



Clinical trial results:

A Phase 1b Study to Evaluate SIMPONI® (golimumab) Therapy in Children, Adolescents, and Young Adults with Pre-Symptomatic Type 1 Diabetes

Summary

EudraCT number	2017-000225-12
Trial protocol	SE FI
Global end of trial date	20 December 2020

Results information

Result version number	v1 (current)
This version publication date	07 July 2021
First version publication date	07 July 2021

Trial information

Trial identification

Sponsor protocol code	CNT0148DML1001
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03298542
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Research and Development, LLC
Sponsor organisation address	920, US Highway, Route 202, South Raritan, United States, 08869
Public contact	Clinical Registry Group, Janssen Research and Development, LLC, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen Research and 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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	20 December 2020
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	20 December 2020
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 determine the safety and tolerability of golimumab in children, adolescents, and young adults with pre-symptomatic Stage 2 Type 1 diabetes (T1D).

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. Safety evaluations included regular monitoring for clinically related adverse events (AEs), monitoring of clinical laboratory changes (that is hematological and serum chemistry panel) and active monitoring of early detection of active tuberculosis (TB), vital signs and physical examination findings were evaluated. Monitoring of cytomegalovirus (CMV) and Epstein-Barr virus (EBV) viral load was done to detect if there is any study treatment effect on primary immune response to these infections that often take place during childhood and adolescence or could impact reactivation of these viruses in those who have been infected previously.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	22 January 2018
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	Finland: 2
Country: Number of subjects enrolled	United States: 6
Worldwide total number of subjects	8
EEA total number of subjects	2

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)	6

Adolescents (12-17 years)	2
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 21 subjects were screened of which 8 subjects with Stage 2 Type 1 Diabetes (T1D) were enrolled.

Period 1

Period 1 title	Active Treatment Period (Week 0-26)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Subjects received a subcutaneous (SC) placebo injection every 2 weeks (q2w) through Week 26 to match the active arm.

Arm type	Placebo
Investigational medicinal product name	Placebo (for Golimumab)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received a SC placebo injection q2w through Week 26 to match the active arm.

Arm title	Golimumab
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Arm description:

Subjects weighing (<) 45 kilograms (kg) received an induction dose of golimumab 60 milligrams per meter square (mg/m²) SC at Weeks 0 and 2 followed by a maintenance dose of 30 mg/m² SC at Week 4 and q2w through Week 26. Participants weighing greater than or equal to (>=) 45 kg received an induction dose of golimumab 100 mg SC at Weeks 0 and 2 followed by a maintenance dose of golimumab 50 mg SC at Week 4 and q2w through Week 26.

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

Dosage and administration details:

Subjects <45 kg received an induction dose of golimumab 60 mg/m² SC at Weeks 0 and 2 followed by a maintenance dose of 30 mg/m² SC at Week 4 and q2w through Week 26. Participants weighing >= 45 kg received an induction dose of golimumab 100 mg SC at Weeks 0 and 2 followed by a maintenance dose of golimumab 50 mg SC at Week 4 and q2w through Week 26.

Number of subjects in period 1	Placebo	Golimumab
Started	3	5
Completed	3	5

Period 2

Period 2 title	Off-therapy Follow-up Period(Week 26-52)
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Following the 26-week active treatment period, participants were monitored for an additional 26 weeks for safety.

Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	Golimumab

Arm description:

Following the 26-week active treatment period, participants were monitored for an additional 26 weeks for safety.

Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 2	Placebo	Golimumab
Started	3	5
Completed	3	5

Baseline characteristics

Reporting groups

Reporting group title	Placebo
Reporting group description: Subjects received a subcutaneous (SC) placebo injection every 2 weeks (q2w) through Week 26 to match the active arm.	
Reporting group title	Golimumab
Reporting group description: Subjects weighing (<) 45 kilograms (kg) received an induction dose of golimumab 60 milligrams per meter square (mg/m ²) SC at Weeks 0 and 2 followed by a maintenance dose of 30 mg/m ² SC at Week 4 and q2w through Week 26. Participants weighing greater than or equal to (>=) 45 kg received an induction dose of golimumab 100 mg SC at Weeks 0 and 2 followed by a maintenance dose of golimumab 50 mg SC at Week 4 and q2w through Week 26.	

Reporting group values	Placebo	Golimumab	Total
Number of subjects	3	5	8
Title for AgeCategorical Units: subjects			
Children (2-11 years)	2	3	5
Adolescents (12-17 years)	1	2	3
Adults (18-64 years)	0	0	0
From 65 to 84 years	0	0	0
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	10.04	11.08	
standard deviation	± 1.873	± 2.79	-
Title for Gender Units: subjects			
Female	1	0	1
Male	2	5	7

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: Subjects received a subcutaneous (SC) placebo injection every 2 weeks (q2w) through Week 26 to match the active arm.	
Reporting group title	Golimumab
Reporting group description: Subjects weighing (<) 45 kilograms (kg) received an induction dose of golimumab 60 milligrams per meter square (mg/m ²) SC at Weeks 0 and 2 followed by a maintenance dose of 30 mg/m ² SC at Week 4 and q2w through Week 26. Participants weighing greater than or equal to (>=) 45 kg received an induction dose of golimumab 100 mg SC at Weeks 0 and 2 followed by a maintenance dose of golimumab 50 mg SC at Week 4 and q2w through Week 26.	
Reporting group title	Placebo
Reporting group description: Following the 26-week active treatment period, participants were monitored for an additional 26 weeks for safety.	
Reporting group title	Golimumab
Reporting group description: Following the 26-week active treatment period, participants were monitored for an additional 26 weeks for safety.	
Subject analysis set title	Placebo
Subject analysis set type	Safety analysis
Subject analysis set description: Subjects who received at least 1 dose of study agent.	
Subject analysis set title	Golimumab
Subject analysis set type	Safety analysis
Subject analysis set description: Subjects who received at least 1 dose of study agent.	

Primary: Percentage of Subjects with Treatment-emergent Adverse Events (TEAEs) Up to Week 26

End point title	Percentage of Subjects with Treatment-emergent Adverse Events (TEAEs) Up to Week 26 ^[1]
End point description: An adverse event (AE) was defined as any untoward medical occurrence in clinical study subject administered medicinal product. It could be any unfavorable and unintended sign (including an abnormal finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not related to that medicinal product. Treatment emergent AEs were defined as AEs with onset during the treatment phase or that are a consequence of a pre-existing condition that has worsened since baseline. Safety analysis set included all subjects who had received at least 1 dose of study agent.	
End point type	Primary
End point timeframe: Up to Week 26	

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: Descriptive statistics was done, no inferential statistical analysis was performed.

End point values	Placebo	Golimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	5		
Units: percentage of subjects				
number (not applicable)	100	100		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects with Treatment-emergent Serious Adverse Events (SAEs) Up to Week 26

End point title	Percentage of Subjects with Treatment-emergent Serious Adverse Events (SAEs) Up to Week 26 ^[2]
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End point description:

An AE was defined as any untoward medical occurrence in clinical study subject administered medicinal product. It could be any unfavorable and unintended sign (including an abnormal finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not related to that medicinal product. A SAE was defined as any untoward medical occurrence that at any dose: resulted in death, was life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity, was a congenital anomaly/birth defect, was a suspected transmission of any infectious treatment via medicinal product and was medically important. Safety analysis set included all subjects who had received at least 1 dose of study agent.

End point type	Primary
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End point timeframe:

Up to Week 26

Notes:

[2] - 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: Descriptive statistics was done, no inferential statistical analysis was performed.

End point values	Placebo	Golimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	5		
Units: percentage of subjects				
number (not applicable)	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects with Treatment-emergent AEs Up to Week 52

End point title	Percentage of Subjects with Treatment-emergent AEs Up to Week 52 ^[3]
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End point description:

An adverse event (AE) was defined as any untoward medical occurrence in clinical study subject administered medicinal product. It could be any unfavorable and unintended sign (including an abnormal finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not related to that medicinal product. Treatment emergent AEs were defined as AEs with onset during the treatment phase or that are a consequence of a pre-existing condition that has worsened since baseline.

Safety analysis set included all subjects who had received at least 1 dose of study agent.

End point type	Primary
End point timeframe:	
Up to Week 52	

Notes:

[3] - 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: Descriptive statistics was done, no inferential statistical analysis was performed.

End point values	Placebo	Golimumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	3	5		
Units: percentage of subjects				
number (not applicable)	100	100		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects with Treatment-emergent SAEs Up to Week 52

End point title	Percentage of Subjects with Treatment-emergent SAEs Up to Week 52 ^[4]
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End point description:

An AE was defined as any untoward medical occurrence in clinical study subject administered medicinal product. It could be any unfavorable and unintended sign (including an abnormal finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not related to that medicinal product. A SAE was defined as any untoward medical occurrence that at any dose: resulted in death, was life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity, was a congenital anomaly/birth defect, was a suspected transmission of any infectious treatment via medicinal product and was medically important. Safety analysis set included all subjects who had received at least 1 dose of study agent.

End point type	Primary
End point timeframe:	
Up to Week 52	

Notes:

[4] - 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: Descriptive statistics was done, no inferential statistical analysis was performed.

End point values	Placebo	Golimumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	3	5		
Units: percentage of subjects				
number (not applicable)	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects with Treatment-emergent Infections Up to Week 26

End point title	Percentage of Subjects with Treatment-emergent Infections Up to Week 26 ^[5]
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End point description:

Subjects who had developed non-severe infections such as influenza, upper respiratory tract infection, rhinitis, nasopharyngitis, otitis externa (active), and gastroenteritis were reported. The safety analysis set included all subjects who had received at least 1 dose of study agent.

End point type	Primary
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End point timeframe:

Up to Week 26

Notes:

[5] - 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: Descriptive statistics was done, no inferential statistical analysis was performed.

End point values	Placebo	Golimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	5		
Units: percentage of subjects				
number (not applicable)	100	60		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects with Treatment-emergent Infections Up to Week 52

End point title	Percentage of Subjects with Treatment-emergent Infections Up to Week 52 ^[6]
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End point description:

Subjects who had developed non-severe infections such as influenza, upper respiratory tract infection, rhinitis, nasopharyngitis, otitis externa (active), and gastroenteritis were reported. The safety analysis set included all subjects who had received at least 1 dose of study agent.

End point type	Primary
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End point timeframe:

Up to Week 52

Notes:

[6] - 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: Descriptive statistics was done, no inferential statistical analysis was performed.

End point values	Placebo	Golimumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	3	5		
Units: percentage of subjects				
number (not applicable)	100	60		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects with Study Treatment Injection Site Reactions

End point title	Percentage of Subjects with Study Treatment Injection Site Reactions ^[7]
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End point description:

An injection site reaction was any unfavorable or unintended sign that occurred at the study agent injection site. If an injection site reaction was observed, the participant was treated at the investigator's discretion. The safety analysis set included all subjects who had received at least 1 dose of study agent.

End point type	Primary
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End point timeframe:

Up to Week 52

Notes:

[7] - 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: Descriptive statistics was done, no inferential statistical analysis was performed.

End point values	Placebo	Golimumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	3	5		
Units: percentage of subjects				
number (not applicable)	0	40		

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentrations of Golimumab

End point title	Serum Concentrations of Golimumab ^[8]
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End point description:

Serum samples for the measurement of golimumab concentrations were collected at Weeks 0, 2, 4, 8, 12, and 26. Samples at Week 0, 2, and 4 were associated with the induction doses administered at Weeks 0 and 2. Pharmacokinetics (PK) analysis set included 5 subjects who received at least 1 golimumab injection and had sufficient PK samples for analysis. Here 'n' (number analyzed) included all subjects who were analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Weeks 0, 2, 4, 8, 12 and 26

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Endpoint was planned to be analyzed for specified arms only.

End point values	Golimumab			
Subject group type	Reporting group			
Number of subjects analysed	5			
Units: micrograms per milliliter (µg/mL)				
arithmetic mean (standard deviation)				
Week 0: Preinjection (n=5)	0 (± 0)			

Week 2: Preinjection (n=4)	5.09 (± 1.351)			
Week 4: Preinjection (n=5)	9.01 (± 2.78)			
Week 8: Preinjection (n=5)	5.09 (± 2.211)			
Week 12: Preinjection (n=5)	4.52 (± 2.404)			
Week 26: Preinjection (n=5)	3.95 (± 2.845)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Antibodies to Golimumab

End point title	Number of Subjects with Antibodies to Golimumab ^[9]
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End point description:

Number of subjects with antibodies to golimumab were reported. Full Analysis Set included all subjects who received at least 1 dose of golimumab and had appropriate samples for detection of antibodies to golimumab.

End point type	Secondary
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End point timeframe:

Up to Week 26

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Endpoint was planned to be analyzed for specified arms only.

End point values	Golimumab			
Subject group type	Reporting group			
Number of subjects analysed	5			
Units: subjects	2			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to Week 52

Adverse event reporting additional description:

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

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	23.0
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Reporting groups

Reporting group title	Placebo (Week 0 - 26)
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Reporting group description:

Subjects received a SC placebo injection q2w through Week 26 to match the active arm.

Reporting group title	Golimumab (Week 0 - 26)
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Reporting group description:

Subjects <45 kg received an induction dose of golimumab 60 mg/m² SC at Weeks 0 and 2 followed by a maintenance dose of 30 mg/m² SC at Week 4 and q2w through Week 26. Participants weighing ≥ 45 kg received an induction dose of golimumab 100 mg SC at Weeks 0 and 2 followed by a maintenance dose of golimumab 50 mg SC at Week 4 and q2w through Week 26.

Reporting group title	Placebo (Week 26 - 52)
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Reporting group description:

Following the 26-week active treatment period, participants were monitored for an additional 26 weeks for safety.

Reporting group title	Golimumab (Week 26 - 52)
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Reporting group description:

Following the 26-week active treatment period, participants were monitored for an additional 26 weeks for safety.

Serious adverse events	Placebo (Week 0 - 26)	Golimumab (Week 0 - 26)	Placebo (Week 26 - 52)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

Serious adverse events	Golimumab (Week 26 - 52)		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 5 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

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

Non-serious adverse events	Placebo (Week 0 - 26)	Golimumab (Week 0 - 26)	Placebo (Week 26 - 52)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	5 / 5 (100.00%)	3 / 3 (100.00%)
General disorders and administration site conditions			
Injection Site Pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Injection Site Urticaria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Immune system disorders			
Serum Sickness			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Nasal Congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Investigations			
Body Temperature Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

Head Injury subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Skin Abrasion subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	1 / 5 (20.00%) 1	1 / 3 (33.33%) 1
Nervous system disorders Dizziness subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 3	1 / 5 (20.00%) 2	1 / 3 (33.33%) 1
Syncope subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Blood and lymphatic system disorders Neutropenia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 5 (20.00%) 7	0 / 3 (0.00%) 0
Eye disorders Eye Pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 5 (20.00%) 1	0 / 3 (0.00%) 0
Gastrointestinal disorders Abdominal Pain subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Skin and subcutaneous tissue disorders Dermatitis Atopic subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 5 (20.00%) 1	0 / 3 (0.00%) 0
Nail Bed Inflammation subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 5 (20.00%) 1	0 / 3 (0.00%) 0
Papule			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pigmentation Disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Influenza			
subjects affected / exposed	1 / 3 (33.33%)	1 / 5 (20.00%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
Nasopharyngitis			
subjects affected / exposed	2 / 3 (66.67%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	2	1	0
Otitis Externa			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Upper Respiratory Tract Infection			

subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	1 / 5 (20.00%) 1	1 / 3 (33.33%) 2
Metabolism and nutrition disorders Type 1 Diabetes Mellitus subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 5 (20.00%) 1	0 / 3 (0.00%) 0

Non-serious adverse events	Golimumab (Week 26 - 52)		
Total subjects affected by non-serious adverse events subjects affected / exposed	5 / 5 (100.00%)		
General disorders and administration site conditions Injection Site Pain subjects affected / exposed occurrences (all) Injection Site Urticaria subjects affected / exposed occurrences (all) Malaise subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0 0 / 5 (0.00%) 0 0 / 5 (0.00%) 0		
Immune system disorders Serum Sickness subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) Nasal Congestion subjects affected / exposed occurrences (all) Oropharyngeal Pain subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0 1 / 5 (20.00%) 1 1 / 5 (20.00%) 1		
Investigations			

Body Temperature Decreased subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1		
Injury, poisoning and procedural complications Head Injury subjects affected / exposed occurrences (all) Skin Abrasion subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0 1 / 5 (20.00%) 2		
Nervous system disorders Dizziness subjects affected / exposed occurrences (all) Headache subjects affected / exposed occurrences (all) Syncope subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0 0 / 5 (0.00%) 0 0 / 5 (0.00%) 0		
Blood and lymphatic system disorders Neutropenia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0		
Eye disorders Eye Pain subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0		
Gastrointestinal disorders Abdominal Pain subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0		
Skin and subcutaneous tissue disorders Dermatitis Atopic subjects affected / exposed occurrences (all) Nail Bed Inflammation	0 / 5 (0.00%) 0		

subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Papule			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Pigmentation Disorder			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Rash			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Urticaria			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Myalgia			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Influenza			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	3		
Nasopharyngitis			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	2		
Otitis Externa			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Rhinitis			

subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0		
Upper Respiratory Tract Infection subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1		
Metabolism and nutrition disorders Type 1 Diabetes Mellitus subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 April 2019	Amendment 2 had the following key changes: This sample size no longer supported the stratification on HbA1c and the population PK modeling or PK/PD analysis that was planned, which had been removed from the protocol. A change in randomization ratio from 2:1 to 6:1 (active:placebo) provided a more customary proportion of subjects on active drug to assess safety and allowed for improved recruitment, and had a higher proportion of subjects exposed to active treatment. Due to the reduced number of study subjects, the number of database locks (DBLs) had been reduced to one final DBL at Week 52.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

Sample size of 5 subjects in golimumab treatment and 3 in placebo group. For safety (5 on treatment), the limitation gives early read of safety of golimumab in younger population; also makes it not possible to draw conclusions on metabolic assessments.

Notes: