMARDs)/systemic immunosuppressive agents and intra-articular, intramuscular (IM), or IV corticosteroids were changed to specify the prohibited use (in weeks or months) relative to screening instead of the administration of study agent. Gout was added to the list of excluded inflammatory diseases other than RA. Infraclavicular was changed to supraclavicular regarding location of lymph nodes in exclusion criteria for symptoms of possible lymphoproliferative disease. The description of the assessment and documentation of joints that were replaced before the study was modified to clarify that an entry in the electronic case report form (eCRF) indicating "nonevaluable" for a replaced joint would supersede the blinded value from the independent joint assessment on the joint assessment worksheet. This amendment also specified that Participants who participated in the extension would not be unblinded to their main study treatment assignment at the time of study extension entry.
28 January 2011	The overall reason for the amendment was to include the following changes: HBV testing at the next study visit for all Participants who were currently participating in the trial and to use the results to determine continued subject participation in the trial. The definition of a serious adverse event was updated to include the suspected transmission of an infectious agent by a medicinal product per the current definition in Volume 9A of The Rules Governing Medicinal Products in the European Union – Guidelines on Pharmacovigilance for Medicinal Products for Human Use (September 2008).
12 October 2011	The overall reason for the amendment was to include the following changes: to add prefilled syringes as an additional method of administering study agent to ensure that Participants would not miss an administration of study drug should autoinjector supplies become limited. The use of corticosteroids in the study was clarified. This amendment also included/corrected text describing when a subject should have been discontinued from the study in the event he/she tested positive for hepatitis B virus (HBV) during the study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The presence of TNF-resistant Participants who enriched the double blind phase of the study since they had already failed to respond to at least 2 anti-TNF agents (etanercept and/or adalimumab and golimumab).

Notes: