Clinical trial results:
A Phase-IV, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Trial to Evaluate the Efficacy and Safety of Golimumab (MK-8259 [SCH900259]) After Treatment Withdrawal, Compared With Continued Treatment (Either Full- or Reduced-Treatment Regimen), In Subjects With Non-Radiographic Axial Spondyloarthritis

Summary

EudraCT number	2015-004020-65
Trial protocol	DE CZ ES NL PL RO
Global end of trial date	17 March 2021

Results information

Result version number	v1
This version publication date	30 March 2022
First version publication date	30 March 2022

Trial information

Trial identification

Sponsor protocol code	8259-038

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03253796
WHO universal trial number (UTN)	-
Other trial identifiers	GO-BACK: Merck study name

Notes:

Sponsors

Sponsor organisation name	Merck Sharp & Dohme Corp.
Sponsor organisation address	2000 Galloping Hill Road, Kenilworth, NJ, United States, 07033
Public contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com
Scientific contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.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	17 March 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	17 March 2021
Global end of trial reached?	Yes
Global end of trial date	17 March 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to evaluate the effect of treatment withdrawal vs continued treatment with golimumab (GLM) administered by subcutaneous (SC) injection on the incidence of a "flare" in non-radiographic axial spondyloarthritis over up to 12 months. The primary hypothesis is that continued treatment with golimumab is superior to treatment withdrawal, based on the percentage of participants without a "flare" during up to 12 months of blinded therapy.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 November 2017
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	Czechia: 80
Country: Number of subjects enrolled	Germany: 19
Country: Number of subjects enrolled	Netherlands: 3
Country: Number of subjects enrolled	Poland: 75
Country: Number of subjects enrolled	Romania: 24
Country: Number of subjects enrolled	Russian Federation: 30
Country: Number of subjects enrolled	Spain: 5
Country: Number of subjects enrolled	Ukraine: 67
Country: Number of subjects enrolled	Turkey: 20
Worldwide total number of subjects	323
EEA total number of subjects	206

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
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)	323
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Adult subjects with active non-radiographic axial spondyloarthritis (nr-AxSpA), who had objective signs of inflammation and intolerance or inadequate response to non-steroidal anti-inflammatory drugs (NSAIDs), were enrolled in this trial.

Period 1

Period 1 title	Period 1: Run-In
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Open-Label Run-In Golimumab QM

Arm description:

Participants were treated with open-label subcutaneous (SC) injections of 50 mg golimumab once a month (QM) for up to 10 months. Participants with a body weight greater than 100 kg may have received 100 mg injections of golimumab at the discretion of the investigator.

Arm type	Experimental
Investigational medicinal product name	golimumab
Investigational medicinal product code	
Other name	MK-8259 Simponi®
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subcutaneous (SC) injections of 50 mg golimumab once a month (QM) for up to 10 months. Participants with a body weight greater than 100 kg may have received 100 mg injections of golimumab at the discretion of the investigator.

Number of subjects in period 1	Open-Label Run-In Golimumab QM
Started	323
Completed	207
Not completed	116
Consent withdrawn by subject	8
Adverse event, non-fatal	4
Lack of Qualifying Event	98
Lack of efficacy	1
Protocol deviation	5

Period 2

Period 2 title	Period 2: Withdrawal vs Continued Tx
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Golimumab QM (Full Treatment Regimen)

Arm description:

Participants were treated with double-blinded SC injections of 50 mg golimumab QM for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study. Participants who experienced a disease flare during double-blinded treatment in Period 2 discontinued blinded treatment and were retreated with open-label golimumab.

Arm type	Experimental
Investigational medicinal product name	golimumab
Investigational medicinal product code	
Other name	MK-8259 Simponi®
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subcutaneous (SC) injections of 50 mg golimumab once a month (QM) for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study.

Arm title	Golimumab Q2M (Reduced Treatment Regimen)

Arm description:

Participants were treated with double-blinded SC injections of 50 mg golimumab every other month (Q2M) alternating with matching placebo to golimumab every other month for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study. Participants who experienced a disease flare during double-blinded treatment in Period 2 discontinued blinded treatment and were retreated with open-label golimumab.

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

Dosage and administration details:

Double-blinded SC injections of placebo to golimumab every other month (Q2M) for up to 12 months.

Investigational medicinal product name	golimumab
Investigational medicinal product code	
Other name	MK-8259 Simponi®
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Double-blinded SC injections of 50 mg golimumab every other month (Q2M) for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study.

Arm title	Placebo (Treatment Withdrawal Regimen)

Arm description:

Participants were treated with double-blinded SC injections of placebo for up to 12 months. Participants who experienced a disease flare during double-blinded treatment in Period 2 discontinued blinded treatment and were retreated with open-label golimumab.

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

Dosage and administration details:

Double-blinded SC injections of placebo to golimumab once a month (QM) for up to 12 months.

Number of subjects in period 2[1]	Golimumab QM (Full Treatment Regimen)	Golimumab Q2M (Reduced Treatment Regimen)	Placebo (Treatment Withdrawal Regimen)
Started	63	64	62
Completed	53	43	21
Not completed	10	21	41
Disease Flare, moved to Open-label retreatment	10	15	38
Physician decision	-	1	-
Consent withdrawn by subject	-	2	3
Adverse event, non-fatal	-	2	-
Did not attain inactive disease in Period 1	-	1	-

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: 18 participants did not continue into Period 2

Period 3

Period 3 title	Period 2: Open-Label Retreatment
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Open-Label Retreatment

Arm description:

Participants who experienced a disease flare were treated with open-label SC injections of 50 mg golimumab QM for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study.

Arm type	Experimental
Investigational medicinal product name	golimumab
Investigational medicinal product code	
Other name	Simponi®
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Subcutaneous (SC) injections of 50 mg golimumab once a month (QM) for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study.

Number of subjects in period 3[2]	Open-Label Retreatment
Started	63
Completed	58
Not completed	5
Consent withdrawn by subject	5

Notes:

[2] - 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 experienced disease flare discontinued double-blind treatment and entered open-label retreatment

Baseline characteristics

Reporting groups	
Reporting group title	Open-Label Run-In Golimumab QM
Reporting group description:	
Participants were treated with open-label subcutaneous (SC) injections of 50 mg golimumab once a month (QM) for up to 10 months. Participants with a body weight greater than 100 kg may have received 100 mg injections of golimumab at the discretion of the investigator.	

Reporting group values	Open-Label Run-In Golimumab QM	Total	
Number of subjects	323	323	
Age categorical Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		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)		0	
From 65-84 years		0	
85 years and over		0	
Age Continuous Units: years			
arithmetic mean	32.5		
standard deviation	± 7.2	-	
Sex: Female, Male Units: Participants			
Female	109	109	
Male	214	214	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	0	0	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	0	0	
White	323	323	
More than one race	0	0	
Unknown or Not Reported	0	0	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	2	2	
Not Hispanic or Latino	321	321	
Unknown or Not Reported	0	0	
C-Reactive Protein (CRP) Category at Enrollment Units: Subjects			

> 6 mg/L	196	196	
≤ 6 mg/L	127	127	

End points reporting groups

Reporting group title	Open-Label Run-In Golimumab QM

Reporting group description:

Participants were treated with open-label subcutaneous (SC) injections of 50 mg golimumab once a month (QM) for up to 10 months. Participants with a body weight greater than 100 kg may have received 100 mg injections of golimumab at the discretion of the investigator.

Reporting group title	Golimumab QM (Full Treatment Regimen)

Reporting group description:

Participants were treated with double-blinded SC injections of 50 mg golimumab QM for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study. Participants who experienced a disease flare during double-blinded treatment in Period 2 discontinued blinded treatment and were retreated with open-label golimumab.

Reporting group title	Golimumab Q2M (Reduced Treatment Regimen)

Reporting group description:

Participants were treated with double-blinded SC injections of 50 mg golimumab every other month (Q2M) alternating with matching placebo to golimumab every other month for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study. Participants who experienced a disease flare during double-blinded treatment in Period 2 discontinued blinded treatment and were retreated with open-label golimumab.

Reporting group title	Placebo (Treatment Withdrawal Regimen)

Reporting group description:

Participants were treated with double-blinded SC injections of placebo for up to 12 months. Participants who experienced a disease flare during double-blinded treatment in Period 2 discontinued blinded treatment and were retreated with open-label golimumab.

Reporting group title	Open-Label Retreatment

Reporting group description:

Participants who experienced a disease flare were treated with open-label SC injections of 50 mg golimumab QM for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study.

Subject analysis set title	Golimumab Q2M and Placebo (Withdrawal Regimens)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants were treated with double-blinded SC injections of 50 mg golimumab Q2M alternating with matching placebo to golimumab every other month or with placebo for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study.

Primary: Percentage of Participants Without a Disease Activity Flare During Period 2

End point title	Percentage of Participants Without a Disease Activity Flare During Period 2

End point description:

Disease flare is defined as Ankylosing Spondylitis Disease Activity Score (ASDAS) at 2 consecutive visits that both show either score ≥2.1 or a post-withdrawal increase of ≥1.1 relative to baseline prior to the first dose in Period 2. ASDAS is a composite index assessing disease activity in axial spondyloarthropathies consisting of 4 self-assessed parameters and 1 laboratory parameter. The parameters of back pain, duration of morning stiffness, Patient Global Disease Assessment (PGDn), and peripheral pain/swelling are scored on a numeric scale of 0 (low activity/impact) to 10 (high activity/impact). The self-assessed criteria and the laboratory value of CRP are combined to provide the total ASDAS score, which has a lower limit of 0.6 and no defined upper limit. A higher score indicates greater disease activity. The analysis population is all participants who had inactive disease in Period 1, were randomized in Period 2, and received ≥1 dose of double-blind study intervention.

End point type	Primary

End point timeframe:

Up to 12 months

End point values	Golimumab QM (Full Treatment Regimen)	Golimumab Q2M (Reduced Treatment Regimen)	Placebo (Treatment Withdrawal Regimen)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	63	63	62	
Units: Percentage of participants				
number (not applicable)	84.1	68.3	33.9	

Statistical analyses

Statistical analysis title	Full Treatment Regimen vs Placebo
Statistical analysis description:	
Derived based on the stratified Miettinen and Nurminen method with CRP level (>6 mg/L or ≤ 6 mg/L) as a stratification factor	
Comparison groups	Golimumab QM (Full Treatment Regimen) v Placebo (Treatment Withdrawal Regimen)
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Miettinen and Nurminen
Parameter estimate	Difference in percentage
Point estimate	50.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	34.1
upper limit	63.6

Statistical analysis title	Reduced Treatment Regimen vs Placebo
Statistical analysis description:	
Derived based on the stratified Miettinen and Nurminen method with CRP level (>6 mg/L or ≤ 6 mg/L) as a stratification factor	
Comparison groups	Golimumab Q2M (Reduced Treatment Regimen) v Placebo (Treatment Withdrawal Regimen)
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Miettinen and Nurminen
Parameter estimate	Difference in percentage
Point estimate	34.4

Confidence interval	
level	95 %
sides	2-sided
lower limit	17
upper limit	49.7

Secondary: Percentage of Participants with a Flare Who Show a Clinical Response Within 3 Months of Open-Label Golimumab Retreatment

End point title	Percentage of Participants with a Flare Who Show a Clinical Response Within 3 Months of Open-Label Golimumab Retreatment

End point description:

Clinical response is defined as BASDAI (Bath Ankylosing Spondylitis Disease Assessment Index) score improvement of ≥2.0 or ≥50% improvement within 3 months of the start of retreatment, relative to the mean of the 2 consecutive BASDAI scores that defined the flare. Sustained clinical response is clinical response and maintenance of BASDAI criteria during 3-month retreatment period. BASDAI is a summary of 6 participant-assessed measures rated on scales of 0 (none) to 10 (very severe): fatigue, spinal pain, joint pain/swelling, tenderness, morning stiffness, and duration of morning stiffness [0 (0 hours) to 10 (2 or more hours)]. BASDAI score is the mean of responses to the 6 questions (range of 0 to 10). A higher score indicates greater disease activity. The population is all participants who had inactive disease in Period 1, were randomized to reduced-treatment regimen or placebo in Period 2, received ≥1 dose of double-blind study intervention, and had disease flare in Period 2.

End point type	Secondary

End point timeframe:

Up to 3 months following start of retreatment

End point values	Open-Label Retreatment			
Subject group type	Reporting group			
Number of subjects analysed	53			
Units: Percentage of participants				
number (confidence interval 95%)				
Within 1 month of retreatment	90.6 (79.3 to 96.9)			
Within 2 months of retreatment	96.2 (87.0 to 99.5)			
Within 3 months of retreatment	96.2 (87.0 to 99.5)			
Sustained clinical response	71.7 (57.7 to 83.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Time to First Disease Flare

End point title	Time to First Disease Flare

End point description:

The Kaplan-Meier analysis of time to first "flare" in Period 2 is represented by the percentage of participants who experienced a disease flare relative to baseline prior to the first dose of double-blind treatment in Period 2. Disease flare is defined as ASDAS at two consecutive visits that both show either absolute score ≥2.1 or a post-withdrawal increase of ≥1.1. The analysis population is all participants who had inactive disease in Period 1, were randomized in Period 2, and received ≥1 dose of double-blind study intervention.

End point type	Secondary

End point timeframe:

Month 3, Month 6, Month 9, and Month 12

End point values	Golimumab QM (Full Treatment Regimen)	Golimumab Q2M (Reduced Treatment Regimen)	Placebo (Treatment Withdrawal Regimen)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	63	63	62	
Units: Percentage of participants				
number (not applicable)				
Month 3	14.3	7.9	41.9	
Month 6	14.3	17.5	58.1	
Month 9	14.3	20.6	61.3	
Month 12	15.9	23.8	61.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving ASAS20 (Assessment in SpondyloArthritis international Society) Response (Double-blind treatment)

End point title	Percentage of Participants Achieving ASAS20 (Assessment in SpondyloArthritis international Society) Response (Double-blind treatment)

End point description:

ASAS20 is 20% improvement in response (per the Assessment in Ankylosing Spondylitis International Working Group) meeting 2 criteria: 1) improvement of ≥20% from Baseline and an improvement from Baseline of ≥1.0 in at least 3 of 4 domains, and 2) absence of deterioration from Baseline (defined as a ≥20% worsening and an absolute worsening of ≥1.0) in the potential remaining domain. Baseline is defined as the last ASAS score prior to the first dose of double-blind treatment in Period 2. The ASAS consists of 4 domains: the PGDn, total back pain, Bath Ankylosing Spondylitis Functional Index (BASFI), and morning stiffness (mean of questions 5 and 6 of BASDAI). Each domain is measured on a 10-point scale from 0=no disease symptoms/impact to 10=extreme disease symptoms/impact. A higher score indicates more severe impairment. The analysis population is all participants who had inactive disease in Period 1, were randomized in Period 2, and received ≥1 dose of double-blind study intervention.

End point type	Secondary

End point timeframe:

Up to 12 months

End point values	Golimumab QM (Full Treatment Regimen)	Golimumab Q2M (Reduced Treatment Regimen)	Placebo (Treatment Withdrawal Regimen)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	63	63	62	
Units: Percentage of participants				
number (not applicable)	9.5	3.2	0.0	

Statistical analyses

Statistical analysis title	Full Treatment Regimen vs Placebo
Statistical analysis description:	
Derived based on the stratified Miettinen and Nurminen method with CRP level (>6 mg/L or ≤ 6 mg/L) as a stratification factor	
Comparison groups	Golimumab QM (Full Treatment Regimen) v Placebo (Treatment Withdrawal Regimen)
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in percentage
Point estimate	9.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.3
upper limit	19.4

Statistical analysis title	Reduced Treatment Regimen vs Placebo
Statistical analysis description:	
Derived based on the stratified Miettinen and Nurminen method with CRP level (>6 mg/L or ≤ 6 mg/L) as a stratification factor	
Comparison groups	Golimumab Q2M (Reduced Treatment Regimen) v Placebo (Treatment Withdrawal Regimen)
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in percentage
Point estimate	3.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.8
upper limit	10.9

Secondary: Percentage of Participants Achieving ASAS20 Response (Open-label

retreatment)

End point title	Percentage of Participants Achieving ASAS20 Response (Open-label retreatment)

End point description:

ASAS20 is 20% improvement in response (per the Assessment in Ankylosing Spondylitis International Working Group) meeting 2 criteria: 1) improvement of ≥20% from Baseline and an improvement from Baseline of ≥1.0 in at least 3 of 4 domains, and 2) absence of deterioration from Baseline (defined as a ≥20% worsening and an absolute worsening of ≥1.0) in the potential remaining domain. Baseline is defined as the last ASAS score prior to the first dose of double-blind treatment in Period 2. The ASAS consists of 4 domains: the PGDn, total back pain, BASFI, and morning stiffness (mean of questions 5 and 6 of BASDAI). Each domain is measured on a 10-point scale from 0=no disease symptoms/impact to 10=extreme disease symptoms/impact. A higher score indicates more severe impairment. The analysis population is all participants who had inactive disease in Period 1, were randomized in Period 2, and received ≥1 dose of double-blind study intervention.

End point type	Secondary

End point timeframe:

Up to 12 months

End point values	Open-Label Retreatment			
Subject group type	Reporting group			
Number of subjects analysed	53			
Units: Percentage of participants				
number (confidence interval 95%)	94.3 (84.3 to 98.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving ASAS40 Response (Double-blind treatment)

End point title	Percentage of Participants Achieving ASAS40 Response (Double-blind treatment)

End point description:

ASAS40 is 40% improvement in response (per the Assessment in Ankylosing Spondylitis International Working Group) meeting 2 criteria: 1) improvement of ≥40% from Baseline and an improvement from Baseline of ≥2.0 in at least 3 of 4 domains, and 2) no deterioration from in the potential remaining domain. Baseline is defined as the last ASAS score prior to the first dose of double-blind treatment in Period 2. The ASAS consists of 4 domains: the PGDn, total back pain, BASFI, and morning stiffness (mean of questions 5 and 6 of BASDAI). Each domain is measured on a 10-point scale from 0=no disease symptoms/impact to 10=extreme disease symptoms/impact. A higher score indicates more severe impairment. The analysis population is all participants who had inactive disease in Period 1, were randomized in Period 2, and received ≥1 dose of double-blind study intervention.

End point type	Secondary

End point timeframe:

Up to 12 months

End point values	Golimumab QM (Full Treatment Regimen)	Golimumab Q2M (Reduced Treatment Regimen)	Placebo (Treatment Withdrawal Regimen)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	63	63	62	
Units: Percentage of participants	0	0	0	

Statistical analyses

Statistical analysis title	Full Treatment Regimen vs Placebo
Statistical analysis description:	
Derived based on the stratified Miettinen and Nurminen method with CRP level (>6 mg/L or ≤ 6 mg/L) as a stratification factor	
Comparison groups	Golimumab QM (Full Treatment Regimen) v Placebo (Treatment Withdrawal Regimen)
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in percentage
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.9
upper limit	5.8

Statistical analysis title	Reduced Treatment Regimen vs Placebo
Statistical analysis description:	
Derived based on the stratified Miettinen and Nurminen method with CRP level (>6 mg/L or ≤ 6 mg/L) as a stratification factor	
Comparison groups	Golimumab Q2M (Reduced Treatment Regimen) v Placebo (Treatment Withdrawal Regimen)
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in percentage
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.9
upper limit	5.8

Secondary: Percentage of Participants Achieving ASAS40 Response (Open-label retreatment)

End point title	Percentage of Participants Achieving ASAS40 Response (Open-label retreatment)

End point description:

ASAS40 is 40% improvement in response (per the Assessment in Ankylosing Spondylitis International Working Group) meeting 2 criteria: 1) improvement of ≥40% from Baseline and an improvement from Baseline of ≥2.0 in at least 3 of 4 domains, and 2) no deterioration from in the potential remaining domain. Baseline is defined as the last ASAS score prior to the first dose of double-blind treatment in Period 2. The ASAS consists of 4 domains: the PGDn, total back pain, BASFI, and morning stiffness (mean of questions 5 and 6 of BASDAI). Each domain is measured on a 10-point scale from 0=no disease symptoms/impact to 10=extreme disease symptoms/impact. A higher score indicates more severe impairment. The analysis population is all participants who had inactive disease in Period 1, were randomized in Period 2, and received ≥1 dose of double-blind study intervention.

End point type	Secondary

End point timeframe:

Up to 12 months

End point values	Open-Label Retreatment			
Subject group type	Reporting group			
Number of subjects analysed	53			
Units: Percentage of participants				
number (confidence interval 95%)	90.6 (79.3 to 96.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving ASAS Partial Remission (Double-blind treatment)

End point title	Percentage of Participants Achieving ASAS Partial Remission (Double-blind treatment)

End point description:

ASAS partial remission is defined as a score of ≤2 in all 4 ASAS domains. Baseline for this analysis is defined as the ASAS score prior to the first dose of double-blind treatment in Period 2. The ASAS consists of 4 domains: Patient Global Disease Assessment (PGDn), total back pain, function (Bath Ankylosing Spondylitis Functional Index [BASFI]), and morning stiffness (mean of questions 5 and 6 of Bath Ankylosing Spondylitis Disease Activity Index [BASDAI]). Each domain is measured on a 10-point numeric scale from 0=no disease symptoms/impact to 10=extreme disease symptoms/impact, with a higher score indicating more severe impairment. The analysis population is all participants who had inactive disease in Period 1, were randomized in Period 2, and received ≥1 dose of double-blind study intervention.

End point type	Secondary

End point timeframe:

Up to 12 months

End point values	Golimumab QM (Full Treatment Regimen)	Golimumab Q2M (Reduced Treatment Regimen)	Placebo (Treatment Withdrawal Regimen)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	63	63	62	
Units: Percentage of participants				
number (not applicable)	85.7	85.7	71.0	

Statistical analyses

Statistical analysis title	Reduced Treatment Regimen vs Placebo
Statistical analysis description:	
Derived based on the stratified Miettinen and Nurminen method with CRP level (>6 mg/L or ≤ 6 mg/L) as a stratification factor	
Comparison groups	Golimumab Q2M (Reduced Treatment Regimen) v Placebo (Treatment Withdrawal Regimen)
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in percentage
Point estimate	14.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.2
upper limit	29.1

Statistical analysis title	Full Treatment Regimen vs Placebo
Statistical analysis description:	
Derived based on the stratified Miettinen and Nurminen method with CRP level (>6 mg/L or ≤ 6 mg/L) as a stratification factor	
Comparison groups	Golimumab QM (Full Treatment Regimen) v Placebo (Treatment Withdrawal Regimen)
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in percentage
Point estimate	14.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.2
upper limit	29

Secondary: Percentage of Participants Achieving ASAS Partial Remission (Open-

label retreatment)

End point title	Percentage of Participants Achieving ASAS Partial Remission (Open-label retreatment)

End point description:

ASAS partial remission is defined as a score of ≤2 in all 4 ASAS domains. Baseline for this analysis is defined as the ASAS score prior to the first dose of open-label retreatment in Period 2. The ASAS consists of 4 domains: Patient Global Disease Assessment (PGDn), total back pain, function (Bath Ankylosing Spondylitis Functional Index [BASFI]), and morning stiffness (mean of questions 5 and 6 of Bath Ankylosing Spondylitis Disease Activity Index [BASDAI]). Each domain is measured on a 10-point numeric scale from 0=no disease symptoms/impact to 10=extreme disease symptoms/impact, with a higher score indicating more severe impairment. The population is all participants who had inactive disease in Period 1, were randomized to reduced-treatment regimen or placebo in Period 2, received ≥1 dose of double-blind study intervention, and experienced disease flare in Period 2.

End point type	Secondary

End point timeframe:

Up to 12 months

End point values	Open-Label Retreatment			
Subject group type	Reporting group			
Number of subjects analysed	53			
Units: Percentage of participants				
number (confidence interval 95%)	92.5 (81.8 to 97.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving BASDAI50 Response (Double-blind Treatment)

End point title	Percentage of Participants Achieving BASDAI50 Response (Double-blind Treatment)

End point description:

BASDAI50 is defined as ≥50% improvement from baseline in the Bath Ankylosing Spondylitis Disease Assessment Index (BASDAI) score. Baseline for BASDAI50 analysis is defined as the last BASDAI score prior to the first dose of double-blind treatment in Period 2. The BASDAI is a summary of 6 participant-assessed measures rated on scales of 0 (none) to 10 (very severe): fatigue, spinal pain, joint pain/swelling, tenderness, morning stiffness, and duration of morning stiffness [0 (zero) to 10 (2 or more hours)]. The BASDAI score is the mean of responses to the 6 questions with a minimum of 0 and a maximum of 10. A higher score indicates greater disease activity. The analysis population is all participants who had inactive disease in Period 1, were randomized in Period 2, and received ≥1 dose of double-blind study intervention.

End point type	Secondary

End point timeframe:

Up to 12 months

End point values	Golimumab QM (Full Treatment Regimen)	Golimumab Q2M (Reduced Treatment Regimen)	Placebo (Treatment Withdrawal Regimen)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	63	63	62	
Units: Percentage of participants				
number (not applicable)	49.2	30.2	24.2	

Statistical analyses

Statistical analysis title	Full Treatment Regimen vs Placebo
Statistical analysis description:	
Derived based on the stratified Miettinen and Nurminen method with CRP level (>6 mg/L or ≤ 6 mg/L) as a stratification factor	
Comparison groups	Golimumab QM (Full Treatment Regimen) v Placebo (Treatment Withdrawal Regimen)
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in percentage
Point estimate	24.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.5
upper limit	40.3

Statistical analysis title	Reduced Treatment Regimen vs Placebo
Statistical analysis description:	
Derived based on the stratified Miettinen and Nurminen method with CRP level (>6 mg/L or ≤ 6 mg/L) as a stratification factor	
Comparison groups	Golimumab Q2M (Reduced Treatment Regimen) v Placebo (Treatment Withdrawal Regimen)
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in percentage
Point estimate	5.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.9
upper limit	21.3

Secondary: Percentage of Participants Achieving BASDAI50 Response (Open-label

Retreatment)

End point title	Percentage of Participants Achieving BASDAI50 Response (Open-label Retreatment)

End point description:

BASDAI50 is defined as ≥50% improvement from baseline in the Bath Ankylosing Spondylitis Disease Assessment Index (BASDAI) score. Baseline for BASDAI50 analysis is defined as the last BASDAI score prior to the first dose of open-label retreatment in Period 2. The BASDAI is a summary of 6 participant-assessed measures rated on scales of 0 (none) to 10 (very severe): fatigue, spinal pain, joint pain/swelling, tenderness, morning stiffness, and duration of morning stiffness [0 (zero) to 10 (2 or more hours)]. The BASDAI score is the mean of responses to the 6 questions with a minimum of 0 and a maximum of 10. A higher score indicates greater disease activity. The population is all participants who had inactive disease in Period 1, were randomized to reduced-treatment regimen or placebo in Period 2, received ≥1 dose of double-blind study intervention, and experienced disease flare in Period 2.

End point type	Secondary

End point timeframe:

Up to 12 months

End point values	Open-Label Retreatment			
Subject group type	Reporting group			
Number of subjects analysed	53			
Units: Percentage of participants				
number (confidence interval 95%)	98.1 (89.9 to 100.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Inactive Disease Status (Double-Blind Treatment)

End point title	Percentage of Participants Achieving Inactive Disease Status (Double-Blind Treatment)

End point description:

Inactive disease status is defined as an ASDAS score <1.3. The ASDAS is a composite index assessing disease activity in axial spondyloarthropathies that consists of 4 self-assessed parameters and 1 laboratory parameter. The self-assessed parameters of back pain, duration of morning stiffness, Patient Global Disease Assessment (PGDn), and peripheral pain/swelling are individually scored on a numeric scale of 0 to 10, with 0 being low activity/impact and 10 being high activity/impact. The self-assessed criteria and the laboratory value of CRP are combined to provide the total ASDAS score, which has a lower limit of 0.6 and no defined upper limit. A higher score indicates greater disease activity. The analysis population is all participants who had inactive disease in Period 1, were randomized in Period 2, and received ≥1 dose of double-blind study intervention.

End point type	Secondary

End point timeframe:

Up to 12 months

End point values	Golimumab QM (Full Treatment Regimen)	Golimumab Q2M (Reduced Treatment Regimen)	Placebo (Treatment Withdrawal Regimen)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	63	63	62	
Units: Percentage of participants				
number (not applicable)	85.7	84.1	61.3	

Statistical analyses

Statistical analysis title	Full Treatment Regimen vs Placebo
Statistical analysis description:	
Derived based on the stratified Miettinen and Nurminen method with CRP level (>6 mg/L or ≤ 6 mg/L) as a stratification factor	
Comparison groups	Golimumab QM (Full Treatment Regimen) v Placebo (Treatment Withdrawal Regimen)
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in percentage
Point estimate	24.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.1
upper limit	39

Statistical analysis title	Reduced Treatment Regimen vs Placebo
Statistical analysis description:	
Derived based on the stratified Miettinen and Nurminen method with CRP level (>6 mg/L or ≤ 6 mg/L) as a stratification factor	
Comparison groups	Golimumab Q2M (Reduced Treatment Regimen) v Placebo (Treatment Withdrawal Regimen)
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in percentage
Point estimate	22.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.3
upper limit	37.7

Secondary: Percentage of Participants Achieving Inactive Disease Status (Open-

label retreatment)

End point title	Percentage of Participants Achieving Inactive Disease Status (Open-label retreatment)

End point description:

Inactive disease status is defined as an ASDAS score <1.3. The ASDAS is a composite index assessing disease activity in axial spondyloarthropathies that consists of 4 self-assessed parameters and 1 laboratory parameter. The self-assessed parameters of back pain, duration of morning stiffness, Patient Global Disease Assessment (PGDn), and peripheral pain/swelling are individually scored on a numeric scale of 0 to 10, with 0 being low activity/impact and 10 being high activity/impact. The self-assessed criteria and the laboratory value of CRP are combined to provide the total ASDAS score, which has a lower limit of 0.6 and no defined upper limit. A higher score indicates greater disease activity. The population is all participants who had inactive disease in Period 1, were randomized to reduced-treatment regimen or placebo in Period 2, received ≥1 dose of double-blind study intervention, and experienced disease flare in Period 2.

End point type	Secondary

End point timeframe:

Up to 12 months

End point values	Open-Label Retreatment			
Subject group type	Reporting group			
Number of subjects analysed	53			
Units: Percentage of participants				
number (confidence interval 95%)	90.6 (79.3 to 96.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Experienced an Adverse Event (AE) in Period 2

End point title	Percentage of Participants Who Experienced an Adverse Event (AE) in Period 2

End point description:

This endpoint evaluated the safety and tolerability of withdrawing from or continuing treatment with golimumab in Period 2. An AE is defined as any untoward medical occurrence in a participant or clinical investigation participant administered a study treatment and which does not necessarily have to have a causal relationship with this treatment. An AE could be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a study treatment, whether or not considered related to the study treatment. Any worsening (i.e., any clinically significant adverse change in frequency and/or intensity) of a preexisting condition that is temporally associated with the use of study treatment, is also an AE. The analysis includes AEs that occurred through 90 days after the last dose of study treatment. The analysis population consists of all participants who received at least one dose of study intervention in Period 2.

End point type	Secondary

End point timeframe:

Up to approximately 15 months

End point values	Golimumab QM (Full Treatment Regimen)	Open-Label Retreatment	Golimumab Q2M (Reduced Treatment Regimen)	Placebo (Treatment Withdrawal Regimen)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	63	64	62
Units: Percentage of participants				
number (not applicable)	46.0	41.3	46.9	32.3

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Discontinued Study Treatment Due to an AE in Period 2

End point title	Percentage of Participants Who Discontinued Study Treatment Due to an AE in Period 2

End point description:

This endpoint evaluated the safety and tolerability of withdrawing from or continuing treatment with golimumab in Period 2. An AE is defined as any untoward medical occurrence in a participant or clinical investigation participant administered a study treatment and which does not necessarily have to have a causal relationship with this treatment. An AE could be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a study treatment, whether or not considered related to the study treatment. Any worsening (i.e., any clinically significant adverse change in frequency and/or intensity) of a preexisting condition that is temporally associated with the use of study treatment, is also an AE. The analysis population consists of all participants who received at least one dose of study intervention in Period 2.

End point type	Secondary

End point timeframe:

Up to approximately 12 months

End point values	Golimumab QM (Full Treatment Regimen)	Open-Label Retreatment	Golimumab Q2M (Reduced Treatment Regimen)	Placebo (Treatment Withdrawal Regimen)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	63	64	62
Units: Percentage of participants				
number (not applicable)	0.0	0.0	4.7	1.6

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Participants Without a Disease Activity Flare During Period 2 (Full Treatment Regimen versus Withdrawal Regimens)

End point title	Percentage of Participants Without a Disease Activity Flare During Period 2 (Full Treatment Regimen versus Withdrawal Regimens)

End point description:

Disease flare is defined as Ankylosing Spondylitis Disease Activity Score (ASDAS) at 2 consecutive visits that both show either score ≥2.1 or a post-withdrawal increase of ≥1.1 relative to baseline prior to the first dose in Period 2. ASDAS is a composite index assessing disease activity in axial spondyloarthropathies consisting of 4 self-assessed parameters and 1 laboratory parameter. The parameters of back pain, duration of morning stiffness, Patient Global Disease Assessment (PGDn), and peripheral pain/swelling are scored on a numeric scale of 0 (low activity/impact) to 10 (high activity/impact). The self-assessed criteria and the laboratory value of CRP are combined to provide the total ASDAS score, which has a lower limit of 0.6 and no defined upper limit. A higher score indicates greater disease activity. The analysis population is all participants who had inactive disease in Period 1, were randomized in Period 2, and received ≥1 dose of double-blind study intervention.

End point type	Other pre-specified

End point timeframe:

Up to 12 months

End point values	Golimumab QM (Full Treatment Regimen)	Golimumab Q2M and Placebo (Withdrawal Regimens)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	63	125		
Units: Percentage of participants				
number (not applicable)	84.1	51.2		

Statistical analyses

Statistical analysis title	Full Treatment Regimen vs Withdrawal Regimens

Statistical analysis description:

Derived based on the stratified Miettinen and Nurminen method with CRP level (>6 mg/L or ≤ 6 mg/L) as a stratification factor

Comparison groups	Golimumab QM (Full Treatment Regimen) v Golimumab Q2M and Placebo (Withdrawal Regimens)
Number of subjects included in analysis	188
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Miettinen and Nurminen
Parameter estimate	Difference in percentage
Point estimate	32.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	19.2
upper limit	44.5

Other pre-specified: Percentage of Participants Without a Disease Activity Flare During Period 2 (Full Treatment Regimen versus Reduced Treatment Regimen)

End point title	Percentage of Participants Without a Disease Activity Flare During Period 2 (Full Treatment Regimen versus Reduced Treatment Regimen)

End point description:

Disease flare is defined as Ankylosing Spondylitis Disease Activity Score (ASDAS) at 2 consecutive visits that both show either score ≥2.1 or a post-withdrawal increase of ≥1.1 relative to baseline prior to the first dose in Period 2. ASDAS is a composite index assessing disease activity in axial spondyloarthropathies consisting of 4 self-assessed parameters and 1 laboratory parameter. The parameters of back pain, duration of morning stiffness, Patient Global Disease Assessment (PGDn), and peripheral pain/swelling are scored on a numeric scale of 0 (low activity/impact) to 10 (high activity/impact). The self-assessed criteria and the laboratory value of CRP are combined to provide the total ASDAS score, which has a lower limit of 0.6 and no defined upper limit. A higher score indicates greater disease activity. The analysis population is all participants who had inactive disease in Period 1, were randomized in Period 2, and received ≥1 dose of double-blind golimumab.

End point type	Other pre-specified

End point timeframe:

Up to 12 months

End point values	Golimumab QM (Full Treatment Regimen)	Golimumab Q2M (Reduced Treatment Regimen)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	63	63		
Units: Percentage of participants				
number (not applicable)	84.1	68.3		

Statistical analyses

Statistical analysis title	Full Treatment vs Reduced Treatment

Statistical analysis description:

Derived based on the stratified Miettinen and Nurminen method with CRP level (>6 mg/L or ≤ 6 mg/L) as a stratification factor

Comparison groups	Golimumab QM (Full Treatment Regimen) v Golimumab Q2M (Reduced Treatment Regimen)
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.037
Method	Miettinen and Nurminen
Parameter estimate	Difference in percentage
Point estimate	15.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	30.5

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 10 months in Period 1 (Open-Label Run-in) and up to 15 months in Period 2 (Withdrawal vs Continued Treatment) for a total of up to 25 months.

Adverse event reporting additional description:

The safety analysis population includes all participants who received at least one dose of study intervention. Reporting includes treatment-emergent adverse events occurring through 90 days after the last dose of study treatment.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.0

Reporting groups

Reporting group title	Open-Label Run-In Golimumab QM

Reporting group description:

Participants were treated with open-label subcutaneous (SC) injections of 50 mg golimumab once a month (QM) for up to 10 months. Participants with a body weight greater than 100 kg may have received 100 mg injections of golimumab at the discretion of the investigator.

Reporting group title	Golimumab QM (Full Treatment Regimen)

Reporting group description:

Participants were treated with double-blinded SC injections of 50 mg golimumab QM for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study. Participants who experienced a disease flare during double-blinded treatment in Period 2 discontinued blinded treatment and were retreated with open-label golimumab.

Reporting group title	Golimumab Q2M (Reduced Treatment Regimen)

Reporting group description:

Participants were treated with double-blinded SC injections of 50 mg golimumab every other month (Q2M) alternating with matching placebo to golimumab every other month for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study. Participants who experienced a disease flare during double-blinded treatment in Period 2 discontinued blinded treatment and were retreated with open-label golimumab.

Reporting group title	Placebo (Treatment Withdrawal Regimen)

Reporting group description:

Participants were treated with double-blinded SC injections of placebo for up to 12 months. Participants who experienced a disease flare during double-blinded treatment in Period 2 discontinued blinded treatment and were retreated with open-label golimumab.

Reporting group title	Open-Label Retreatment

Reporting group description:

Participants who experienced a disease flare were treated with open-label SC injections of 50 mg golimumab QM for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study.

Serious adverse events	Open-Label Run-In Golimumab QM	Golimumab QM (Full Treatment Regimen)	Golimumab Q2M (Reduced Treatment Regimen)
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 323 (2.17%)	1 / 63 (1.59%)	1 / 64 (1.56%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Joint injury			
subjects affected / exposed	0 / 323 (0.00%)	1 / 63 (1.59%)	0 / 64 (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
Meniscus injury			
subjects affected / exposed	0 / 323 (0.00%)	0 / 63 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis chronic			
subjects affected / exposed	1 / 323 (0.31%)	0 / 63 (0.00%)	0 / 64 (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 colic			
subjects affected / exposed	1 / 323 (0.31%)	0 / 63 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	1 / 323 (0.31%)	0 / 63 (0.00%)	0 / 64 (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
Exostosis			
subjects affected / exposed	1 / 323 (0.31%)	0 / 63 (0.00%)	0 / 64 (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
Joint instability			
subjects affected / exposed	1 / 323 (0.31%)	0 / 63 (0.00%)	0 / 64 (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			

Pilonidal cyst			
subjects affected / exposed	1 / 323 (0.31%)	0 / 63 (0.00%)	0 / 64 (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 acute			
subjects affected / exposed	0 / 323 (0.00%)	0 / 63 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis bacterial			
subjects affected / exposed	1 / 323 (0.31%)	0 / 63 (0.00%)	0 / 64 (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

Serious adverse events	Placebo (Treatment Withdrawal Regimen)	Open-Label Retreatment	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 62 (1.61%)	0 / 63 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
Joint injury			
subjects affected / exposed	0 / 62 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus injury			
subjects affected / exposed	1 / 62 (1.61%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis chronic			
subjects affected / exposed	0 / 62 (0.00%)	0 / 63 (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 colic			

subjects affected / exposed	0 / 62 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exostosis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint instability			
subjects affected / exposed	0 / 62 (0.00%)	0 / 63 (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			
Pilonidal cyst			
subjects affected / exposed	0 / 62 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	0 / 62 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinusitis bacterial			
subjects affected / exposed	0 / 62 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Open-Label Run-In Golimumab QM	Golimumab QM (Full Treatment Regimen)	Golimumab Q2M (Reduced Treatment Regimen)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	79 / 323 (24.46%)	13 / 63 (20.63%)	17 / 64 (26.56%)
Nervous system disorders			
Headache			
subjects affected / exposed	24 / 323 (7.43%)	4 / 63 (6.35%)	2 / 64 (3.13%)
occurrences (all)	39	8	3
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	36 / 323 (11.15%)	6 / 63 (9.52%)	6 / 64 (9.38%)
occurrences (all)	39	7	6
Pharyngitis			
subjects affected / exposed	12 / 323 (3.72%)	2 / 63 (3.17%)	6 / 64 (9.38%)
occurrences (all)	14	2	9
Upper respiratory tract infection			
subjects affected / exposed	16 / 323 (4.95%)	2 / 63 (3.17%)	3 / 64 (4.69%)
occurrences (all)	24	5	3

Non-serious adverse events	Placebo (Treatment Withdrawal Regimen)	Open-Label Retreatment	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 62 (17.74%)	11 / 63 (17.46%)	
Nervous system disorders			
Headache			
subjects affected / exposed	4 / 62 (6.45%)	1 / 63 (1.59%)	
occurrences (all)	5	2	
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	3 / 62 (4.84%)	4 / 63 (6.35%)	
occurrences (all)	4	4	
Pharyngitis			
subjects affected / exposed	3 / 62 (4.84%)	1 / 63 (1.59%)	
occurrences (all)	4	1	
Upper respiratory tract infection			
subjects affected / exposed	2 / 62 (3.23%)	5 / 63 (7.94%)	
occurrences (all)	3	5	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
25 April 2017	Amendment 1 added language regarding male contraception, pregnancy follow-up, and clarified timing of several study procedures.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported