Clinical trial results:
A Phase 1b Open-Label Study to Assess the Safety and Pharmacokinetics of Subcutaneously Administered Golimumab, a Human Anti-TNF Antibody, in Pediatric Subjects With Moderately to Severely Active Ulcerative Colitis

Summary

EudraCT number	2012-004366-18
Trial protocol	AT BE DE NL DK FR
Global end of trial date	01 September 2022

Results information

Result version number	v1 (current)
This version publication date	07 May 2023
First version publication date	07 May 2023

Trial information

Trial identification

Sponsor protocol code	CNTO148UCO1001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01900574
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Biologics BV
Sponsor organisation address	Einsteinweg 101, CB Leiden, Netherlands, 2333
Public contact	Clinical Registry Group, Janssen Biologics BV, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen Biologics BV, ClinicalTrialsEU@its.jnj.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-000265-PIP02-11
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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	01 September 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	01 September 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this study was to evaluate the pharmacokinetics (PK) of golimumab in pediatric subjects (aged 2 to 17 years) 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 (GCPs) and applicable regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	25 September 2013
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	Austria: 1
Country: Number of subjects enrolled	Canada: 2
Country: Number of subjects enrolled	Germany: 2
Country: Number of subjects enrolled	France: 3
Country: Number of subjects enrolled	Israel: 3
Country: Number of subjects enrolled	Poland: 5
Country: Number of subjects enrolled	United States: 19
Worldwide total number of subjects	35
EEA total number of subjects	11

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)	10

Adolescents (12-17 years)	25
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 56 subjects were screened at 24 sites. Of these, 35 pediatric subjects were enrolled.

Period 1

Period 1 title	Main Part (14 Weeks)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Golimumab

Arm description:

Subjects with moderately to severely active ulcerative colitis (UC), received subcutaneous (SC) golimumab based on body weight in main part of study that is (i.e.) body weight less than (<) 45 kilogram (kg) received 90 milligrams per meter squared (mg/m^2) (up to maximum of 200 milligrams [mg]) at Week 0 and 45 mg/m^2 (up to maximum of 100 mg) at Week 2. Subjects with body weight greater than or equal to (>=) 45 kg received 200 mg at Week 0 and 100 mg at Week 2. Subjects with clinical response at Week 6 received same previous dose at Weeks 6 and 10.

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

Dosage and administration details:

Subjects received SC golimumab injection based on body weight at Weeks 0 and 2. Subjects with clinical response at Week 6 received same previous dose at Weeks 6 and 10.

Number of subjects in period 1	Golimumab
Started	35
Completed	31
Not completed	4
Consent withdrawn by subject	2
Unspecified	1
Lost to follow-up	1

Period 2

Period 2 title	Extension Part (112 Weeks)
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Golimumab

Arm description:

Subjects with clinical response at Week 6 entered study extension part at Week 14 and received maintenance therapy of golimumab 100 mg (body weight >=45 kg) or 45 mg/m^2 (body weight <45 kg) every 4 weeks (q4w) through Week 110. Subjects who did not continue to receive golimumab after Week 110, returned for a final visit at Week 126. At Week 114, subjects who, in the opinion of the investigator, were benefited from continued treatment, received golimumab through Week 126 in extension part and then continued the treatment with Golimumab in long term extension part.

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

Dosage and administration details:

Subjects received SC golimumab injection every 4 weeks based on body weight from Week 14 through Week 126.

Number of subjects in period 2[1]	Golimumab
Started	20
Completed	18
Not completed	2
Unspecified	2

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: Only eligible subjects entered into Extension Part.

Period 3

Period 3 title	Long Term Extension Part (308 weeks)
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Golimumab

Arm description:

At Week 114, subjects who, in the opinion of the investigator, were benefited from continued treatment, received similar golimumab dose through Week 126 in extension part and then continued the treatment with Golimumab, every 4 weeks from Week 126 through Week 434 in long term extension part.

Arm type	Experimental

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

Dosage and administration details:

Subjects received SC golimumab injection every 4 weeks from Week 126 through Week 434.

Number of subjects in period 3[2]	Golimumab
Started	11
Completed	11

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: Only eligible subjects entered into Extension Part.

Baseline characteristics

Reporting groups	
Reporting group title	Golimumab

Reporting group description:

Subjects with moderately to severely active ulcerative colitis (UC), received subcutaneous (SC) golimumab based on body weight in main part of study that is (i.e.) body weight less than (<) 45 kilogram (kg) received 90 milligrams per meter squared (mg/m^2) (up to maximum of 200 milligrams [mg]) at Week 0 and 45 mg/m^2 (up to maximum of 100 mg) at Week 2. Subjects with body weight greater than or equal to (>=) 45 kg received 200 mg at Week 0 and 100 mg at Week 2. Subjects with clinical response at Week 6 received same previous dose at Weeks 6 and 10.

Reporting group values	Golimumab	Total	
Number of subjects	35	35	
Title for AgeCategorical Units: subjects			
Children (2-11 years)	10	10	
Adolescents (12-17 years)	25	25	
Adults (18-64 years)	0	0	
From 65 to 84 years	0	0	
85 years and over	0	0	
Title for AgeContinuous Units: years			
arithmetic mean	13.4		
standard deviation	± 3.21	-	
Title for Gender Units: subjects			
Female	18	18	
Male	17	17	

End points

End points reporting groups

Reporting group title	Golimumab

Reporting group description:

Subjects with moderately to severely active ulcerative colitis (UC), received subcutaneous (SC) golimumab based on body weight in main part of study that is (i.e.) body weight less than (<) 45 kilogram (kg) received 90 milligrams per meter squared (mg/m^2) (up to maximum of 200 milligrams [mg]) at Week 0 and 45 mg/m^2 (up to maximum of 100 mg) at Week 2. Subjects with body weight greater than or equal to (>=) 45 kg received 200 mg at Week 0 and 100 mg at Week 2. Subjects with clinical response at Week 6 received same previous dose at Weeks 6 and 10.

Reporting group title	Golimumab

Reporting group description:

Subjects with clinical response at Week 6 entered study extension part at Week 14 and received maintenance therapy of golimumab 100 mg (body weight >=45 kg) or 45 mg/m^2 (body weight <45 kg) every 4 weeks (q4w) through Week 110. Subjects who did not continue to receive golimumab after Week 110, returned for a final visit at Week 126. At Week 114, subjects who, in the opinion of the investigator, were benefited from continued treatment, received golimumab through Week 126 in extension part and then continued the treatment with Golimumab in long term extension part.

Reporting group title	Golimumab

Reporting group description:

At Week 114, subjects who, in the opinion of the investigator, were benefited from continued treatment, received similar golimumab dose through Week 126 in extension part and then continued the treatment with Golimumab, every 4 weeks from Week 126 through Week 434 in long term extension part.

Subject analysis set title	Golimumab
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects with moderately to severely active UC, received SC golimumab based on body weight in main part of study that is (i.e.) body <45 kg received 90 mg/m^2 (up to maximum of 200 mg) at Week 0 and 45 mg/m^2 (up to maximum of 100 mg) at Week 2. Subjects with body weight >=45 kg received 200 mg at Week 0 and 100 mg at Week 2. Subjects with clinical response at Week 6 received same previous dose at Weeks 6 and 10. Subjects with clinical response at Week 6 entered study extension part at Week 14 and received maintenance therapy of golimumab 100 mg (body weight >=45 kg) or 45 mg/m^2 (body weight <45 kg) q4w through study end (week 434).

Primary: Serum Golimumab Concentrations at Week 6

End point title	Serum Golimumab Concentrations at Week 6[1]

End point description:

Serum golimumab concentrations at Week 6 in the overall pediatric ulcerative colitis subjects was reported. Pharmacokinetic (PK) analysis set included all enrolled subjects who received at least 1 administration (partial or complete) of study agent and who had one or more PK blood samples obtained after the first golimumab SC injection (partial or complete).Here, N (number of subjects analysed) signifies subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

pre-dose at Week 6

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: Only descriptive data was planned to be reported for this endpoint.

End point values	Golimumab			
Subject group type	Subject analysis set			
Number of subjects analysed	31			
Units: micrograms per milliliter				
arithmetic mean (standard deviation)	2.56 (± 1.657)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects who Achieved Clinical Response at Week 6

End point title	Number of Subjects who Achieved Clinical Response at Week 6

End point description:

Clinical response was defined as a decrease from baseline in the Mayo score by greater than or equal to (>=) 30 percent (%) and >= to 3 points, with either a decrease from baseline in the rectal bleeding subscore of 1 or more or a rectal bleeding subscore of 0 or 1. The Mayo score consists of 4 subscores (stool frequency, rectal bleeding, endoscopy findings, and physician's global assessment), rated as 0 (normal) to 3 (severe). Total score was calculated as the sum of 4 subscores and values ranged from 0 to 12 scores, where 3 to 5 = mild disease; 6 to 10 = moderate disease; and 11 to 12 = severe disease. Higher scores indicated worsening of the disease. Analysis population included all enrolled subjects who received at least one administration of golimumab.

End point type	Secondary

End point timeframe:

Week 6

End point values	Golimumab			
Subject group type	Subject analysis set			
Number of subjects analysed	35			
Units: subjects	21			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects who Achieved Clinical Remission at Week 6 Measured by the Mayo Score

End point title	Number of Subjects who Achieved Clinical Remission at Week 6 Measured by the Mayo Score

End point description:

Clinical remission was defined as a Mayo score less than or equal to (<=) 2 points, with no individual subscore greater than (>) 1. The Mayo score consists of 4 subscores (stool frequency, rectal bleeding, endoscopy findings, and physician's global assessment), rated as 0 (normal) to 3 (severe). Total score was calculated as the sum of 4 subscores and values range from 0 to 12 scores, where 3 to 5 = mild; 6 to 10 = moderate; and 11 to 12 = severe. Higher scores indicated worsening of the disease. Analysis population included all enrolled subjects who received at least one administration of golimumab.

End point type	Secondary

End point timeframe:

Week 6

End point values	Golimumab			
Subject group type	Subject analysis set			
Number of subjects analysed	35			
Units: subjects	15			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects who Achieved Clinical Remission at Week 6 Measured by Pediatric Ulcerative Colitis Activity Index (PUCAI) Score

End point title	Number of Subjects who Achieved Clinical Remission at Week 6 Measured by Pediatric Ulcerative Colitis Activity Index (PUCAI) Score

End point description:

Clinical remission as per PUCAI score was defined as PUCAI score of less than (<) 10, a noninvasive measure of ulcerative colitis disease activity. The PUCAI score consists of 6 scales (abdominal pain [points 0 to 10], rectal bleeding [points 0 to 30], stool consistency [points 0 to 10], number of stools [points 0 to 15], nocturnal bowel movement [points 0 to 10], and activity level [points 0 to 10]). The total score ranges from 0 and 85 points, where it was calculated as the sum of the 6 scales and decrease of 20 points was considered a minimally clinically important change. Higher scores indicated a more severe disease. Analysis population included all enrolled subjects who received at least one administration of golimumab.

End point type	Secondary

End point timeframe:

Week 6

End point values	Golimumab			
Subject group type	Subject analysis set			
Number of subjects analysed	35			
Units: subjects	12			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Mucosal Healing at Week 6

End point title	Number of Subjects with Mucosal Healing at Week 6

End point description:

Mucosal healing was defined as an endoscopy subscore of the Mayo score of 0 (normal or inactive

disease) or 1 (mild disease). The Mayo score consists of 4 subscores (stool frequency, rectal bleeding, endoscopy findings, and physician's global assessment), rated as 0 (normal) to 3 (severe). Total score was calculated as the sum of 4 subscores and values range from 0 to 12 scores, where 3 to 5 = mild; 6 to 10 = moderate; and 11 to 12 = severe. Higher scores indicated worsening of the disease. Analysis population included all enrolled subjects who received at least one administration of golimumab.

End point type	Secondary

End point timeframe:

Week 6

End point values	Golimumab			
Subject group type	Subject analysis set			
Number of subjects analysed	35			
Units: subjects	19			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects who Achieved Clinical Remission at Week 54 and Week 110 Measured by Pediatric Ulcerative Colitis Activity Index (PUCAI) Score

End point title	Number of Subjects who Achieved Clinical Remission at Week 54 and Week 110 Measured by Pediatric Ulcerative Colitis Activity Index (PUCAI) Score

End point description:

Clinical remission as per PUCAI score was defined as PUCAI score of less than (<) 10, a noninvasive measure of ulcerative colitis disease activity. The PUCAI score consists of 6 scales (abdominal pain [points 0 to 10], rectal bleeding [points 0 to 30], stool consistency [points 0 to 10], number of stools [points 0 to 15], nocturnal bowel movement [points 0 to 10], and activity level [points 0 to 10]). The total score ranges from 0 and 85 points, where it was calculated as the sum of the 6 scales and decrease of 20 points is considered a minimally clinically important change. Higher scores indicated a more severe disease. Analysis population included subjects treated with golimumab in study extension part (Week 14 to Week 126) of study. The median change in PUCAI score from Week 110 was maintained at 0.0 at all visits assessed after Week 126. Here, N (number of subjects analysed) signifies subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Week 54 and Week 110

End point values	Golimumab			
Subject group type	Subject analysis set			
Number of subjects analysed	20			
Units: subjects				
Week 54	11			
Week 110	10			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline up to Week 434

Adverse event reporting additional description:

The safety analysis set included all subjects who received at least 1 dose of study intervention.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.0

Reporting groups

Reporting group title	Golimumab

Reporting group description:

Subjects with moderately to severely active ulcerative colitis (UC), received subcutaneous (SC) golimumab based on body weight in main part of study that is (i.e.) body weight less than (<) 45 kilogram (kg) received 90 milligrams per meter squared (mg/m^2) (up to maximum of 200 milligrams [mg]) at Week 0 and 45 mg/m^2 (up to maximum of 100 mg) at Week 2. Subjects with body weight greater than or equal to (>=) 45 kg received 200 mg at Week 0 and 100 mg at Week 2. Subjects with clinical response at Week 6 received same previous dose at Weeks 6 and 10. Subjects with clinical response at Week 6 entered study extension part at Week 14 and received maintenance therapy of golimumab 100 mg (body weight >=45 kg) or 45 mg/m^2 (body weight <45 kg) every 4 weeks (q4w) through study end (week 434).

Serious adverse events	Golimumab		
Total subjects affected by serious adverse events			
subjects affected / exposed	16 / 35 (45.71%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Forearm Fracture			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Iron Deficiency Anaemia			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Pancreatitis Acute			

subjects affected / exposed	1 / 35 (2.86%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Colitis Ulcerative				
subjects affected / exposed	13 / 35 (37.14%)			
occurrences causally related to treatment / all	0 / 13			
deaths causally related to treatment / all	0 / 0			
Abdominal Pain				
subjects affected / exposed	1 / 35 (2.86%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Cholangitis Sclerosing				
subjects affected / exposed	1 / 35 (2.86%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Urinary Tract Infection				
subjects affected / exposed	1 / 35 (2.86%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory Tract Infection				
subjects affected / exposed	1 / 35 (2.86%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Decreased Appetite				
subjects affected / exposed	1 / 35 (2.86%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

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

Non-serious adverse events	Golimumab		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	30 / 35 (85.71%)		
General disorders and administration site conditions			
Injection Site Irritation			
subjects affected / exposed	2 / 35 (5.71%)		
occurrences (all)	47		
Injection Site Erythema			
subjects affected / exposed	4 / 35 (11.43%)		
occurrences (all)	7		
Fatigue			
subjects affected / exposed	7 / 35 (20.00%)		
occurrences (all)	15		
Pyrexia			
subjects affected / exposed	3 / 35 (8.57%)		
occurrences (all)	4		
Non-Cardiac Chest Pain			
subjects affected / exposed	2 / 35 (5.71%)		
occurrences (all)	2		
Injection Site Pain			
subjects affected / exposed	5 / 35 (14.29%)		
occurrences (all)	11		
Immune system disorders			
Seasonal Allergy			
subjects affected / exposed	3 / 35 (8.57%)		
occurrences (all)	3		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	5 / 35 (14.29%)		
occurrences (all)	9		
Nasal Congestion			
subjects affected / exposed	2 / 35 (5.71%)		
occurrences (all)	4		
Oropharyngeal Pain			
subjects affected / exposed	4 / 35 (11.43%)		
occurrences (all)	6		

Rhinitis Allergic subjects affected / exposed occurrences (all) Sinus Congestion subjects affected / exposed occurrences (all)	2 / 35 (5.71%) 2 2 / 35 (5.71%) 3		
Psychiatric disorders Anxiety subjects affected / exposed occurrences (all)	2 / 35 (5.71%) 2		
Investigations Weight Decreased subjects affected / exposed occurrences (all)	3 / 35 (8.57%) 3		
Injury, poisoning and procedural complications Arthropod Bite subjects affected / exposed occurrences (all) Ligament Sprain subjects affected / exposed occurrences (all) Contusion subjects affected / exposed occurrences (all)	2 / 35 (5.71%) 2 3 / 35 (8.57%) 3 2 / 35 (5.71%) 2		
Nervous system disorders Syncope subjects affected / exposed occurrences (all) Headache subjects affected / exposed occurrences (all) Dizziness subjects affected / exposed occurrences (all)	2 / 35 (5.71%) 2 12 / 35 (34.29%) 32 2 / 35 (5.71%) 2		
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	7 / 35 (20.00%)		
occurrences (all)	8		
Leukopenia			
subjects affected / exposed	2 / 35 (5.71%)		
occurrences (all)	3		
Eye disorders			
Ocular Hyperaemia			
subjects affected / exposed	2 / 35 (5.71%)		
occurrences (all)	2		
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	2 / 35 (5.71%)		
occurrences (all)	4		
Colitis Ulcerative			
subjects affected / exposed	12 / 35 (34.29%)		
occurrences (all)	20		
Abdominal Pain Upper			
subjects affected / exposed	2 / 35 (5.71%)		
occurrences (all)	2		
Diarrhoea Haemorrhagic			
subjects affected / exposed	2 / 35 (5.71%)		
occurrences (all)	2		
Diarrhoea			
subjects affected / exposed	6 / 35 (17.14%)		
occurrences (all)	11		
Abdominal Pain			
subjects affected / exposed	9 / 35 (25.71%)		
occurrences (all)	21		
Gastrooesophageal Reflux Disease			
subjects affected / exposed	2 / 35 (5.71%)		
occurrences (all)	2		
Nausea			
subjects affected / exposed	7 / 35 (20.00%)		
occurrences (all)	10		
Rectal Haemorrhage			

subjects affected / exposed	3 / 35 (8.57%)		
occurrences (all)	3		
Vomiting			
subjects affected / exposed	3 / 35 (8.57%)		
occurrences (all)	7		
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	2 / 35 (5.71%)		
occurrences (all)	2		
Acne			
subjects affected / exposed	4 / 35 (11.43%)		
occurrences (all)	4		
Erythema			
subjects affected / exposed	3 / 35 (8.57%)		
occurrences (all)	3		
Pruritus			
subjects affected / exposed	3 / 35 (8.57%)		
occurrences (all)	5		
Rash			
subjects affected / exposed	3 / 35 (8.57%)		
occurrences (all)	3		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 35 (5.71%)		
occurrences (all)	7		
Musculoskeletal Chest Pain			
subjects affected / exposed	4 / 35 (11.43%)		
occurrences (all)	4		
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	5 / 35 (14.29%)		
occurrences (all)	8		
Influenza			
subjects affected / exposed	3 / 35 (8.57%)		
occurrences (all)	3		
Herpes Zoster			

subjects affected / exposed	2 / 35 (5.71%)			
occurrences (all)	2			
Gastroenteritis				
subjects affected / exposed	2 / 35 (5.71%)			
occurrences (all)	2			
Ear Infection				
subjects affected / exposed	3 / 35 (8.57%)			
occurrences (all)	6			
Clostridium Difficile Infection				
subjects affected / exposed	2 / 35 (5.71%)			
occurrences (all)	4			
Clostridium Difficile Colitis				
subjects affected / exposed	2 / 35 (5.71%)			
occurrences (all)	2			
Bacterial Infection				
subjects affected / exposed	2 / 35 (5.71%)			
occurrences (all)	2			
Pharyngitis				
subjects affected / exposed	4 / 35 (11.43%)			
occurrences (all)	6			
Upper Respiratory Tract Infection				
subjects affected / exposed	8 / 35 (22.86%)			
occurrences (all)	19			
Sinusitis				
subjects affected / exposed	2 / 35 (5.71%)			
occurrences (all)	3			
Rhinitis				
subjects affected / exposed	2 / 35 (5.71%)			
occurrences (all)	2			
Pneumonia				
subjects affected / exposed	3 / 35 (8.57%)			
occurrences (all)	3			
Pharyngitis Streptococcal				
subjects affected / exposed	2 / 35 (5.71%)			
occurrences (all)	2			
Viral Infection				

subjects affected / exposed	2 / 35 (5.71%)		
occurrences (all)	3		
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	3 / 35 (8.57%)		
occurrences (all)	4		
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	4 / 35 (11.43%)		
occurrences (all)	5		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 December 2013	Subjects in clinical response was continued receiving open-label maintenance therapy with golimumab and had the opportunity to participate in the study extension at Week 14. For subject convenience, the option of at-home golimumab administration is added during the study extension for subjects greater than or equal to (>=) 45 kilograms (kg). Addition of the option of at-home golimumab administration during the study extension for subjects with body weight >=45 kg: This was added for subject convenience. Addition of the option for subjects to decrease their dose to golimumab 50 mg or 22.5 mg/m2 at Week 14 or thereafter at the discretion of the investigator: Once a subject's dose was reduced, a single dose increase back to 100 mg or 45 mg/m2 was permitted based on the investigator's assessment of an increase in a subject's UC disease activity. A more flexible dosage strategy during the study extension allowed investigators to use the lowest effective dose and provided some discretion to investigators to increase the dose to manage the subject's clinical condition. Collection of a digital image of the screening and Week 6 endoscopies: A digital image of the endoscopy supported documentation of a subject's disease activity at the time of the assessment of the endoscopic score. Addition of a biomarker evaluation for mucosal biopsy ribonucleic acid (RNA): This analysis enables examination of gene expression associated with pediatric UC. Update of the reference point for the stable concomitant UC therapy inclusion criteria: To minimize the period of time in which subjects were not receiving effective therapy, the reference point for stable concomitant UC therapy was modified from the screening procedures for the Mayo score to the first dose of study agent (Week 0).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported