Clinical trial results:
A Phase 2A Randomized, double-blind, Active-controlled, Parallel-group, Multicenter, Proof-of-concept Clinical Study to Evaluate the Efficacy and safety of Combination Therapy With Guselkumab and Golimumab in Participants With Moderately to Severely Active Ulcerative Colitis

Summary

EudraCT number	2018-001510-15
Trial protocol	DE PL
Global end of trial date	15 November 2021

Results information

Result version number	v1 (current)
This version publication date	15 December 2022
First version publication date	15 December 2022

Trial information

Trial identification

Sponsor protocol code	CNTO1959UCO2002

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03662542
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Research & Development, LLC
Sponsor organisation address	920 Route 202 South, Raritan, United States, 08869
Public contact	Clinical Registry Group, Janssen Research & Development, LLC, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen Research & Development, LLC, 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	15 November 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	15 November 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this trial was to evaluate the clinical efficacy and safety of combination therapy with guselkumab and golimumab in subjects with moderately to severely active ulcerative colitis (UC).

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices and applicable regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 November 2018
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	Argentina: 4
Country: Number of subjects enrolled	Australia: 4
Country: Number of subjects enrolled	Brazil: 9
Country: Number of subjects enrolled	Germany: 2
Country: Number of subjects enrolled	Mexico: 4
Country: Number of subjects enrolled	Poland: 40
Country: Number of subjects enrolled	Russian Federation: 71
Country: Number of subjects enrolled	Ukraine: 68
Country: Number of subjects enrolled	United States: 12
Worldwide total number of subjects	214
EEA total number of subjects	42

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)	213
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 214 subjects were enrolled and received guselkumab and/or golimumab.

Period 1

Period 1 title	Combination Phase (Through Week 12)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Arm 1: Golimumab Monotherapy

Arm description:

Subjects received golimumab 200 milligrams (mg) as subcutaneous (SC) injection at Week 0, followed by golimumab 100 mg at Weeks 2, 6 and 10. Subjects received placebo as intravenous (IV) infusion at Weeks 0, 4 and 8.

Arm type	Active comparator
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received placebo as intravenous (IV) infusion at Weeks 0, 4 and 8.

Investigational medicinal product name	Golimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received golimumab 200 mg as SC injection at Week 0, followed by golimumab 100 mg at Weeks 2, 6 and 10.

Arm title	Arm 2: Guselkumab Monotherapy

Arm description:

Subjects received guselkumab 200 mg as IV infusion at Weeks 0, 4 and 8. Subjects received placebo as SC injection at Weeks 0, 2, 6, and 10.

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received placebo as SC injection at Weeks 0, 2, 6, and 10.

Investigational medicinal product name	Guselkumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received guselkumab 200 mg as IV infusion at Weeks 0, 4 and 8.

Arm title	Arm 3: Combination Therapy

Arm description:

Subjects received guselkumab 200 mg as IV infusion at Weeks 0, 4, and 8. Subjects received golimumab 200 mg as SC injection at Week 0, followed by golimumab 100 mg as SC injection at Weeks 2, 6, and 10.

Arm type	Experimental
Investigational medicinal product name	Golimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received golimumab 200 mg as SC injection at Week 0, followed by golimumab 100 mg as SC injection at Weeks 2, 6, and 10.

Investigational medicinal product name	Guselkumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received guselkumab 200 mg as IV infusion at Weeks 0, 4, and 8.

Number of subjects in period 1	Arm 1: Golimumab Monotherapy	Arm 2: Guselkumab Monotherapy	Arm 3: Combination Therapy
Started	72	71	71
Completed	67	70	71
Not completed	5	1	0
Consent withdrawn by subject	3	-	-
Adverse event, non-fatal	-	1	-
Unspecified	2	-	-

Period 2

Period 2 title	Monotherapy Phase (Week 12 to Week 38)
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	Arm 1: Golimumab Monotherapy

Arm description:

Subjects received golimumab 100 mg at Weeks 14, 18, 22, 26, 30, and 34 and placebo as SC injection at Weeks 16, 24, and 32.

Arm type	Active comparator
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received placebo as SC injection at Weeks 16, 24, and 32.

Investigational medicinal product name	Golimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received golimumab 100 mg at Weeks 14, 18, 22, 26, 30, and 34.

Arm title	Arm 2: Guselkumab Monotherapy

Arm description:

Subjects received guselkumab 100 mg as SC injection at Weeks 16, 24, and 32 and placebo as SC injection at Weeks 14, 18, 22, 26, 30, and 34.

Arm type	Active comparator
Investigational medicinal product name	Guselkumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received guselkumab 100 mg as SC injection at Weeks 16, 24, and 32.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received placebo as SC injection at Weeks 14, 18, 22, 26, 30, and 34.

Arm title	Arm 3: Combination Therapy

Arm description:

Subjects received guselkumab 100 mg as SC injection at Weeks 16, 24 and 32 and placebo as SC injection at Weeks 14, 18, 22, 26, 30, and 34.

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details: Subjects received placebo as SC injection at Weeks 14, 18, 22, 26, 30, and 34.	
Investigational medicinal product name	Guselkumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: Subjects received guselkumab 100 mg as SC injection at Weeks 16, 24 and 32.	

Number of subjects in period 2	Arm 1: Golimumab Monotherapy	Arm 2: Guselkumab Monotherapy	Arm 3: Combination Therapy
Started	67	70	71
Completed	62	67	65
Not completed	5	3	6
Consent withdrawn by subject	4	1	1
Adverse event, non-fatal	-	-	2
Death	-	-	1
Unspecified	-	1	2
Lost to follow-up	1	1	-

Period 3	
Period 3 title	Safety Follow-up Phase (Week 38- EOS)
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	Arm 1: Golimumab Monotherapy
Arm description: Subjects were followed up after Week 38 to Week 50 (end of study [EOS]) and did not receive any additional medication in the safety follow-up phase.	
Arm type	Active comparator
Investigational medicinal product name	Golimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: Subjects did not receive any additional medication in the safety follow-up phase.	
Arm title	Arm 2: Guselkumab Monotherapy

Arm description:

Subjects were followed up after Week 38 to Week 50 (EOS) and did not receive any additional medication in the safety follow-up phase.

Arm type	Active comparator
Investigational medicinal product name	Guselkumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion, Injection
Routes of administration	Intravenous use, Subcutaneous use

Dosage and administration details:

Subjects did not receive any additional medication in the safety follow-up phase.

Arm title	Arm 3: Combination Therapy

Arm description:

Subjects were followed up after Week 38 to Week 50 (EOS) and did not receive any additional medication in the safety follow-up phase.

Arm type	Experimental
Investigational medicinal product name	Guselkumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion, Injection
Routes of administration	Subcutaneous use, Intravenous use

Dosage and administration details:

Subjects did not receive any additional medication in the safety follow-up phase.

Investigational medicinal product name	Golimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects did not receive any additional medication in the safety follow-up phase.

Number of subjects in period 3[1]	Arm 1: Golimumab Monotherapy	Arm 2: Guselkumab Monotherapy	Arm 3: Combination Therapy
Started	58	65	60
Completed	55	58	55
Not completed	3	7	5
Consent withdrawn by subject	1	-	2
Death	-	1	-
Unspecified	1	6	2
Lost to follow-up	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: Out of 194 subjects (who completed Period-2 [monotherapy phase]), 183 subjects started the Period-3 (safety follow-up phase).

Baseline characteristics

Reporting groups	
Reporting group title	Arm 1: Golimumab Monotherapy
Reporting group description:	
Subjects received golimumab 200 milligrams (mg) as subcutaneous (SC) injection at Week 0, followed by golimumab 100 mg at Weeks 2, 6 and 10. Subjects received placebo as intravenous (IV) infusion at Weeks 0, 4 and 8.	
Reporting group title	Arm 2: Guselkumab Monotherapy
Reporting group description:	
Subjects received guselkumab 200 mg as IV infusion at Weeks 0, 4 and 8. Subjects received placebo as SC injection at Weeks 0, 2, 6, and 10.	
Reporting group title	Arm 3: Combination Therapy
Reporting group description:	
Subjects received guselkumab 200 mg as IV infusion at Weeks 0, 4, and 8. Subjects received golimumab 200 mg as SC injection at Week 0, followed by golimumab 100 mg as SC injection at Weeks 2, 6, and 10.	

Reporting group values	Arm 1: Golimumab Monotherapy	Arm 2: Guselkumab Monotherapy	Arm 3: Combination Therapy
Number of subjects	72	71	71
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	72	70	71
From 65 to 84 years	0	1	0
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	38.1	39.1	37.8
standard deviation	± 10.47	± 13.67	± 11.69
Title for Gender Units: subjects			
Female	30	31	37
Male	42	40	34

Reporting group values	Total		
Number of subjects	214		
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	213		
From 65 to 84 years	1		
85 years and over	0		
Title for AgeContinuous Units: years			
arithmetic mean			
standard deviation	-		

Title for Gender Units: subjects			
Female	98		
Male	116		

End points

End points reporting groups

Reporting group title	Arm 1: Golimumab Monotherapy
Reporting group description:	
Subjects received golimumab 200 milligrams (mg) as subcutaneous (SC) injection at Week 0, followed by golimumab 100 mg at Weeks 2, 6 and 10. Subjects received placebo as intravenous (IV) infusion at Weeks 0, 4 and 8.	
Reporting group title	Arm 2: Guselkumab Monotherapy
Reporting group description:	
Subjects received guselkumab 200 mg as IV infusion at Weeks 0, 4 and 8. Subjects received placebo as SC injection at Weeks 0, 2, 6, and 10.	
Reporting group title	Arm 3: Combination Therapy
Reporting group description:	
Subjects received guselkumab 200 mg as IV infusion at Weeks 0, 4, and 8. Subjects received golimumab 200 mg as SC injection at Week 0, followed by golimumab 100 mg as SC injection at Weeks 2, 6, and 10.	
Reporting group title	Arm 1: Golimumab Monotherapy
Reporting group description:	
Subjects received golimumab 100 mg at Weeks 14, 18, 22, 26, 30, and 34 and placebo as SC injection at Weeks 16, 24, and 32.	
Reporting group title	Arm 2: Guselkumab Monotherapy
Reporting group description:	
Subjects received guselkumab 100 mg as SC injection at Weeks 16, 24, and 32 and placebo as SC injection at Weeks 14, 18, 22, 26, 30, and 34.	
Reporting group title	Arm 3: Combination Therapy
Reporting group description:	
Subjects received guselkumab 100 mg as SC injection at Weeks 16, 24 and 32 and placebo as SC injection at Weeks 14, 18, 22, 26, 30, and 34.	
Reporting group title	Arm 1: Golimumab Monotherapy
Reporting group description:	
Subjects were followed up after Week 38 to Week 50 (end of study [EOS]) and did not receive any additional medication in the safety follow-up phase.	
Reporting group title	Arm 2: Guselkumab Monotherapy
Reporting group description:	
Subjects were followed up after Week 38 to Week 50 (EOS) and did not receive any additional medication in the safety follow-up phase.	
Reporting group title	Arm 3: Combination Therapy
Reporting group description:	
Subjects were followed up after Week 38 to Week 50 (EOS) and did not receive any additional medication in the safety follow-up phase.	

Primary: Percentage of Subjects Who Achieved Clinical Response at Week 12

End point title	Percentage of Subjects Who Achieved Clinical Response at Week 12[1]
End point description:	
Clinical response is defined as a decrease from baseline in the Mayo score greater than or equal to (>=) 30 percent (%) and >=3 points with either a decrease from baseline in the rectal bleeding subscore (RBS) >=1 or a RBS of 0 or 1. The Mayo score was calculated as the sum of 4 subscores (stool frequency, rectal bleeding, physician's global assessment, and endoscopy findings - each with score range of 0 (normal activity) to 3 (severe activity) and a total score range of 0 to 12 points. A score of 3 to 5 points indicates mildly active disease, a score of 6 to 10 points indicates moderately active disease, and a score of 11 to 12 points indicates severely active disease. Efficacy analyses were based on the Full Analysis Set (FAS), which included all randomised subjects who received at least 1 (partial or complete)	

dose of study intervention.

End point type	Primary

End point timeframe:

Week 12

Notes:

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

End point values	Arm 1: Golimumab Monotherapy	Arm 2: Guselkumab Monotherapy	Arm 3: Combination Therapy	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	72	71	71	
Units: Percentage of subjects				
number (not applicable)	61.1	74.6	83.1	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Clinical Remission at Week 12

End point title	Percentage of Subjects Who Achieved Clinical Remission at Week 12

End point description:

Clinical remission (legacy definition) is defined as the Mayo score less than or equal to (<=) 2 with no individual subscore greater than (>) 1. The Mayo score was calculated as the sum of 4 subscores (stool frequency, rectal bleeding, physician's global assessment, and endoscopy findings) each with score range of 0 (normal activity) to 3 (severe activity) and a total score range of 0 to 12 points. A score of 3 to 5 points indicates mildly active disease, a score of 6 to 10 points indicates moderately active disease, and a score of 11 to 12 points indicates severely active disease. Efficacy analyses were based on the FAS, which included all randomised subjects who received at least 1 (partial or complete) dose of study intervention.

End point type	Secondary

End point timeframe:

Week 12

End point values	Arm 1: Golimumab Monotherapy	Arm 2: Guselkumab Monotherapy	Arm 3: Combination Therapy	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	72	71	71	
Units: Percentage of subjects				
number (not applicable)	22.2	21.1	36.6	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to Week 50

Adverse event reporting additional description:

The safety analysis set included all randomised subjects who received at least 1 (partial or complete) dose of study intervention.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	Combination Phase: Arm 1: Golimumab Monotherapy

Reporting group description:

Subjects received golimumab 200 milligrams (mg) as subcutaneous (SC) injection at Week 0, followed by golimumab 100 mg at Weeks 2, 6 and 10. Subjects received placebo as intravenous (IV) infusion at Weeks 0, 4 and 8.

Reporting group title	Safety Follow-up Phase: Arm 2: Guselkumab Monotherapy

Reporting group description:

Subjects were followed up after Week 38 to Week 50 (EOS) and did not receive any additional medication in the safety follow-up phase.

Reporting group title	Safety Follow-up Phase: Arm 3: Combination Therapy

Reporting group description:

Subjects were followed up after Week 38 to Week 50 (EOS) and did not receive any additional medication in the safety follow-up phase.

Reporting group title	Monotherapy Phase: Arm 3: Combination Therapy

Reporting group description:

Subjects received guselkumab 100 mg as SC injection at Weeks 16, 24 and 32 and placebo as SC injection at Weeks 14, 18, 22, 26, 30, and 34.

Reporting group title	Combination Phase: Arm 3: Combination Therapy

Reporting group description:

Subjects received guselkumab 200 mg as IV infusion at Weeks 0, 4, and 8. Subjects received golimumab 200 mg as SC injection at Week 0, followed by golimumab 100 mg as SC injection at Weeks 2, 6, and 10.

Reporting group title	Monotherapy Phase: Arm 1: Golimumab Monotherapy

Reporting group description:

Subjects received golimumab 100 mg at Week 14, 18, 22, 26, 30, and 34 and placebo as SC injection at Weeks 16, 24, and 32.

Reporting group title	Monotherapy Phase: Arm 2: Guselkumab Monotherapy

Reporting group description:

Subjects received guselkumab 100 mg as SC injection at Weeks 16, 24, and 32 and placebo as SC injection at Weeks 14, 18, 22, 26, 30, and 34.

Reporting group title	Safety Follow-up Phase: Arm 1: Golimumab Monotherapy

Reporting group description:

Subjects were followed up after Week 38 to Week 50 (end of study [EOS]) and did not receive any additional medication in the safety follow-up phase.

Reporting group title	Combination Phase: Arm 2: Guselkumab Monotherapy

Reporting group description:

Subjects received guselkumab 200 mg as IV infusion at Week 0, 4 and 8. Subjects received placebo as SC injection at Weeks 0, 2, 6, and 10.

Serious adverse events	Combination Phase: Arm 1: Golimumab Monotherapy	Safety Follow-up Phase: Arm 2: Guselkumab Monotherapy	Safety Follow-up Phase: Arm 3: Combination Therapy
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 72 (1.39%)	2 / 65 (3.08%)	0 / 60 (0.00%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of Colon			
subjects affected / exposed	0 / 72 (0.00%)	1 / 65 (1.54%)	0 / 60 (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
Injury, poisoning and procedural complications			
Poisoning			
subjects affected / exposed	0 / 72 (0.00%)	0 / 65 (0.00%)	0 / 60 (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			
Atrial Fibrillation			
subjects affected / exposed	0 / 72 (0.00%)	0 / 65 (0.00%)	0 / 60 (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			
Colitis Ulcerative			
subjects affected / exposed	1 / 72 (1.39%)	0 / 65 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 72 (0.00%)	1 / 65 (1.54%)	0 / 60 (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 / 72 (0.00%)	0 / 65 (0.00%)	0 / 60 (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			
Pulmonary Embolism			
subjects affected / exposed	0 / 72 (0.00%)	0 / 65 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 72 (0.00%)	0 / 65 (0.00%)	0 / 60 (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
Chronic Sinusitis			
subjects affected / exposed	0 / 72 (0.00%)	0 / 65 (0.00%)	0 / 60 (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
Covid-19			
subjects affected / exposed	0 / 72 (0.00%)	1 / 65 (1.54%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Covid-19 Pneumonia			
subjects affected / exposed	0 / 72 (0.00%)	0 / 65 (0.00%)	0 / 60 (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
Influenza			
subjects affected / exposed	0 / 72 (0.00%)	0 / 65 (0.00%)	0 / 60 (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
Sepsis			
subjects affected / exposed	0 / 72 (0.00%)	0 / 65 (0.00%)	0 / 60 (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

Tuberculosis of Intrathoracic Lymph Nodes			
subjects affected / exposed	0 / 72 (0.00%)	0 / 65 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 72 (0.00%)	0 / 65 (0.00%)	0 / 60 (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	Monotherapy Phase: Arm 3: Combination Therapy	Combination Phase: Arm 3: Combination Therapy	Monotherapy Phase: Arm 1: Golimumab Monotherapy
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 71 (4.23%)	1 / 71 (1.41%)	3 / 67 (4.48%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of Colon			
subjects affected / exposed	0 / 71 (0.00%)	0 / 71 (0.00%)	0 / 67 (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			
Poisoning			
subjects affected / exposed	1 / 71 (1.41%)	0 / 71 (0.00%)	0 / 67 (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
Cardiac disorders			
Atrial Fibrillation			
subjects affected / exposed	0 / 71 (0.00%)	0 / 71 (0.00%)	0 / 67 (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			
Colitis Ulcerative			

subjects affected / exposed	0 / 71 (0.00%)	0 / 71 (0.00%)	0 / 67 (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 Haemorrhage			
subjects affected / exposed	0 / 71 (0.00%)	0 / 71 (0.00%)	0 / 67 (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
Small Intestinal Obstruction			
subjects affected / exposed	0 / 71 (0.00%)	0 / 71 (0.00%)	0 / 67 (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			
Pulmonary Embolism			
subjects affected / exposed	1 / 71 (1.41%)	0 / 71 (0.00%)	1 / 67 (1.49%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 71 (0.00%)	0 / 67 (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
Chronic Sinusitis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 71 (0.00%)	1 / 67 (1.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Covid-19			
subjects affected / exposed	0 / 71 (0.00%)	0 / 71 (0.00%)	0 / 67 (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
Covid-19 Pneumonia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 71 (0.00%)	1 / 67 (1.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Influenza			
subjects affected / exposed	0 / 71 (0.00%)	1 / 71 (1.41%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 71 (0.00%)	1 / 71 (1.41%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tuberculosis of Intrathoracic Lymph Nodes			
subjects affected / exposed	1 / 71 (1.41%)	0 / 71 (0.00%)	0 / 67 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 71 (1.41%)	0 / 71 (0.00%)	0 / 67 (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	Monotherapy Phase: Arm 2: Guselkumab Monotherapy	Safety Follow-up Phase: Arm 1: Golimumab Monotherapy	Combination Phase: Arm 2: Guselkumab Monotherapy
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 70 (1.43%)	0 / 58 (0.00%)	2 / 71 (2.82%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of Colon			
subjects affected / exposed	0 / 70 (0.00%)	0 / 58 (0.00%)	0 / 71 (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			
Poisoning			
subjects affected / exposed	0 / 70 (0.00%)	0 / 58 (0.00%)	0 / 71 (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			
Atrial Fibrillation			
subjects affected / exposed	0 / 70 (0.00%)	0 / 58 (0.00%)	1 / 71 (1.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis Ulcerative			
subjects affected / exposed	0 / 70 (0.00%)	0 / 58 (0.00%)	0 / 71 (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 Haemorrhage			
subjects affected / exposed	0 / 70 (0.00%)	0 / 58 (0.00%)	0 / 71 (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
Small Intestinal Obstruction			
subjects affected / exposed	0 / 70 (0.00%)	0 / 58 (0.00%)	1 / 71 (1.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary Embolism			
subjects affected / exposed	0 / 70 (0.00%)	0 / 58 (0.00%)	0 / 71 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 70 (1.43%)	0 / 58 (0.00%)	0 / 71 (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
Chronic Sinusitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 58 (0.00%)	0 / 71 (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
Covid-19			

subjects affected / exposed	0 / 70 (0.00%)	0 / 58 (0.00%)	0 / 71 (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
Covid-19 Pneumonia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 58 (0.00%)	0 / 71 (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
Influenza			
subjects affected / exposed	0 / 70 (0.00%)	0 / 58 (0.00%)	0 / 71 (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
Sepsis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 58 (0.00%)	0 / 71 (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
Tuberculosis of Intrathoracic Lymph Nodes			
subjects affected / exposed	0 / 70 (0.00%)	0 / 58 (0.00%)	0 / 71 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 70 (0.00%)	0 / 58 (0.00%)	0 / 71 (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

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

Non-serious adverse events	Combination Phase: Arm 1: Golimumab Monotherapy	Safety Follow-up Phase: Arm 2: Guselkumab Monotherapy	Safety Follow-up Phase: Arm 3: Combination Therapy
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 72 (26.39%)	2 / 65 (3.08%)	0 / 60 (0.00%)
Nervous system disorders			

Headache			
subjects affected / exposed	2 / 72 (2.78%)	0 / 65 (0.00%)	0 / 60 (0.00%)
occurrences (all)	2	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	5 / 72 (6.94%)	1 / 65 (1.54%)	0 / 60 (0.00%)
occurrences (all)	5	1	0
Neutropenia			
subjects affected / exposed	2 / 72 (2.78%)	0 / 65 (0.00%)	0 / 60 (0.00%)
occurrences (all)	2	0	0
Gastrointestinal disorders			
Colitis Ulcerative			
subjects affected / exposed	8 / 72 (11.11%)	1 / 65 (1.54%)	0 / 60 (0.00%)
occurrences (all)	8	1	0
Infections and infestations			
Upper Respiratory Tract Infection			
subjects affected / exposed	4 / 72 (5.56%)	0 / 65 (0.00%)	0 / 60 (0.00%)
occurrences (all)	5	0	0

Non-serious adverse events	Monotherapy Phase: Arm 3: Combination Therapy	Combination Phase: Arm 3: Combination Therapy	Monotherapy Phase: Arm 1: Golimumab Monotherapy
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 71 (19.72%)	14 / 71 (19.72%)	12 / 67 (17.91%)
Nervous system disorders			
Headache			
subjects affected / exposed	3 / 71 (4.23%)	4 / 71 (5.63%)	2 / 67 (2.99%)
occurrences (all)	6	8	4
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 71 (0.00%)	4 / 71 (5.63%)	2 / 67 (2.99%)
occurrences (all)	0	5	2
Neutropenia			
subjects affected / exposed	2 / 71 (2.82%)	2 / 71 (2.82%)	1 / 67 (1.49%)
occurrences (all)	3	4	1
Gastrointestinal disorders			
Colitis Ulcerative			
subjects affected / exposed	6 / 71 (8.45%)	4 / 71 (5.63%)	5 / 67 (7.46%)
occurrences (all)	6	4	5
Infections and infestations			

Upper Respiratory Tract Infection			
subjects affected / exposed	6 / 71 (8.45%)	1 / 71 (1.41%)	2 / 67 (2.99%)
occurrences (all)	6	1	2

Non-serious adverse events	Monotherapy Phase: Arm 2: Guselkumab Monotherapy	Safety Follow-up Phase: Arm 1: Golimumab Monotherapy	Combination Phase: Arm 2: Guselkumab Monotherapy
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 70 (22.86%)	3 / 58 (5.17%)	16 / 71 (22.54%)
Nervous system disorders			
Headache			
subjects affected / exposed	5 / 70 (7.14%)	0 / 58 (0.00%)	3 / 71 (4.23%)
occurrences (all)	9	0	3
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	6 / 70 (8.57%)	0 / 58 (0.00%)	6 / 71 (8.45%)
occurrences (all)	7	0	7
Neutropenia			
subjects affected / exposed	2 / 70 (2.86%)	0 / 58 (0.00%)	4 / 71 (5.63%)
occurrences (all)	2	0	4
Gastrointestinal disorders			
Colitis Ulcerative			
subjects affected / exposed	4 / 70 (5.71%)	3 / 58 (5.17%)	1 / 71 (1.41%)
occurrences (all)	5	3	1
Infections and infestations			
Upper Respiratory Tract Infection			
subjects affected / exposed	2 / 70 (2.86%)	0 / 58 (0.00%)	5 / 71 (7.04%)
occurrences (all)	4	0	5

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported