Clinical trial results:
A Phase 2, Multicenter, Randomized, Placebo-Controlled, Double-Blind, Proof-of-Concept Study to Evaluate Guselkumab for the Treatment of Subjects with Moderate to Severe Hidradenitis Suppurativa

Summary

EudraCT number	2018-001176-38
Trial protocol	FR DE NL DK
Global end of trial date	22 May 2020

Results information

Result version number	v1 (current)
This version publication date	03 June 2021
First version publication date	03 June 2021

Trial information

Trial identification

Sponsor protocol code	CNTO1959HDS2001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03628924
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Research and Development LLC
Sponsor organisation address	920 US, Route 202, P.O. Box 300, Raritan, United States, 08869
Public contact	Clinical Registry Group, Janssen Research and Development, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen Research and Development, 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	19 June 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	22 May 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 evaluate the initial efficacy, safety, and tolerability of guselkumab in adult subjects with moderate to severe Hidradenitis Suppurativa (HS).

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 was evaluated based on adverse events (AEs) and clinical laboratory test results (that is, hematology and serum chemistry).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 September 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	Canada: 22
Country: Number of subjects enrolled	Germany: 36
Country: Number of subjects enrolled	Denmark: 4
Country: Number of subjects enrolled	France: 51
Country: Number of subjects enrolled	Netherlands: 7
Country: Number of subjects enrolled	United States: 61
Worldwide total number of subjects	181
EEA total number of subjects	98

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)	177
From 65 to 84 years	4
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 236 subjects were screened of which 184 subjects were enrolled in the study. Of the 184 subjects, 3 subjects were randomized but did not receive treatment and 181 subjects were randomized and dosed into guselkumab 200 mg and 1200 mg and placebo groups.

Period 1

Period 1 title	Placebo Controlled Period (Week 0-16)
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	Placebo (Week 0 - 16)

Arm description:

Subjects received placebo intravenously (IV) and subcutaneously (SC) at Weeks 0, 4, 8 and an additional SC placebo at Week 12.

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

Dosage and administration details:

Subjects received placebo SC at Weeks 0, 4, 8, and 12.

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

Dosage and administration details:

Subjects received placebo IV at Weeks 0, 4, and 8.

Arm title	Guselkumab 200 milligrams (mg) SC (Week 0 - 16)

Arm description:

Subjects received 200 mg guselkumab (Gus) SC at Weeks 0, 4, 8, and 12.

Arm type	Experimental
Investigational medicinal product name	Guselkumab
Investigational medicinal product code	
Other name	CNTO1959
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received 200 mg guselkumab SC at Weeks 0, 4, 8, and 12.

Arm title	Guselkumab 1200 mg IV to Gus 200 mg SC (Week 0 - 16)

Arm description:

Subjects received 1200 mg guselkumab IV at Weeks 0, 4, and 8, and 200 mg guselkumab SC at Week 12.

Arm type	Experimental
Investigational medicinal product name	Guselkumab
Investigational medicinal product code	
Other name	CNTO1959
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received 1200 mg guselkumab IV at Weeks 0, 4, and 8.

Number of subjects in period 1	Placebo (Week 0 - 16)	Guselkumab 200 milligrams (mg) SC (Week 0 - 16)	Guselkumab 1200 mg IV to Gus 200 mg SC (Week 0 - 16)
Started	62	59	60
Completed	56	56	57
Not completed	6	3	3
Adverse event, serious fatal	-	1	-
Lost to follow-up	2	-	-
Protocol deviation	1	2	1
Lack of efficacy	3	-	1
Withdrawal by subject	-	-	1

Period 2

Period 2 title	Active Treatment Period (Week 16-48)
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	Placebo Crossover to Guselkumab 100 mg SC (Week 16 - 48)

Arm description:

At Week 16, subjects receiving placebo during placebo-controlled period were re-randomized to receive 100 mg guselkumab SC at Weeks 16, 20, 28 and 36 and placebo at Weeks 24 and 32. All subjects entered safety follow-up at Week 36 through Week 48.

Arm type	Experimental
Investigational medicinal product name	Placebo matching to guselkumab 100 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

At Week 16, subjects receiving placebo during placebo-controlled period were re-randomized to receive 100 mg guselkumab SC at Weeks 16, 20, 28 and 36 and placebo at Weeks 24 and 32.

Arm title	Placebo Crossover to Guselkumab 200 mg SC (Week 16 - 48)

Arm description:

At Week 16, subjects receiving placebo during placebo-controlled period were re-randomized to receive 200 mg guselkumab SC every 4 weeks (q4w) through Week 36. All subjects entered safety follow-up at Week 36 through Week 48.

Arm type	Experimental
Investigational medicinal product name	Placebo matching to guselkumab 200 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

At Week 16, subjects receiving placebo during placebo-controlled period were re-randomized to receive 200 mg guselkumab SC every 4 weeks (q4w) through Week 36.

Arm title	Guselkumab 200 mg SC (Week 16 - 48)

Arm description:

Subjects who were receiving 200 mg guselkumab SC during placebo-controlled period, continued to receive 200 mg guselkumab SC q4w through Week 36. All subjects entered safety follow-up at Week 36 through Week 48.

Arm type	Experimental
Investigational medicinal product name	Guselkumab 200 mg
Investigational medicinal product code	
Other name	CNTO1959
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects who were receiving 200 mg guselkumab SC during placebo-controlled period, continued to receive 200 mg guselkumab SC q4w through Week 36.

Arm title	Gus 1200 mg IV Crossover to Gus 200 mg SC (Week 16 - 48)

Arm description:

Subjects who were receiving 1200 mg guselkumab IV during placebo-controlled period switched treatment at Week 12 to receive guselkumab 200 mg SC q4w through Week 36. All subjects entered safety follow-up at Week 36 through Week 48.

Arm type	Experimental
Investigational medicinal product name	Guselkumab 200 mg
Investigational medicinal product code	
Other name	CNTO1959
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects who were receiving 1200 mg guselkumab IV during placebo-controlled period switched treatment at Week 12 to receive guselkumab 200 mg SC q4w through Week 36.

Number of subjects in period 2	Placebo Crossover to Guselkumab 100 mg SC (Week 16 - 48)	Placebo Crossover to Guselkumab 200 mg SC (Week 16 - 48)	Guselkumab 200 mg SC (Week 16 - 48)
Started	28	28	56
Completed	20	24	43
Not completed	8	4	13
Adverse event, serious fatal	-	-	1
Adverse event, non-fatal	1	-	1
Lost to follow-up	1	1	2
Lack of efficacy	5	1	4
Protocol deviation	1	1	-
Withdrawal by subject	-	1	5

Number of subjects in period 2	Gus 1200 mg IV Crossover to Gus 200 mg SC (Week 16 - 48)
Started	57
Completed	46
Not completed	11
Adverse event, serious fatal	-
Adverse event, non-fatal	4
Lost to follow-up	1
Lack of efficacy	2
Protocol deviation	1
Withdrawal by subject	3

Baseline characteristics

Reporting groups	
Reporting group title	Placebo (Week 0 - 16)
Reporting group description:	
Subjects received placebo intravenously (IV) and subcutaneously (SC) at Weeks 0, 4, 8 and an additional SC placebo at Week 12.	
Reporting group title	Guselkumab 200 milligrams (mg) SC (Week 0 - 16)
Reporting group description:	
Subjects received 200 mg guselkumab (Gus) SC at Weeks 0, 4, 8, and 12.	
Reporting group title	Guselkumab 1200 mg IV to Gus 200 mg SC (Week 0 - 16)
Reporting group description:	
Subjects received 1200 mg guselkumab IV at Weeks 0, 4, and 8, and 200 mg guselkumab SC at Week 12.	

Reporting group values	Placebo (Week 0 - 16)	Guselkumab 200 milligrams (mg) SC (Week 0 - 16)	Guselkumab 1200 mg IV to Gus 200 mg SC (Week 0 - 16)
Number of subjects	62	59	60
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	60	57	60
From 65 to 84 years	2	2	0
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	38.2	39	37.2
standard deviation	± 11.55	± 12.37	± 10.92
Title for Gender Units: subjects			
Female	38	32	45
Male	24	27	15

Reporting group values	Total		
Number of subjects	181		
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	177		
From 65 to 84 years	4		
85 years and over	0		
Title for AgeContinuous Units: years			
arithmetic mean			
standard deviation	-		

Title for Gender Units: subjects			
Female	115		
Male	66		

End points

End points reporting groups

Reporting group title	Placebo (Week 0 - 16)
Reporting group description:	
Subjects received placebo intravenously (IV) and subcutaneously (SC) at Weeks 0, 4, 8 and an additional SC placebo at Week 12.	
Reporting group title	Guselkumab 200 milligrams (mg) SC (Week 0 - 16)
Reporting group description:	
Subjects received 200 mg guselkumab (Gus) SC at Weeks 0, 4, 8, and 12.	
Reporting group title	Guselkumab 1200 mg IV to Gus 200 mg SC (Week 0 - 16)
Reporting group description:	
Subjects received 1200 mg guselkumab IV at Weeks 0, 4, and 8, and 200 mg guselkumab SC at Week 12.	
Reporting group title	Placebo Crossover to Guselkumab 100 mg SC (Week 16 - 48)
Reporting group description:	
At Week 16, subjects receiving placebo during placebo-controlled period were re-randomized to receive 100 mg guselkumab SC at Weeks 16, 20, 28 and 36 and placebo at Weeks 24 and 32. All subjects entered safety follow-up at Week 36 through Week 48.	
Reporting group title	Placebo Crossover to Guselkumab 200 mg SC (Week 16 - 48)
Reporting group description:	
At Week 16, subjects receiving placebo during placebo-controlled period were re-randomized to receive 200 mg guselkumab SC every 4 weeks (q4w) through Week 36. All subjects entered safety follow-up at Week 36 through Week 48.	
Reporting group title	Guselkumab 200 mg SC (Week 16 - 48)
Reporting group description:	
Subjects who were receiving 200 mg guselkumab SC during placebo-controlled period, continued to receive 200 mg guselkumab SC q4w through Week 36. All subjects entered safety follow-up at Week 36 through Week 48.	
Reporting group title	Gus 1200 mg IV Crossover to Gus 200 mg SC (Week 16 - 48)
Reporting group description:	
Subjects who were receiving 1200 mg guselkumab IV during placebo-controlled period switched treatment at Week 12 to receive guselkumab 200 mg SC q4w through Week 36. All subjects entered safety follow-up at Week 36 through Week 48.	

Primary: Percentage of Subjects Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) at Week 16

End point title	Percentage of Subjects Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) at Week 16
End point description:	
HiSCR is defined as at least 50 percent (%) reduction in total abscess and inflammatory nodule (AN) count with no increase in abscess count and no increase in draining fistula count relative to baseline. Full Analysis Set (FAS) included all randomized subjects who received at least one administration of study intervention. Subjects with missing data after applying treatment failure rules were assumed to be non-responders. Subjects who discontinued study intervention due to lack of efficacy or an Adverse event (AE) of worsening of hidradenitis suppurativa (HS), or who started a protocol-prohibited medication or therapy during the study that could improve HS were considered treatment failures.	
End point type	Primary
End point timeframe:	
Week 16	

End point values	Placebo (Week 0 - 16)	Guselkumab 200 milligrams (mg) SC (Week 0 - 16)	Guselkumab 1200 mg IV to Gus 200 mg SC (Week 0 - 16)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	62	59	60	
Units: percentage of subjects				
number (not applicable)	38.7	50.8	45.0	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo (Week 0 - 16) v Guselkumab 200 milligrams (mg) SC (Week 0 - 16)
Number of subjects included in analysis	121
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.166
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment difference
Point estimate	12.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.6
upper limit	29.8

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo (Week 0 - 16) v Guselkumab 1200 mg IV to Gus 200 mg SC (Week 0 - 16)
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.459
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment difference
Point estimate	6.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.3
upper limit	23.6

Secondary: Change From Baseline in Subjects Total Abscess and Inflammatory Nodule (AN) Count at Week 16

End point title	Change From Baseline in Subjects Total Abscess and

	Inflammatory Nodule (AN) Count at Week 16

End point description:

Change from baseline in total AN count at Week 16 was reported. Abscess and inflammatory nodule were counted for the HS affected anatomical regions. The AN count is the sum of number of abscess and inflammatory nodules across anatomical regions. FAS included all randomized subjects who received at least one administration of study intervention. The analysis was based on observed data after applying treatment failure rules (the change from baseline using observed data or 0 [no improvement] if a subject met treatment failure [TF] criteria).Here, N (number of subjects analyzed) signifies subjects evaluated for this endpoint.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Placebo (Week 0 - 16)	Guselkumab 200 milligrams (mg) SC (Week 0 - 16)	Guselkumab 1200 mg IV to Gus 200 mg SC (Week 0 - 16)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	59	57	59	
Units: count of abscess and inflammatory nodule				
arithmetic mean (standard deviation)	-3.2 (± 7.37)	-5.3 (± 9.29)	-5.3 (± 6.53)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Dermatology Life Quality Index (DLQI) Total Score at Week 16

End point title	Change From Baseline in Dermatology Life Quality Index (DLQI) Total Score at Week 16

End point description:

DLQI is a simple, compact, and practical questionnaire to assess limitations related to the impact of skin disease. The instrument contains ten items dealing with the subject's skin. The subject responds on a four-point scale, ranging from "Very Much" (score 3) to "Not at All" or "Not relevant" (score 0). The DLQI total score is derived by summing all item scores, which has a possible range of 0 to 30, with 30 corresponding to the worst quality of life, and 0 corresponding to the best. A lower score (that is, negative change score) indicates improvement in the Quality of Life. FAS included all randomized subjects who received at least one administration of study intervention. The analysis was based on observed data after applying treatment failure rules (the change from baseline using observed data or 0 [no improvement] if a subject met TF criteria). Here, N (number of subjects analyzed) signifies subjects who were evaluated for this outcome measure.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Placebo (Week 0 - 16)	Guselkumab 200 milligrams (mg) SC (Week 0 - 16)	Guselkumab 1200 mg IV to Gus 200 mg SC (Week 0 - 16)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	59	56	57	
Units: units on a scale				
arithmetic mean (standard deviation)	-0.7 (± 5.17)	-3.4 (± 6.81)	-2.5 (± 6.13)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Hidradenitis Suppurativa (HS)-Related Pain Symptom Score in the Past 24 Hours Based on Hidradenitis Suppurativa Symptom Diary (HSSD) Questionnaire at Week 16

End point title	Change From Baseline in Hidradenitis Suppurativa (HS)-Related Pain Symptom Score in the Past 24 Hours Based on Hidradenitis Suppurativa Symptom Diary (HSSD) Questionnaire at Week 16

End point description:

HSSD is 7-item patient self-reported questionnaire assesses 5 HS-related symptoms (pain, tenderness, hot skin feeling, odor, and itchiness). Subjects rated severity of each symptom on 0 (no symptom) to 10 (worst possible symptom) scale. All 5 symptoms have recall period of past 7 days, except 2 additional items of pain that is current pain and pain in past 24 hours. Total symptom score ranged from 0 (no symptom) to 10 (worst possible symptom), which is average of 5 individual scale scores that utilize past 7-day recall period. Change from baseline in HR-related pain symptom score based on HSSD was reported. FAS included all randomized subjects who received at least 1 dose of study intervention. Subjects who received analgesic therapy for HS within 1 day of scheduled visit date, were considered TF at that visit (change from baseline using observed data/ 0 [no improvement] if subject met TF criteria). Here, N (number of subjects analyzed) signifies subjects evaluated for this endpoint.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Placebo (Week 0 - 16)	Guselkumab 200 milligrams (mg) SC (Week 0 - 16)	Guselkumab 1200 mg IV to Gus 200 mg SC (Week 0 - 16)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	55	56	
Units: units on a scale				
arithmetic mean (standard deviation)	-0.3 (± 3.17)	-1.6 (± 3.05)	-1.2 (± 2.93)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved at Least 50 Percent Reduction in

Total Abscess and Inflammatory Nodule Count at Week 16

End point title	Percentage of Subjects Who Achieved at Least 50 Percent Reduction in Total Abscess and Inflammatory Nodule Count at Week 16

End point description:

Percentage of subjects achieving at least 50 percent reduction in total AN count at Week 16 was reported. Abscess and inflammatory nodule were counted for the HS affected anatomical regions. The AN count is the sum of number of abscess and inflammatory nodules across anatomical regions. FAS included all randomized subjects who received at least one administration of study intervention. Subjects with missing data after applying treatment failure rules were assumed to be non-responders.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo (Week 0 - 16)	Guselkumab 200 milligrams (mg) SC (Week 0 - 16)	Guselkumab 1200 mg IV to Gus 200 mg SC (Week 0 - 16)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	62	59	60	
Units: percentage of subjects				
number (not applicable)	45.2	55.9	51.7	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved at Least 75 Percent Reduction in Total Abscess and Inflammatory Nodule Count at Week 16

End point title	Percentage of Subjects Who Achieved at Least 75 Percent Reduction in Total Abscess and Inflammatory Nodule Count at Week 16

End point description:

Percentage of subjects achieving at least 75 percent reduction in total AN count at Week 16 was reported. Abscess and inflammatory nodule were counted for the HS affected anatomical regions. The AN count is the sum of number of abscess and inflammatory nodules across anatomical regions. FAS included all randomized subjects who received at least one administration of study intervention. Subjects with missing data after applying treatment failure rules were assumed to be non-responders.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo (Week 0 - 16)	Guselkumab 200 milligrams (mg) SC (Week 0 - 16)	Guselkumab 1200 mg IV to Gus 200 mg SC (Week 0 - 16)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	62	59	60	
Units: percentage of subjects				
number (not applicable)	30.6	40.7	26.7	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved at Least 90 Percent Reduction in Total Abscess and Inflammatory Nodule Count at Week 16

End point title	Percentage of Subjects Who Achieved at Least 90 Percent Reduction in Total Abscess and Inflammatory Nodule Count at Week 16

End point description:

Percentage of subjects achieving at least 90 percent reduction in total AN count at Week 16 was reported. Abscess and inflammatory nodule were counted for the HS affected anatomical regions. The AN count is the sum of number of abscess and inflammatory nodules across anatomical regions. FAS included all randomized subjects who received at least one administration of study intervention. Subjects with missing data after applying treatment failure rules were assumed to be non-responders.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo (Week 0 - 16)	Guselkumab 200 milligrams (mg) SC (Week 0 - 16)	Guselkumab 1200 mg IV to Gus 200 mg SC (Week 0 - 16)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	62	59	60	
Units: percentage of subjects				
number (not applicable)	17.7	22.0	15.0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved 100 Percent Reduction in Total Abscess and Inflammatory Nodule Count at Week 16

End point title	Percentage of Subjects Who Achieved 100 Percent Reduction in Total Abscess and Inflammatory Nodule Count at Week 16

End point description:

Percentage of subjects achieving 100 percent reduction in total AN count at Week 16 was reported. Abscess and inflammatory nodule were counted for the HS affected anatomical regions. The AN count is

the sum of number of abscess and inflammatory nodules across anatomical regions. FAS included all randomized subjects who received at least one administration of study intervention. Subjects with missing data after applying treatment failure rules were assumed to be non-responders.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo (Week 0 - 16)	Guselkumab 200 milligrams (mg) SC (Week 0 - 16)	Guselkumab 1200 mg IV to Gus 200 mg SC (Week 0 - 16)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	62	59	60	
Units: percentage of subjects				
number (not applicable)	14.5	15.3	15.0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved an Abscess and Inflammatory Nodule Count of 0/1 and AN Count of 0/1/2 at Week 16

End point title	Percentage of Subjects Who Achieved an Abscess and Inflammatory Nodule Count of 0/1 and AN Count of 0/1/2 at Week 16

End point description:

Percentage of subjects who achieved an AN count of 0/1 and AN Count of 0/1/2 at Week 16 were reported. Abscess and inflammatory nodule were counted for the HS affected anatomical regions. The AN count is the sum of number of abscess and inflammatory nodules across anatomical regions. FAS included all randomized subjects who received at least one administration of study intervention. Subjects with missing data after applying treatment failure rules were assumed to be non-responders.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo (Week 0 - 16)	Guselkumab 200 milligrams (mg) SC (Week 0 - 16)	Guselkumab 1200 mg IV to Gus 200 mg SC (Week 0 - 16)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	62	59	60	
Units: percentage of subjects				
number (not applicable)				
AN Count of 0/1	27.4	30.5	23.3	
AN Count of 0/1/2	33.9	39.0	31.7	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Abscess Count of 0 at Week 16 For Subjects With Baseline Abscess Count Greater Than 0

End point title	Percentage of Subjects Who Achieved Abscess Count of 0 at Week 16 For Subjects With Baseline Abscess Count Greater Than 0

End point description:

Percentage of subjects who achieved abscess count of 0 at Week 16 for subjects with baseline abscess count greater than (>) 0 were reported. Population analyzed included FAS subjects with baseline abscess count > 0. Subjects with missing data after applying treatment failure rules were assumed to be non-responders.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo (Week 0 - 16)	Guselkumab 200 milligrams (mg) SC (Week 0 - 16)	Guselkumab 1200 mg IV to Gus 200 mg SC (Week 0 - 16)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	28	36	31	
Units: percentage of subjects				
number (not applicable)	39.3	63.9	45.2	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Number of Abscesses at Week 16

End point title	Change From Baseline in the Number of Abscesses at Week 16

End point description:

Change from baseline in number of abscesses at Week 16 was reported. FAS included all randomized subjects who received at least one administration of study intervention. The analysis was based on observed data after applying treatment failure rules (the change from baseline using observed data or 0 (no improvement) if a subject met TF criteria). Here, N (number of subjects analyzed) signifies subjects who were evaluated for this outcome measure.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Placebo (Week 0 - 16)	Guselkumab 200 milligrams (mg) SC (Week 0 - 16)	Guselkumab 1200 mg IV to Gus 200 mg SC (Week 0 - 16)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	59	57	59	
Units: abscess				
arithmetic mean (standard deviation)	-0.4 (± 2.72)	-2.1 (± 4.56)	-1.6 (± 3.90)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in HSSD Symptom Scale Total Score at Week 16

End point title	Change From Baseline in HSSD Symptom Scale Total Score at Week 16

End point description:

HSSD is 7-item patient self-reported questionnaire assesses 5 HS-related symptoms (pain, tenderness, hot skin feeling, odor, and itchiness). Subjects were asked to rate severity of each symptom on 0 to 10 numerical rating scale, with 0 (no symptom) and 10 (worst possible symptom). All 5 symptoms have a recall period of past 7 days, except for 2 additional questions on pain which evaluate current pain and pain in the past 24 hours. A total symptom score, also ranged from 0 (no symptom) to 10 (worst possible symptom), was derived by averaging the 5 individual scale scores that utilize the past 7-day recall period. FAS included all randomized subjects who received at least 1 administration of study intervention. The analysis was based on observed data after applying treatment failure rules (the change from baseline using observed data or 0 (no improvement) if a subject met TF criteria). Here, N (number of subjects analyzed) signifies subjects evaluated for this endpoint.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Placebo (Week 0 - 16)	Guselkumab 200 milligrams (mg) SC (Week 0 - 16)	Guselkumab 1200 mg IV to Gus 200 mg SC (Week 0 - 16)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	59	56	57	
Units: units on a scale				
arithmetic mean (standard deviation)	-0.19 (± 2.124)	-1.71 (± 2.325)	-0.82 (± 2.148)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in HSSD Symptom Scale Score (Other Than Pain in the Past 24 Hours) at Week 16

End point title	Change from Baseline in HSSD Symptom Scale Score (Other Than Pain in the Past 24 Hours) at Week 16

End point description:

HSSD - 7-item patient self-reported questionnaire assesses 5 HS-related symptoms (pain, tenderness, hot skin feeling, odor, and itchiness). Subjects rated severity of each symptom on 0 (no symptoms) to 10 (worst possible symptoms) scale. All 5 symptoms have recall period of past 7 days, except 2 additional items of pain which are current pain and pain in past 24 hours. Change from baseline in each individual HSSD component scale (other than pain in past 24 hours) tenderness, hot skin feeling, odor and itchiness symptom, pain, and current pain score were reported. FAS included all subjects who received at least 1 dose of study intervention. Analysis was based on observed data after applying TF rules (change from baseline using observed data or 0 [no improvement] if subject met TF criteria). Here, N (number of subjects analyzed) signifies subjects evaluated for this endpoint and 'n' (number of subjects analyzed) signifies subjects evaluated for this endpoint for specified categories.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Placebo (Week 0 - 16)	Guselkumab 200 milligrams (mg) SC (Week 0 - 16)	Guselkumab 1200 mg IV to Gus 200 mg SC (Week 0 - 16)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	59	56	57	
Units: Units on a scale				
arithmetic mean (standard deviation)				
Change in HSSD Tenderness Scale Score (n=59,56,57)	-0.4 (± 2.78)	-2.1 (± 2.93)	-1.3 (± 2.56)	
Change in HSSD Hot Skin Feeling Score(n=59,56,57)	0.1 (± 2.85)	-1.6 (± 3.12)	-0.2 (± 3.16)	
Change in HSSD Odor Scale Score (n=59,56,57)	-0.4 (± 2.73)	-1.9 (± 2.58)	-1.2 (± 2.77)	
Change in HSSD Itchiness Scale Score (n=59,56,57)	0.1 (± 2.82)	-1.1 (± 3.28)	-0.5 (± 2.85)	
Change in HSSD Pain Scale Score (n=56,55,56)	-0.3 (± 2.64)	-1.8 (± 2.86)	-0.9 (± 2.34)	
Change in HSSD Current Pain Score (n=56,55,56)	-0.4 (± 2.71)	-1.5 (± 2.94)	-1.2 (± 2.76)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Draining Fistula Count of 0 at Week 16 for Subjects With Baseline Draining Fistula Count Greater Than 0

End point title	Percentage of Subjects Who Achieved Draining Fistula Count of 0 at Week 16 for Subjects With Baseline Draining Fistula Count Greater Than 0

End point description:

Percentage of subjects who achieved draining fistulas count of 0 at Week 16 for subjects with baseline draining fistula count >0 were reported. Draining fistula were defined as fistulas that drain serous or purulent fluid, either spontaneously or by gentle palpation. Population analyzed included FAS subjects

with baseline draining fistula count > 0. Subjects with missing data after applying treatment failure rules were assumed to be non-responders.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo (Week 0 - 16)	Guselkumab 200 milligrams (mg) SC (Week 0 - 16)	Guselkumab 1200 mg IV to Gus 200 mg SC (Week 0 - 16)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	41	42	39	
Units: percentage of subjects				
number (not applicable)	36.6	31.0	20.5	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Number of Draining Fistulas at Week 16

End point title	Change From Baseline in Number of Draining Fistulas at Week 16

End point description:

Change from baseline in number of draining fistulas at Week 16 was reported. Draining fistula are defined as fistulas that drain serous or purulent fluid, either spontaneously or by gentle palpation. FAS included all randomized subjects who received at least one administration of study intervention. The analysis was based on observed data after applying treatment failure rules (the change from baseline using observed data or 0 [no improvement] if a subject met TF criteria). Here, N (number of subjects analyzed) signifies subjects evaluated for this endpoint.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Placebo (Week 0 - 16)	Guselkumab 200 milligrams (mg) SC (Week 0 - 16)	Guselkumab 1200 mg IV to Gus 200 mg SC (Week 0 - 16)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	59	57	59	
Units: fistulas				
arithmetic mean (standard deviation)	-0.5 (± 2.87)	-1.7 (± 3.77)	-0.8 (± 2.08)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Inflammatory Nodules Count of 0 at Week 16 for Subjects with Baseline Inflammatory Nodule Count Greater Than 0

End point title	Percentage of Subjects Who Achieved Inflammatory Nodules Count of 0 at Week 16 for Subjects with Baseline Inflammatory Nodule Count Greater Than 0

End point description:

Percentage of subjects who achieved inflammatory nodules count of 0 at Week 16 for subjects with baseline inflammatory nodules count >0 were reported. Population analyzed included FAS subjects with baseline inflammatory nodule count > 0. Subjects with missing data after applying treatment failure rules were assumed to be non-responders.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo (Week 0 - 16)	Guselkumab 200 milligrams (mg) SC (Week 0 - 16)	Guselkumab 1200 mg IV to Gus 200 mg SC (Week 0 - 16)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	62	58	59	
Units: percentage of subjects				
number (not applicable)	17.7	17.2	18.6	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Number of Inflammatory Nodules at Week 16

End point title	Change From Baseline in Number of Inflammatory Nodules at Week 16

End point description:

Change from baseline in number of inflammatory nodules at Week 16 was reported. FAS included all randomized subjects who received at least one administration of study intervention. The analysis was based on observed data after applying treatment failure rules (the change from baseline using observed data or 0 (no improvement) if a subject met TF criteria). Here, N (number of subjects analyzed) signifies subjects who were evaluated for this outcome measure.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Placebo (Week 0 - 16)	Guselkumab 200 milligrams (mg) SC (Week 0 - 16)	Guselkumab 1200 mg IV to Gus 200 mg SC (Week 0 - 16)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	59	57	59	
Units: inflammatory nodule				
arithmetic mean (standard deviation)	-2.8 (± 6.96)	-3.2 (± 7.84)	-3.7 (± 4.91)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Hidradenitis Suppurativa-investigator's Global Assessment (HS-IGA) Score of Inactive (0), Almost Inactive (1), or Mild Activity (2) and With at Least 2-Grade Improvement Relative to Baseline at Week 16

End point title	Percentage of Subjects With Hidradenitis Suppurativa-investigator's Global Assessment (HS-IGA) Score of Inactive (0), Almost Inactive (1), or Mild Activity (2) and With at Least 2-Grade Improvement Relative to Baseline at Week 16

End point description:

The HS-IGA documents the investigator's assessment of the subject's HS at a given timepoint. The anatomic region with the most severe HS activity at the baseline was evaluated for erythema, drainage, and pain and/or tenderness to palpation for each subject. The subject's HS is assessed as inactive (0), almost inactive (1), mild activity (2), moderate activity (3), or severe activity (4). A higher score indicates more severe disease. Percentage of subjects with HS-IGA score of inactive (0), almost inactive (1), or mild activity (2) and with at least 2-grade improvement relative to baseline at Week 16 was determined. FAS included all randomized subjects who received at least one administration of study intervention. Subjects with missing data after applying treatment failure rules were assumed to be non-responders.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo (Week 0 - 16)	Guselkumab 200 milligrams (mg) SC (Week 0 - 16)	Guselkumab 1200 mg IV to Gus 200 mg SC (Week 0 - 16)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	62	59	60	
Units: percentage of subjects				
number (not applicable)				
HS-IGA scores of inactive (0)	16.1	13.6	13.3	
HS-IGA scores of 0 or almost inactive (1)	24.2	28.8	23.3	
HS-IGA scores of 0, 1, or mild activity (2)	24.2	35.6	31.7	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With HS-IGA Score of Inactive (0) or Almost Inactive (1) at Week 16 Among Subjects with HS-IGA Score of Moderate Activity (3) or Severe Activity (4) at Baseline

End point title	Percentage of Subjects With HS-IGA Score of Inactive (0) or Almost Inactive (1) at Week 16 Among Subjects with HS-IGA Score of Moderate Activity (3) or Severe Activity (4) at Baseline

End point description:

The HS-IGA documents the investigator's assessment of the subjects HS at a given timepoint. The anatomic region with the most severe HS activity at the baseline was evaluated for erythema, drainage, and pain and/or tenderness to palpation for each subject. Among subjects with score of moderate activity (3) or severe activity (4) at baseline, the same anatomic site selected for evaluation at the baseline will be re-evaluated at Week 16. The subjects HS is assessed as inactive (0), almost inactive (1), mild activity (2), moderate activity (3), or severe activity (4). A higher score indicates more severe disease. Percentage of subjects with HS-IGA score of inactive (0), almost inactive (1) at Week 16 among subjects with HS-IGA score of 3 or 4 at baseline were reported. Population analyzed included FAS subjects with HS-IGA scores of 3 or 4 at baseline. Subjects with missing data after applying treatment failure rules were assumed to be non-responders.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo (Week 0 - 16)	Guselkumab 200 milligrams (mg) SC (Week 0 - 16)	Guselkumab 1200 mg IV to Gus 200 mg SC (Week 0 - 16)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	62	59	60	
Units: percentage of subjects				
number (not applicable)	27.3	32.7	25.0	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Hospital Anxiety and Depression Scale (HADS) Total Score at Week 16

End point title	Change From Baseline in Hospital Anxiety and Depression Scale (HADS) Total Score at Week 16

End point description:

The HADS comprises of 14 items, seven to assess anxiety (HADS-A), namely items 1, 3, 5, 7, 9, 11, and 13; and seven to assess depression (HADS-D), items 2, 4, 6, 8, 10, 12, and 14. Each item receives a score from 0 to 3 on a Likert Scale. The total score for each HADS-A and HADS-D scale is obtained by adding the individual scores for each item, with the maximum score 21. The presence or absence of depression and anxiety was defined, for each respective scale, based on the following cutoff values: HADS (anxiety): 0-8 equal to (=) no anxiety; >9 = anxiety; HADS (depression): 0-8 = no depression; >9 = depression. FAS included all randomized subjects who received at least one administration of study intervention. The analysis was based on observed data after applying treatment failure rules (the change from baseline using observed data or 0 [no improvement] if a subject met TF criteria). Here, N (number of subjects analyzed) signifies subjects who were evaluated for this outcome measure.

End point type	Secondary
End point timeframe: Baseline and Week 16	

End point values	Placebo (Week 0 - 16)	Guselkumab 200 milligrams (mg) SC (Week 0 - 16)	Guselkumab 1200 mg IV to Gus 200 mg SC (Week 0 - 16)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	59	57	57	
Units: units on a scale				
arithmetic mean (standard deviation)				
HADS-A	0.0 (± 2.60)	0.0 (± 2.82)	-0.3 (± 2.56)	
HADS-D	0.2 (± 2.48)	-0.6 (± 2.73)	-0.5 (± 2.69)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in High-Sensitivity C-Reactive Protein (hs-CRP) at Week 16

End point title	Change From Baseline in High-Sensitivity C-Reactive Protein (hs-CRP) at Week 16
End point description: Change from baseline in hs-CRP at Week 16 was reported. Serum samples were collected and analyzed for hsCRP. Change from Baseline was calculated as: ([hsCRP value at Week 16 minus Baseline value] divided by [Baseline value]). FAS included all randomized subjects who received at least one administration of study intervention. Subjects with missing data after applying treatment failure rules were assumed to be non-responders. Here, N (number of subjects analyzed) signifies subjects who were evaluated for this outcome measure.	
End point type	Secondary
End point timeframe: Baseline and Week 16	

End point values	Placebo (Week 0 - 16)	Guselkumab 200 milligrams (mg) SC (Week 0 - 16)	Guselkumab 1200 mg IV to Gus 200 mg SC (Week 0 - 16)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	52	51	52	
Units: milligrams per deciliter				
arithmetic mean (standard deviation)	-0.308 (± 8.0840)	3.238 (± 19.0716)	-2.828 (± 11.1048)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Patient Global Impression of Change (PGIC) of Hidradenitis Suppurativa Severity Scale Score at Week 16

End point title	Number of Subjects with Patient Global Impression of Change (PGIC) of Hidradenitis Suppurativa Severity Scale Score at Week 16

End point description:

The PGIC of HS Severity is a questionnaire that measures subjects perceived change (improvement or deterioration) in severity of their HS. Subjects rated how his/her HS has changed since the beginning of the study using a 7-point scale ranging from 1 which indicates "a lot better now" to 7 which indicates "a lot worse now" with a neutral center point 4 which indicates ("neither better nor worse"). Subjects PGIC of HS Severity at Week 16 were reported. FAS included all randomized subjects who received at least one administration of study intervention. Subjects with missing data after applying treatment failure rules are assumed to be 'Not improved'. Here, N (number of subjects analyzed) signifies subjects who were evaluated for this outcome measure.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo (Week 0 - 16)	Guselkumab 200 milligrams (mg) SC (Week 0 - 16)	Guselkumab 1200 mg IV to Gus 200 mg SC (Week 0 - 16)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	56	56	
Units: subjects				
number (not applicable)				
A lot better now	4	13	10	
Moderately better now	7	14	11	
A little better now	16	10	12	
No change	20	12	18	
A little worse now	3	2	4	
Moderately worse now	5	1	1	
A lot worse now	1	4	0	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 48 weeks

Adverse event reporting additional description:

Safety analysis set included all subjects who received at least 1 dose (complete or partial) of study intervention and subjects were analyzed based on the treatment they actually received, regardless of the treatment groups to which they were assigned.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.0

Reporting groups

Reporting group title	Placebo (Week 0 - 16)

Reporting group description:

Subjects received placebo intravenously (IV) and subcutaneously (SC) at Weeks 0, 4, 8 and an additional SC placebo at Week 12.

Reporting group title	Guselkumab 1200 mg IV to Gus 200 mg SC (Week 0 - 16)

Reporting group description:

Subjects received 1200 mg guselkumab IV at Weeks 0, 4, and 8, and 200 mg guselkumab SC at Week 12.

Reporting group title	Guselkumab 200 milligrams (mg) SC (Week 0 - 16)

Reporting group description:

Subjects received 200 mg guselkumab SC at Weeks 0, 4, 8, and 12.

Reporting group title	Placebo Crossover to Guselkumab 100 mg SC (Week 16 - 48)

Reporting group description:

At Week 16, subjects receiving placebo during placebo-controlled period were re-randomized to receive 100 mg guselkumab SC at Weeks 16, 20, 28 and 36 and placebo at Weeks 24 and 32. All subjects entered safety follow-up at Week 36 through Week 48.

Reporting group title	Placebo Crossover to Guselkumab 200 mg SC (Week 16 - 48)

Reporting group description:

At Week 16, subjects receiving placebo during placebo-controlled period were re-randomized to receive 200 mg guselkumab SC every 4 weeks (q4w) through Week 36. All subjects entered safety follow-up at Week 36 through Week 48.

Reporting group title	Gus 1200 mg IV Crossover to Gus 200 mg SC (Week 16 - 48)

Reporting group description:

Subjects who were receiving 1200 mg guselkumab IV during placebo-controlled period switched treatment at Week 12 to receive guselkumab 200 mg SC q4w through Week 36. All subjects entered safety follow-up at Week 36 through Week 48.

Reporting group title	Guselkumab 200 mg SC (Week 16 - 48)

Reporting group description:

Subjects who were receiving 200 mg guselkumab SC during placebo-controlled period, continued to receive 200 mg guselkumab SC q4w through Week 36. All subjects entered safety follow-up at Week 36 through Week 48.

Serious adverse events	Placebo (Week 0 - 16)	Guselkumab 1200 mg IV to Gus 200 mg SC (Week 0 - 16)	Guselkumab 200 milligrams (mg) SC (Week 0 - 16)
Total subjects affected by serious adverse events			

subjects affected / exposed	3 / 62 (4.84%)	1 / 60 (1.67%)	1 / 59 (1.69%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Vascular disorders			
Aortic Aneurysm			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 59 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	1 / 59 (1.69%)
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			
Dysphagia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 59 (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
Nausea			
subjects affected / exposed	1 / 62 (1.61%)	0 / 60 (0.00%)	0 / 59 (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
Pancreatitis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 59 (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 Perforation			
subjects affected / exposed	1 / 62 (1.61%)	0 / 60 (0.00%)	0 / 59 (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
Vomiting			
subjects affected / exposed	1 / 62 (1.61%)	0 / 60 (0.00%)	0 / 59 (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
Hepatobiliary disorders			

Cholelithiasis			
subjects affected / exposed	0 / 62 (0.00%)	1 / 60 (1.67%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Tonsillar Hypertrophy			
subjects affected / exposed	1 / 62 (1.61%)	0 / 60 (0.00%)	0 / 59 (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
Skin and subcutaneous tissue disorders			
Hidradenitis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 59 (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
Psychiatric disorders			
Depression Suicidal			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 59 (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
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 59 (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
Nephrolithiasis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	1 / 59 (1.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 59 (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
Septic Shock			

subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 59 (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			
Diabetes Mellitus			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 59 (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	Placebo Crossover to Guselkumab 100 mg SC (Week 16 - 48)	Placebo Crossover to Guselkumab 200 mg SC (Week 16 - 48)	Gus 1200 mg IV Crossover to Gus 200 mg SC (Week 16 - 48)
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 28 (10.71%)	0 / 28 (0.00%)	2 / 57 (3.51%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Vascular disorders			
Aortic Aneurysm			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 57 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 57 (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			
Dysphagia			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 57 (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
Pancreatitis			

subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Perforation			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 57 (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
Vomiting			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 57 (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			
Tonsillar Hypertrophy			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 57 (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
Skin and subcutaneous tissue disorders			
Hidradenitis			
subjects affected / exposed	2 / 28 (7.14%)	0 / 28 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression Suicidal			
subjects affected / exposed	1 / 28 (3.57%)	0 / 28 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute Kidney Injury			

subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 57 (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
Nephrolithiasis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 57 (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			
Pneumonia			
subjects affected / exposed	1 / 28 (3.57%)	0 / 28 (0.00%)	0 / 57 (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
Septic Shock			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetes Mellitus			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	0 / 57 (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	Guselkumab 200 mg SC (Week 16 - 48)		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 56 (5.36%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Vascular disorders			
Aortic Aneurysm			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	0 / 56 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Dysphagia			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nausea			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatitis			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small Intestinal Perforation			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Tonsillar Hypertrophy			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Skin and subcutaneous tissue disorders			
Hidradenitis			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Depression Suicidal			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nephrolithiasis			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Septic Shock			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Diabetes Mellitus			
subjects affected / exposed	1 / 56 (1.79%)		
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	Placebo (Week 0 - 16)	Guselkumab 1200 mg IV to Gus 200 mg SC (Week 0 - 16)	Guselkumab 200 milligrams (mg) SC (Week 0 - 16)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	22 / 62 (35.48%)	31 / 60 (51.67%)	28 / 59 (47.46%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin Papilloma			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	7 / 62 (11.29%)	2 / 60 (3.33%)	6 / 59 (10.17%)
occurrences (all)	11	5	9
Migraine			
subjects affected / exposed	0 / 62 (0.00%)	3 / 60 (5.00%)	1 / 59 (1.69%)
occurrences (all)	0	3	1
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	2 / 62 (3.23%)	7 / 60 (11.67%)	2 / 59 (3.39%)
occurrences (all)	2	7	2
Oedema Peripheral			
subjects affected / exposed	0 / 62 (0.00%)	2 / 60 (3.33%)	1 / 59 (1.69%)
occurrences (all)	0	2	1
Gastrointestinal disorders			
Abdominal Pain Upper			
subjects affected / exposed	2 / 62 (3.23%)	3 / 60 (5.00%)	1 / 59 (1.69%)
occurrences (all)	2	3	1
Diarrhoea			
subjects affected / exposed	6 / 62 (9.68%)	6 / 60 (10.00%)	2 / 59 (3.39%)
occurrences (all)	7	7	2
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 62 (1.61%)	0 / 60 (0.00%)	4 / 59 (6.78%)
occurrences (all)	1	0	4
Oropharyngeal Pain			

subjects affected / exposed	0 / 62 (0.00%)	2 / 60 (3.33%)	1 / 59 (1.69%)
occurrences (all)	0	2	1
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	1 / 62 (1.61%)	0 / 60 (0.00%)	0 / 59 (0.00%)
occurrences (all)	1	0	0
Erythema			
subjects affected / exposed	0 / 62 (0.00%)	1 / 60 (1.67%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
Hidradenitis			
subjects affected / exposed	1 / 62 (1.61%)	7 / 60 (11.67%)	3 / 59 (5.08%)
occurrences (all)	1	9	4
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	3 / 59 (5.08%)
occurrences (all)	0	0	3
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 62 (4.84%)	5 / 60 (8.33%)	1 / 59 (1.69%)
occurrences (all)	4	6	1
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	0 / 62 (0.00%)	2 / 60 (3.33%)	0 / 59 (0.00%)
occurrences (all)	0	3	0
Influenza			
subjects affected / exposed	3 / 62 (4.84%)	3 / 60 (5.00%)	1 / 59 (1.69%)
occurrences (all)	3	3	1
Nasopharyngitis			
subjects affected / exposed	2 / 62 (3.23%)	9 / 60 (15.00%)	12 / 59 (20.34%)
occurrences (all)	2	12	12
Upper Respiratory Tract Infection			
subjects affected / exposed	3 / 62 (4.84%)	5 / 60 (8.33%)	3 / 59 (5.08%)
occurrences (all)	3	5	4
Urinary Tract Infection			
subjects affected / exposed	1 / 62 (1.61%)	0 / 60 (0.00%)	0 / 59 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Placebo Crossover to Guselkumab 100 mg SC (Week 16 - 48)	Placebo Crossover to Guselkumab 200 mg SC (Week 16 - 48)	Gus 1200 mg IV Crossover to Gus 200 mg SC (Week 16 - 48)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 28 (42.86%)	9 / 28 (32.14%)	28 / 57 (49.12%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin Papilloma			
subjects affected / exposed	2 / 28 (7.14%)	0 / 28 (0.00%)	0 / 57 (0.00%)
occurrences (all)	2	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	3 / 28 (10.71%)	0 / 28 (0.00%)	3 / 57 (5.26%)
occurrences (all)	4	0	4
Migraine			
subjects affected / exposed	1 / 28 (3.57%)	0 / 28 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 28 (0.00%)	1 / 28 (3.57%)	2 / 57 (3.51%)
occurrences (all)	0	3	3
Oedema Peripheral			
subjects affected / exposed	2 / 28 (7.14%)	0 / 28 (0.00%)	1 / 57 (1.75%)
occurrences (all)	2	0	1
Gastrointestinal disorders			
Abdominal Pain Upper			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	2 / 57 (3.51%)
occurrences (all)	0	0	2
Diarrhoea			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 28 (3.57%)	0 / 28 (0.00%)	3 / 57 (5.26%)
occurrences (all)	1	0	3
Oropharyngeal Pain			

subjects affected / exposed	1 / 28 (3.57%)	0 / 28 (0.00%)	3 / 57 (5.26%)
occurrences (all)	1	0	3
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	3 / 57 (5.26%)
occurrences (all)	0	0	3
Erythema			
subjects affected / exposed	2 / 28 (7.14%)	0 / 28 (0.00%)	0 / 57 (0.00%)
occurrences (all)	2	0	0
Hidradenitis			
subjects affected / exposed	2 / 28 (7.14%)	4 / 28 (14.29%)	4 / 57 (7.02%)
occurrences (all)	2	4	6
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 28 (3.57%)	3 / 28 (10.71%)	0 / 57 (0.00%)
occurrences (all)	1	6	0
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	4 / 57 (7.02%)
occurrences (all)	0	0	4
Influenza			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	4 / 28 (14.29%)	8 / 28 (28.57%)	12 / 57 (21.05%)
occurrences (all)	4	12	18
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 28 (3.57%)	0 / 28 (0.00%)	3 / 57 (5.26%)
occurrences (all)	1	0	3
Urinary Tract Infection			
subjects affected / exposed	2 / 28 (7.14%)	0 / 28 (0.00%)	2 / 57 (3.51%)
occurrences (all)	2	0	2

Non-serious adverse events	Guselkumab 200 mg SC (Week 16 - 48)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 56 (33.93%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin Papilloma			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 56 (3.57%)		
occurrences (all)	5		
Migraine			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	1		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	1		
Oedema Peripheral			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal Pain Upper			
subjects affected / exposed	2 / 56 (3.57%)		
occurrences (all)	2		
Diarrhoea			
subjects affected / exposed	4 / 56 (7.14%)		
occurrences (all)	4		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	1		
Oropharyngeal Pain			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		

Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	3 / 56 (5.36%)		
occurrences (all)	4		
Erythema			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Hidradenitis			
subjects affected / exposed	6 / 56 (10.71%)		
occurrences (all)	8		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	1		
Influenza			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	1		
Nasopharyngitis			
subjects affected / exposed	10 / 56 (17.86%)		
occurrences (all)	11		
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	1		
Urinary Tract Infection			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
02 May 2019	The overall rationale for the changes implemented in the protocol amendment was to include an additional urine pregnancy test at Week 48 of the study, increase the percentage of total subjects who are in Hurley Stage III, make necessary corrections to the total blood volume to be collected from each subject during the study, eliminate certain laboratory tests identified as not needed, resolve inconsistencies identified in the duration of continued contraception after the subject receives their last dose, and other minor typographical issues.

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.

No notable study limitations were identified by the Sponsor.

Notes: