Clinical trial results:
A Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group Study of Guselkumab in Subjects with Active Lupus Nephritis

Summary

EudraCT number	2018-003155-38
Trial protocol	PL
Global end of trial date	01 February 2023

Results information

Result version number	v1 (current)
This version publication date	17 February 2024
First version publication date	17 February 2024

Trial information

Trial identification

Sponsor protocol code	CNTO1959LUN2001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04376827
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Research & Development, LLC
Sponsor organisation address	920, US Highway, South Raritan, NJ, United States, 08869
Public contact	Clinical Registry Group, Janssen Research & Development, LLC, clinicaltrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen Research & Development, LLC, clinicaltrialsEU@its.jnj.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	01 February 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	01 February 2023
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The main objective of this trial was to evaluate the efficacy of guselkumab in subjects with active Lupus Nephritis (LN)

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 November 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 9
Country: Number of subjects enrolled	Mexico: 4
Country: Number of subjects enrolled	Russian Federation: 3
Country: Number of subjects enrolled	Thailand: 1
Country: Number of subjects enrolled	Taiwan: 3
Country: Number of subjects enrolled	Ukraine: 12
Country: Number of subjects enrolled	United States: 1
Worldwide total number of subjects	33
EEA total number of subjects	0

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)	32
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Randomization was stratified by geographic region (North America, Latin America, Asia Pacific and Europe) and Urine Protein to Creatinine Ratio (UPCR) level (less than [<] 3 milligrams per milligram [mg/mg] and greater than or equal to [>=] 3 mg/mg).

Period 1

Period 1 title	Double blind Period: Week 0 to Week 52
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

In double-blind period, subjects received placebo matched to guselkumab (400 milligrams [mg]) intravenous (IV) infusion at Weeks 0, 4 and 8 and placebo matched to guselkumab (200 mg) subcutaneous (SC) injection every 4 weeks (q4w) from Week 12 through Week 48 along with standard-of-care treatment of mycophenolate mofetil (MMF)/mycophenolic acid (MPA) and glucocorticoids. Subjects who achieved complete renal response (CRR) at Week 48 and 52, and completed the Week 52 assessments entered the long-term extension (LTE) phase and continued to receive placebo matched to guselkumab SC injection q4w from Week 52 through Week 84 (that is., up to LTE phase treatment termination).

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

Dosage and administration details:

In double-blind period subjects received placebo matched to guselkumab 200 mg SC q4w from Week 12 through Week 48.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

In double-blind period subjects received placebo matched to guselkumab 400 mg IV at Weeks 0, 4 and 8.

Arm title	Guselkumab

Arm description:

In double-blind period subjects received guselkumab 400 mg IV infusion at Weeks 0, 4 and 8 and guselkumab 200 mg SC injection q4w from Week 12 through Week 48 along with standard-of-care treatment of MMF/MPA and glucocorticoids. Subjects who achieved CRR at Week 48 and 52, and completed the Week 52 assessments entered LTE phase and continued to receive guselkumab 200 mg SC injection q4w from Week 52 through Week 84 (that is., up to LTE phase treatment termination).

Arm type	Experimental

Investigational medicinal product name	Guselkumab
Investigational medicinal product code	
Other name	CNTO1959
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

In double-blind period subjects received guselkumab 400 mg IV infusion at Weeks 0, 4 and 8.

Investigational medicinal product name	Guselkumab
Investigational medicinal product code	
Other name	CNTO1959
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

In double-blind period subjects received guselkumab 200 mg SC injection q4w from Week 12 through Week 48.

Number of subjects in period 1	Placebo	Guselkumab
Started	16	17
Completed	9	8
Not completed	7	9
Consent withdrawn by subject	1	1
Study Terminated by Sponsor	6	8

Period 2

Period 2 title	LTE Phase:Week 52 to 96(LTE termination)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	No
Arm title	Placebo

Arm description:

In double-blind period, subjects received placebo matched to guselkumab (400 milligrams [mg]) intravenous (IV) infusion at Weeks 0, 4 and 8 and placebo matched to guselkumab (200 mg) subcutaneous (SC) injection every 4 weeks (q4w) from Week 12 through Week 48 along with standard-of-care treatment of mycophenolate mofetil (MMF)/mycophenolic acid (MPA) and glucocorticoids. Subjects who achieved complete renal response (CRR) at Week 48 and 52, and completed the Week 52 assessments entered the long-term extension (LTE) phase and continued to receive placebo matched to guselkumab SC injection q4w from Week 52 through Week 84 (that is., up to LTE phase treatment termination).

Arm type	Experimental

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

Dosage and administration details:

In LTE phase subjects received placebo matched to guselkumab 200 mg SC injection q4w from Week 52 through Week 84 (that is., up to LTE phase treatment termination).

Arm title	Guselkumab

Arm description:

In double-blind period subjects received guselkumab 400 mg IV infusion at Weeks 0, 4 and 8 and guselkumab 200 mg SC injection q4w from Week 12 through Week 48 along with standard-of-care treatment of MMF/MPA and glucocorticoids. Participants who achieved CRR at Week 48 and 52, and completed the Week 52 assessments entered LTE phase and continued to receive guselkumab 200 mg SC injection q4w from Week 52 through Week 84 (that is., up to LTE phase treatment termination).

Arm type	Experimental
Investigational medicinal product name	Guselkumab
Investigational medicinal product code	
Other name	CNTO1959
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

In LTE phase subjects received guselkumab 200 mg SC injection q4w from Week 52 through Week 84 (that is., up to LTE phase treatment termination) LTE phase.

Number of subjects in period 2	Placebo	Guselkumab
Started	4	1
Completed	0	0
Not completed	4	1
Consent withdrawn by subject	-	1
Protocol-specified withdrawal criterion met	1	-
Study Terminated by Sponsor	3	-

Baseline characteristics

Reporting groups

Reporting group title	Placebo

Reporting group description:

In double-blind period, subjects received placebo matched to guselkumab (400 milligrams [mg]) intravenous (IV) infusion at Weeks 0, 4 and 8 and placebo matched to guselkumab (200 mg) subcutaneous (SC) injection every 4 weeks (q4w) from Week 12 through Week 48 along with standard-of-care treatment of mycophenolate mofetil (MMF)/mycophenolic acid (MPA) and glucocorticoids. Subjects who achieved complete renal response (CRR) at Week 48 and 52, and completed the Week 52 assessments entered the long-term extension (LTE) phase and continued to receive placebo matched to guselkumab SC injection q4w from Week 52 through Week 84 (that is., up to LTE phase treatment termination).

Reporting group title	Guselkumab

Reporting group description:

In double-blind period subjects received guselkumab 400 mg IV infusion at Weeks 0, 4 and 8 and guselkumab 200 mg SC injection q4w from Week 12 through Week 48 along with standard-of-care treatment of MMF/MPA and glucocorticoids. Subjects who achieved CRR at Week 48 and 52, and completed the Week 52 assessments entered LTE phase and continued to receive guselkumab 200 mg SC injection q4w from Week 52 through Week 84 (that is., up to LTE phase treatment termination).

Reporting group values	Placebo	Guselkumab	Total
Number of subjects	16	17	33
Age Categorical Units: subjects			
>= 55 years	1	1	2
< 55 years	15	16	31
Age continuous Units: years			
arithmetic mean	38.8	35.3	
standard deviation	± 11.69	± 10.07	-
Sex: Female, Male Units: subjects			
Female	14	15	29
Male	2	2	4
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	1	2	3
Asian	3	1	4
Black or African American	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
White	12	14	26
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Region of Enrollment Units: Subjects			
ARGENTINA	5	4	9
MEXICO	1	3	4
RUSSIAN FEDERATION	2	1	3
TAIWAN	3	0	3
THAILAND	0	1	1

UKRAINE	5	7	12
UNITED STATES	0	1	1
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	4	7	11
Not Hispanic or Latino	12	10	22
Unknown or Not Reported	0	0	0

End points

End points reporting groups

Reporting group title	Placebo

Reporting group description:

In double-blind period, subjects received placebo matched to guselkumab (400 milligrams [mg]) intravenous (IV) infusion at Weeks 0, 4 and 8 and placebo matched to guselkumab (200 mg) subcutaneous (SC) injection every 4 weeks (q4w) from Week 12 through Week 48 along with standard-of-care treatment of mycophenolate mofetil (MMF)/mycophenolic acid (MPA) and glucocorticoids. Subjects who achieved complete renal response (CRR) at Week 48 and 52, and completed the Week 52 assessments entered the long-term extension (LTE) phase and continued to receive placebo matched to guselkumab SC injection q4w from Week 52 through Week 84 (that is., up to LTE phase treatment termination).

Reporting group title	Guselkumab

Reporting group description:

In double-blind period subjects received guselkumab 400 mg IV infusion at Weeks 0, 4 and 8 and guselkumab 200 mg SC injection q4w from Week 12 through Week 48 along with standard-of-care treatment of MMF/MPA and glucocorticoids. Subjects who achieved CRR at Week 48 and 52, and completed the Week 52 assessments entered LTE phase and continued to receive guselkumab 200 mg SC injection q4w from Week 52 through Week 84 (that is., up to LTE phase treatment termination).

Reporting group title	Placebo

Reporting group description:

In double-blind period, subjects received placebo matched to guselkumab (400 milligrams [mg]) intravenous (IV) infusion at Weeks 0, 4 and 8 and placebo matched to guselkumab (200 mg) subcutaneous (SC) injection every 4 weeks (q4w) from Week 12 through Week 48 along with standard-of-care treatment of mycophenolate mofetil (MMF)/mycophenolic acid (MPA) and glucocorticoids. Subjects who achieved complete renal response (CRR) at Week 48 and 52, and completed the Week 52 assessments entered the long-term extension (LTE) phase and continued to receive placebo matched to guselkumab SC injection q4w from Week 52 through Week 84 (that is., up to LTE phase treatment termination).

Reporting group title	Guselkumab

Reporting group description:

In double-blind period subjects received guselkumab 400 mg IV infusion at Weeks 0, 4 and 8 and guselkumab 200 mg SC injection q4w from Week 12 through Week 48 along with standard-of-care treatment of MMF/MPA and glucocorticoids. Participants who achieved CRR at Week 48 and 52, and completed the Week 52 assessments entered LTE phase and continued to receive guselkumab 200 mg SC injection q4w from Week 52 through Week 84 (that is., up to LTE phase treatment termination).

Subject analysis set title	Guselkumab Vs Placebo
Subject analysis set type	Per protocol

Subject analysis set description:

In double-blind period, placebo arm subjects received placebo matched to guselkumab (400 mg) IV infusion at Weeks 0, 4 and 8 and placebo matched to guselkumab (200 mg) SC injection q4w from Week 12 through Week 48; Guselkumab arm subjects received guselkumab 400 mg IV infusion at Weeks 0, 4 and 8 and guselkumab 200 mg SC injection q4w from Week 12 through Week 48. All (both arms) subjects received standard-of-care treatment of MMF/MPA and glucocorticoids. Subjects who achieved CRR at Weeks 48 and 52, and completed the Week 52 assessments entered the LTE phase. During the LTE phase, subjects received the same treatment, placebo or guselkumab that was assigned at randomization, SC q4w from Week 52 through Week 84 (that is, up to LTE phase treatment termination).

Primary: Percentage of Subjects Achieving at Least 50 Percent (%) Decrease From Baseline in Proteinuria at Week 24

End point title	Percentage of Subjects Achieving at Least 50 Percent (%) Decrease From Baseline in Proteinuria at Week 24[1]

End point description:

Percentage of subjects achieving at least 50% decrease in proteinuria from baseline at Week 24 was reported. Proteinuria analysis was based on UPCR and was defined as the presence of an excess of serum proteins in the urine, which may be an early sign of kidney disease. Full analysis set (FAS) included all randomised subjects who received at least 1 dose of study intervention.

End point type	Primary

End point timeframe:

Week 24

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	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	17		
Units: percentage of subjects				
number (not applicable)	56.3	35.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Achievement of Complete Renal Response

End point title	Time to Achievement of Complete Renal Response

End point description:

Subject was considered as achieved CRR who did not discontinue study intervention for any reason excluding COVID-19 related discontinuations or met medication intercurrent event (exceeded baseline glucocorticoid dose, increase above 10 mg/d prednisone equivalent after Week 12, use of new or increased dose of concomitant medication related to lupus nephritis (LN) or other immunosuppressive agents, within 8 weeks prior to endpoint time point or initiation of prohibited medications at any time prior to endpoint time point. In below data table, measure type "Number"=hazard ratio and unit of measure is ratio for time to CRR.FAS population. For this endpoint, only summary measure (population-level summary) data were analyzed and reported as planned in study statistical analysis plan. Thus, data were presented for single comparative arm (guselkumab vs placebo). 'N' (number of subjects analysed)=all subjects of both arms with available data for this endpoint.

End point type	Secondary

End point timeframe:

Up to Week 24

End point values	Guselkumab Vs Placebo			
Subject group type	Subject analysis set			
Number of subjects analysed	33			
Units: ratio				
number (confidence interval 80%)	0.62 (0.27 to 1.41)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved Complete Renal Response (CRR)

at Week 24

End point title	Percentage of Subjects who Achieved Complete Renal Response (CRR) at Week 24

End point description:

CRR was defined as UPCR less than (<) 0.5 mg/mg, estimated glomerular filtration rate (eGFR) greater than or equal to (>=) 60 milliliter per minute per 1.73 meter square (mL/min/1.73m^2) or no confirmed decrease >=20% from baseline and prednisone dose less than or equal to (<=) 10 milligrams per day (mg/d). Subject was considered as achieved CRR who did not discontinue study intervention for any reason excluding COVID-19 related discontinuations or met the medication intercurrent event (exceeded baseline glucocorticoid dose, increase above 10 mg/d prednisone equivalent after Week 12, use of new or increased dose of concomitant medication related to LN or other immunosuppressive agents, within 8 weeks prior to the endpoint time point or initiation of prohibited medications at any time prior to the endpoint time point. FAS included all randomised subjects who received at least 1 dose of study intervention.

End point type	Secondary

End point timeframe:

Week 24

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	17		
Units: percentage of subjects				
number (not applicable)	18.8	17.6		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Treatment Failure (TF)

End point title	Time to Treatment Failure (TF)

End point description:

TF:time to first occurrence of TF from baseline. Subject was considered have treatment failure, who did not continue study intervention for any reason excluding COVID-19 related discontinuations or met medication intercurrent event (exceeded baseline glucocorticoid dose, increase above 10 mg/d prednisone equivalent after Week 12, use of new or increased dose of concomitant medication related to LN or other immunosuppressive agents, within 8 weeks prior to endpoint time point or initiation of prohibited medications at any time prior to endpoint time point. In below data table, measure type "Number"= hazard ratio and unit of measure is ratio for time to TF. FAS population. For this endpoint, only summary measure (population-level summary) data were analyzed and reported as planned in study statistical analysis plan. Thus, data were presented for single comparative arm. 'N' (number of subjects analysed) signifies all subjects of both arms with available data for this endpoint.

End point type	Secondary

End point timeframe:

Through Week 52

End point values	Guselkumab Vs Placebo			
Subject group type	Subject analysis set			
Number of subjects analysed	33			
Units: ratio				
number (confidence interval 80%)	1.54 (0.62 to 3.85)			

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentration of Guselkumab

End point title	Serum Concentration of Guselkumab[2]

End point description:

Serum Concentration of guselkumab were reported. Data for this endpoint was not planned to be collected and analysed for the placebo arm. Pharmacokinetic analysis set included all subjects who received at least 1 administration of guselkumab and had at least one post-dose sample collection. Here (number analysed) signifies number of subjects evaluable at specific timepoints. Since a small number of subjects only entered LTE period than the planned enrollment count, planned serum concentration analysis was not performed for the LTE phase for this endpoint.

End point type	Secondary

End point timeframe:

Predose: Weeks 0,4,8,12,16,20,24, 36; Post-dose: Weeks 0 (1 hour after intravenous administration), Day 2, Week 52 and 60

Notes:

[2] - 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: This endpoint was planned to be reported for specified arms only.

End point values	Guselkumab			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: microgram per milliliter				
arithmetic mean (standard deviation)				
Week 0, predose (n=16)	0.00 (± 0.000)			
Week 0, 1h after IV administration (n=16)	146.20 (± 41.273)			
Day 2 post-dose (n=16)	96.55 (± 33.805)			
Week 4, predose (n=16)	11.20 (± 7.175)			
Week 8, predose (n=15)	12.85 (± 9.549)			
Week 12, predose (n=14)	18.17 (± 11.784)			
Week 20, predose (n=14)	7.63 (± 4.689)			
Week 24, predose (n=12)	6.42 (± 3.447)			
Week 36, predose (n=10)	6.57 (± 1.827)			
Week 52 post-dose (n=6)	6.13 (± 3.262)			
Week 60 post-dose (n=4)	0.39 (± 0.641)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving at Least 50% Decrease in Proteinuria From Baseline at Week 52

End point title	Percentage of Subjects Achieving at Least 50% Decrease in Proteinuria From Baseline at Week 52

End point description:

Percentage of subjects achieving at least 50% decrease in proteinuria from baseline at Week 52 were reported.FAS included all randomised subjects who received at least 1 dose of study intervention.

End point type	Secondary

End point timeframe:

Week 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	17		
Units: percentage of subjects				
number (not applicable)	18.8	17.6		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Urine Protein to Creatinine Ratio (UPCR) < 0.5 mg/mg at Week 24

End point title	Percentage of Subjects with Urine Protein to Creatinine Ratio (UPCR) < 0.5 mg/mg at Week 24

End point description:

Percentage of subjects with UPCR <0.5 mg/mg at Week 24 were reported. FAS included all randomised subjects who received at least 1 dose of study intervention.

End point type	Secondary

End point timeframe:

Week 24

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	17		
Units: percentage of subjects				
number (not applicable)	25.0	29.4		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving a Sustained Reduction in Steroid Dose <=10 mg/d of Prednisone or Equivalent From Week 16 through Week 24

End point title	Percentage of Subjects Achieving a Sustained Reduction in Steroid Dose <=10 mg/d of Prednisone or Equivalent From Week 16 through Week 24

End point description:

Percentage of subjects achieving a sustained reduction in steroid dose less than or equal to (<=) 10 mg/day of prednisone or equivalent from week 16 through Week 24 were reported. FAS included all randomised subjects who received at least 1 dose of study intervention.

End point type	Secondary

End point timeframe:

From Week 16 through Week 24

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	17		
Units: percentage of subjects				
number (not applicable)	87.5	94.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with UPCR < 0.75 mg/mg at Week 24

End point title	Percentage of Subjects with UPCR < 0.75 mg/mg at Week 24

End point description:

Percentage of subjects with UPCR less than (<) 0.75 mg/mg at Week 24 were reported. FAS included all randomised subjects who received at least 1 dose of study intervention.

End point type	Secondary

End point timeframe:

Week 24

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	17		
Units: percentage of subjects				
number (not applicable)	37.5	35.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Serious Adverse Events (SAEs)

End point title	Number of Subjects with Serious Adverse Events (SAEs)

End point description:

Number of subjects with AEs were reported. A SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening, required inpatient hospitalisation or prolongation of existing hospitalisation, resulted in persistent or significant disability/incapacity, was a congenital anomaly/birth defect, was a suspected transmission of any infectious agent via a medicinal product, or was medically important. SAS included all subjects who received at least one dose of study intervention. Since a small number of subjects only entered the LTE phase than the planned enrollment count, no separate adverse events analysis was performed for the LTE phase participants and thus, data of both DB period and LTE phase were presented together for this endpoint under the arms: placebo and guselkumab.

End point type	Secondary

End point timeframe:

DB period: From Week 0 up to 12 week safety follow-up (i.e., up to Week 60); LTE phase: From Week 52 up to LTE phase termination (i.e., up to Week 96)

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	17		
Units: subjects	1	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Related AEs

End point title	Number of Subjects with Related AEs

End point description:

Number of subjects with related AEs were reported. An AE was defined as any untoward medical occurrence in a clinical study subject administered a medicinal (investigational or non-investigational) product did not necessarily have a causal relationship with the treatment. Therefore, 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. Related AE was defined as the AE assessed by the investigator related to study agent. SAS included all subjects who received at least one dose of study intervention. Since a small number of subjects only entered the LTE phase than the planned enrollment count, no separate adverse events analysis was performed for the LTE phase subjects and thus, data of both DB period and LTE phase were presented together for this

endpoint under the arms: placebo and guselkumab.

End point type	Secondary

End point timeframe:

DB period: From Week 0 up to 12 week safety follow-up (i.e., up to Week 60); LTE phase: From Week 52 up to LTE phase termination (i.e., up to Week 96)

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	17		
Units: subjects	2	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with AE Leading to Discontinuation of Study Intervention

End point title	Number of Subjects with AE Leading to Discontinuation of Study Intervention

End point description:

Number of subjects with AE leading to discontinuation of study intervention were reported. SAS included all subjects who received at least one dose of study intervention. Since a small number of subjects only entered the LTE phase than the planned enrollment count, no separate adverse events analysis was performed for the LTE phase subjects and thus, data of both DB period and LTE phase were presented together for this endpoint under the arms: placebo and guselkumab.

End point type	Secondary

End point timeframe:

DB period: From Week 0 up to 12 week safety follow-up (i.e., up to Week 60); LTE phase: From Week 52 up to LTE phase termination (i.e., up to Week 96)

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	17		
Units: subjects	1	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Infections

End point title	Number of Subjects with Infections

End point description:

Number of subjects with infections as assessed by the investigator were reported. SAS included all subjects who received at least one dose of study intervention. Since a small number of subjects only entered the LTE phase than the planned enrollment count, no separate adverse events analysis was performed for the LTE phase subjects and thus, data of both DB period and LTE phase were presented together for this endpoint under the arms: placebo and guselkumab.

End point type	Secondary

End point timeframe:

DB period: From Week 0 up to 12 week safety follow-up (i.e., up to Week 60); LTE phase: From Week 52 up to LTE phase termination (i.e., up to Week 96)

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	17		
Units: subjects	5	6		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Serious Infections

End point title	Number of Subjects With Serious Infections

End point description:

Number of subjects with serious infections as assessed by the investigator were reported. SAS included all subjects who received at least one dose of study intervention. Since a small number of subjects only entered the LTE phase than the planned enrollment count, no separate adverse events analysis was performed for the LTE phase subjects and thus, data of both DB period and LTE phase were presented together for this endpoint under the arms: placebo and guselkumab.

End point type	Secondary

End point timeframe:

DB period: From Week 0 up to 12 week safety follow-up (i.e., up to Week 60); LTE phase: From Week 52 up to LTE phase termination (i.e., up to Week 96)

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	17		
Units: subjects	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Adverse Events (AEs)

End point title	Number of Subjects with Adverse Events (AEs)

End point description:

Number of subjects with AEs were reported. An AE was defined as any untoward medical occurrence in a clinical study subject administered a medicinal (investigational or non-investigational) product did not necessarily have a causal relationship with the treatment. Therefore, 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. Safety analysis set (SAS) included all subjects who received at least one dose of study intervention. Since a small number of subjects only entered the LTE phase than the planned enrollment count, no separate adverse events analysis was performed for the LTE phase subjects and thus, data of both DB period and LTE phase were presented together for this endpoint under the arms: placebo and guselkumab.

End point type	Secondary

End point timeframe:

DB period: From Week 0 up to 12 week safety follow-up (i.e., up to Week 60); LTE phase: From Week 52 up to LTE phase termination (i.e., up to Week 96)

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	17		
Units: subjects	12	12		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With AEs with Injection-site Reactions

End point title	Number of Subjects With AEs with Injection-site Reactions

End point description:

Number of subjects with injection-site reactions as assessed by the investigator were reported. An injection-site reaction is any adverse reaction at a SC study intervention injection-site. SAS included all subjects who received at least one dose of study intervention. Since a small number of subjects only entered the LTE phase than the planned enrollment count, no separate adverse events analysis was performed for the LTE phase subjects and thus, data of both DB period and LTE phase were presented together for this endpoint under the arms: placebo and guselkumab.

End point type	Secondary

End point timeframe:

DB period: From Week 0 up to 12 week safety follow-up (i.e., up to Week 60); LTE phase: From Week 52 up to LTE phase termination (i.e., up to Week 96)

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	17		
Units: subjects	1	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Treatment-boosted Anti-drug antibodies (ADA) Response

End point title	Number of Subjects with Treatment-boosted Anti-drug antibodies (ADA) Response[3]

End point description:

Treatment-boosted ADA positive subjects: subjects who were positive at baseline and whose titers increased 2-fold at any time after treatment. Titer values were categorised as<=1:10, 10 to 100, 100 to 1000, >1000. Immunogenecity analysis set inlcuded all subjects who received at least 1 administration of guselkumab and had at least one post-dose sample collection. Here 'n' (number analysed) signifies number of subjects evaluable at specified timepoints. Data for this endpoint was not planned to be collected and analyzed for the placebo arm.

End point type	Secondary

End point timeframe:

From Baseline (Week 0) through Week 24 and Week 60

Notes:

[3] - 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: This endpoint was planned to be reported for specified arms only.

End point values	Guselkumab			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: subjects				
Week 24 (n = 17)	1			
Week 60 (n= 16)	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With AEs Temporally Associated with an Infusion

End point title	Number of Subjects With AEs Temporally Associated with an Infusion

End point description:

Number of subjects with AEs temporally (a reaction that occurred during of within 1 hour after infusion) associated with an infusion were reported. AE is any untoward medical occurrence in a clinical study subject administered a medicinal (investigational or non-investigational) product does not necessarily have a causal relationship with the treatment. Therefore, it can 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. SAS included all subjects who received at least one dose of study intervention. Since a small number of subjects only entered the LTE phase than the planned enrollment count, no separate adverse events analysis was performed for the LTE phase subjects and thus, data of both DB period and LTE phase were presented together for this endpoint under the arms: placebo and guselkumab.

End point type	Secondary

End point timeframe:

DB period: From Week 0 up to 12 week safety follow-up (i.e., up to Week 60); LTE phase: From Week 52 up to LTE phase termination (i.e., up to Week 96)

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	17		
Units: subjects	1	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Infections Requiring Oral or Parenteral Antimicrobial Treatment

End point title	Number of Subjects with Infections Requiring Oral or Parenteral Antimicrobial Treatment

End point description:

Number of subjects with infections requiring oral or parenteral antimicrobial treatment were reported. For this endpoint, no data was collected and analysed due to premature termination of the study.

End point type	Secondary

End point timeframe:

DB period: From Week 0 up to 12 week safety follow-up (i.e., up to Week 60); LTE phase: From Week 52 up to LTE phase termination (i.e., up to Week 96)

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	17		
Units: subjects	9999	9999		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Abnormal Vital Signs: Systolic and Diastolic Blood Pressure

End point title	Percentage of Subjects with Abnormal Vital Signs: Systolic and Diastolic Blood Pressure

End point description:

Percentage of subjects with abnormal vital signs: Systolic and Diastolic blood pressure were reported. SAS included all subjects who received at least one dose of study intervention. Here "mmHg" refers to millimeter(s) of mercury.

End point type	Secondary

End point timeframe:

Up to Week 60

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	17		
Units: percentage of subjects				
number (not applicable)				
Systolic Blood Pressure: <85 mmHg	0	0		
Systolic Blood Pressure::>180 mmHg	6.3	5.9		
Diastolic Blood Pressure: <55 mmHg	6.3	0		
Diastolic Blood Pressure: >115 mmHg	6.3	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Hematology Parameter: Hematocrit

End point title	Change from Baseline in Hematology Parameter: Hematocrit

End point description:

Change from baseline in hematology parameter: hematocrit was reported. SAS population. Here 'n' (number analysed) signifies number of subjects evaluable at specified timepoints. Here 'N' (number of subjects analysed) signifies to number of subjects with available data for this endpoint. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint. 9999=mean and standard deviation (SD) was not evaluated because no subjects were available for analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Week 24, and Week 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	12		
Units: fraction of 1				
arithmetic mean (standard deviation)				
Week 24 (n=13,12)	-0.013 (± 0.0411)	-0.004 (± 0.0356)		
Week 52 (n=2,0)	-0.055 (± 0.0495)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Hematology Parameter: Hemoglobin

End point title	Change from Baseline in Hematology Parameter: Hemoglobin

End point description:

Change from baseline in hematology parameter: hemoglobin was reported. SAS included all subjects who received at least one dose of study intervention. Here 'n' refers to the number of subjects evaluable at specified timepoints. Here 'N' refers to the number of subjects of both with available data for this endpoint. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint.9999=mean and SD was not evaluated because no subjects were available for analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Week 24, and Week 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: grams per liter (g/L)				
arithmetic mean (standard deviation)				
Week 24 (n=13,12) Week 52 (n=2,0)	-5.2 (± 15.57) -17.0 (± 22.63)	-0.3 (± 14.82) 9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Laboratory Parameter:: Leukocytes

End point title	Change from Baseline in Clinical Laboratory Parameter:: Leukocytes

End point description:

Change from baseline in clinical laboratory parameter: leukocytes was reported. SAS population. Here 'n' (number analysed) signifies number of subjects evaluable at specified timepoints. Here 'N' (number of subjects analysed) signifies to number of subjects with available data for this endpoint. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint. 9999=mean and SD was not evaluated because no subjects were available for analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Week 24, and Week 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	17		
Units: 10*9 cells per liter				
arithmetic mean (standard deviation)				
Week 24 (n=13,12)	-0.622 (± 3.8729)	-1.157 (± 3.1246)		
Week 52 (n=2,0)	-5.120 (± 7.7499)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Laboratory Parameter: Lymphocytes

End point title	Change from Baseline in Clinical Laboratory Parameter: Lymphocytes

End point description:

Change from baseline in hematology parameter: lymphocytes was reported. SAS population. Here 'n' (number analysed) signifies number of subjects evaluable at specified timepoints. Here 'N' (number of subjects analysed) signifies to number of subjects with available data for this endpoint. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint. 9999= mean and SD was not evaluated because no subjects were available for analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Week 24, and Week 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	12		
Units: 10*9 cells per Liter				
arithmetic mean (standard deviation)				
Week 24 (n=13,12)	0.006 (± 0.5213)	-0.032 (± 0.3860)		
Week 52 (n=2,0)	-0.545 (± 1.0960)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Laboratory Parameter: Hematology Parameter: Neutrophils, Segmented

End point title	Change from Baseline in Clinical Laboratory Parameter: Hematology Parameter: Neutrophils, Segmented

End point description:

Change from baseline in hematology parameter: neutrophils, segmented was reported. SAS population. Here 'n' (number analysed) signifies number of subjects evaluable at specified timepoints. Here 'N' (number of subjects analysed) signifies to number of subjects with available data for this endpoint. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint. Here, 9999=mean and standard deviation (SD) was not evaluated because no subjects were available for analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Week 24, and Week 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	12		
Units: 10*9 cells per liter				
arithmetic mean (standard deviation)				
Week 24 (n=13,12)	-0.630 (± 3.2494)	-1.074 (± 2.9652)		
Week 52 (n=2,0)	-3.990 (± 5.8548)	99999 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Laboratory Parameter: Monocytes

End point title	Change from Baseline in Clinical Laboratory Parameter: Monocytes

End point description:

Change from baseline in hematology parameter: monocytes was reported. SAS population. Here 'n' (number analysed) signifies number of subjects evaluable at specified timepoints. Here 'N' (number of subjects analysed) signifies to number of subjects with available data for this endpoint. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint. 9999=mean and SD was not evaluated because no subjects were available for analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Week 24, and Week 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	12		
Units: 10*9 cells per liter				
arithmetic mean (standard deviation)				
Week 24 (n=13,12)	-0.014 (± 0.3277)	-0.002 (± 0.1268)		

Week 52 (n=2,0)	-0.510 (± 0.7354)	99999 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Laboratory Parameter: Platelets

End point title	Change from Baseline in Clinical Laboratory Parameter: Platelets

End point description:

Change from baseline in hematology parameter: platelets was reported. SAS population. Here 'n' (number analysed) signifies number of subjects evaluable at specified timepoints. Here 'N' (number of subjects analysed) signifies to number of subjects with available data for this endpoint. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint. Here '9999' signifies that mean and standard deviation (SD) was not evaluated because no subjects were available for analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Week 24, and Week 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	12		
Units: 10*9 cells per liter				
arithmetic mean (standard deviation)				
Week 24 (n=13,12)	-36.7 (± 61.43)	-17.8 (± 61.89)		
Week 52 (n=2,0)	-70.5 (± 67.18)	99999 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Laboratory Parameter: Prothrombin International Normalised Ratio

End point title	Change from Baseline in Clinical Laboratory Parameter: Prothrombin International Normalised Ratio

End point description:

Change from baseline in hematology parameter: prothrombin international normalized ratio was reported. SAS population. Here 'n' (number analysed) signifies number of subjects evaluable at specified timepoints. Here 'N' (number of subjects analysed) signifies to number of subjects with available data for this endpoint. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint. Here '9999' signifies that mean and standard deviation

(SD) was not evaluated because no subjects were available for analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Week 24, and Week 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	13		
Units: RATIO				
arithmetic mean (standard deviation)				
Week 24 (n=13,13)	0.02 (± 0.090)	0.01 (± 0.064)		
Week 52 (n=4,0)	0.00 (± 0.000)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Laboratory Parameter: Reticulocytes/Erythrocytes

End point title	Change from Baseline in Clinical Laboratory Parameter: Reticulocytes/Erythrocytes

End point description:

Change from baseline in hematology parameter:reticulocytes/erythrocytes was reported. SAS population. Here 'n' (number analysed) signifies number of subjects evaluable at specified timepoints. Here 'N' (number of subjects analysed) signifies to number of subjects with available data for this endpoint. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint. Here '9999' signifies that mean and standard deviation (SD) was not evaluated because no subjects were available for analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Week 24, and Week 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	11		
Units: fraction of 1				
arithmetic mean (standard deviation)				
Week 24 (n=13,11)	-0.0007 (± 0.00485)	-0.0001 (± 0.00541)		
Week 52 (2,0)	0.0000 (± 0.01414)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Laboratory Parameter: Prothrombin Time

End point title	Change from Baseline in Clinical Laboratory Parameter: Prothrombin Time

End point description:

Change from baseline in hematology parameter: prothrombin time was reported. SAS population. Here 'n' (number analysed) signifies number of subjects evaluable at specified timepoints. Here 'N' (number of subjects analysed) signifies to number of subjects with available data for this endpoint. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint. Here '9999' signifies that mean and standard deviation (SD) was not evaluated because no subjects were available for analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Week 24, and Week 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	13		
Units: second				
arithmetic mean (standard deviation)				
Week 24 (n=13,13) Week 52(n=4,0)	0.18 (± 0.766) -0.03 (± 0.359)	0.16 (± 0.425) 9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Laboratory Parameter: Alkaline Phosphatase

End point title	Change from Baseline in Clinical Laboratory Parameter: Alkaline Phosphatase

End point description:

Change from baseline in hematology parameter: alkaline phosphatase was reported. SAS population. Here 'n' (number analysed) signifies number of subjects evaluable at specified timepoints. Here 'N' (number of subjects analysed) signifies to number of subjects with available data for this endpoint. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint. Here '9999' signifies that SD was not evaluated because only 1 subject was available for analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Week 24, and Week 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	16		
Units: Enzyme U/L				
arithmetic mean (standard deviation)				
Week 24 (n=14,16)	1.9 (± 16.75)	1.7 (± 8.07)		
Week 52 (n=4,1)	6.5 (± 5.00)	6.0 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Laboratory Parameter: Albumin

End point title	Change from Baseline in Clinical Laboratory Parameter: Albumin

End point description:

Change from baseline in hematology parameter: albumin was reported. SAS population. Here 'n' (number analysed) signifies number of subjects evaluable at specified timepoints. Here 'N' (number of subjects analysed) signifies to number of subjects with available data for this endpoint. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint. Here '9999' signifies that SD was not evaluated because only 1 subject was available for analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Week 24, and Week 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	16		
Units: Grams per Liter (g/L)				
arithmetic mean (standard deviation)				
Week 24 (n=14,16)	2.4 (± 5.57)	1.9 (± 4.58)		
Week 52 (n=4,1)	3.5 (± 5.32)	-3.0 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Laboratory Parameter: Alanine Aminotransferase

End point title	Change from Baseline in Clinical Laboratory Parameter: Alanine Aminotransferase

End point description:

Change from baseline in hematology parameter: alanine aminotransferase was reported. SAS population. Here 'n' (number analysed) signifies number of subjects evaluable at specified timepoints. Here 'N' (number of subjects analysed) signifies to number of subjects with available data for this endpoint. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint. Here '9999' signifies that mean and standard deviation (SD) was not evaluated because no subjects were available for analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Week 24, and Week 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	16		
Units: Enzyme U/L				
arithmetic mean (standard deviation)				
Week 24 (n=14,16)	2.6 (± 10.98)	-3.1 (± 6.57)		
Week 52 (n=4,0)	2.3 (± 4.92)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Laboratory Parameter: Bicarbonate

End point title	Change from Baseline in Clinical Laboratory Parameter: Bicarbonate

End point description:

Change from baseline in hematology parameter: bicarbonate was reported. SAS population. Here 'n' (number analysed) signifies number of subjects evaluable at specified timepoints. Here 'N' (number of subjects analysed) signifies to number of subjects with available data for this endpoint. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint. Here '9999' signifies that mean SD was not evaluated because no subjects were available for analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Week 24, and Week 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	12		
Units: mmol/L				
arithmetic mean (standard deviation)				
Week 24 (n=13,12)	-0.78 (± 4.97)	0.21 (± 5.41)		
Week 52 (n=2,0)	-2.20 (± 2.38)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Laboratory Parameter: Aspartate Aminotransferase

End point title	Change from Baseline in Clinical Laboratory Parameter: Aspartate Aminotransferase

End point description:

Change from baseline in hematology parameter: aspartate aminotransferase was reported. SAS population. Here 'n' (number analysed) signifies number of subjects evaluable at specified timepoints. Here 'N' (number of subjects analysed) signifies to number of subjects with available data for this endpoint. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint. Here '9999' signifies that SD was not evaluated because only 1 subject was available for analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Week 24, and Week 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	13		
Units: Enzyme U/L				
arithmetic mean (standard deviation)				
Week 24 (n=13,13)	0.0 (± 4.97)	-0.7 (± 5.41)		
Week 52 (n=4,1)	1.5 (± 2.38)	1.0 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Laboratory Parameters: Calcium

End point title	Change from Baseline in Clinical Laboratory Parameters: Calcium

End point description:

Change from baseline in chemistry parameter: calcium was reported. SAS population. Here 'n' (number analysed) signifies number of subjects evaluable at specified timepoints. Here 'N' (number of subjects

analysed) signifies to number of subjects with available data for this endpoint. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint. Here '9999' signifies that mean and SD was not evaluated because only 1 subjects was available for analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Week 24, and Week 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	16		
Units: mmol/L				
arithmetic mean (standard deviation)				
Week 24 (n=14,16)	0.039 (± 0.1172)	0.073 (± 0.0958)		
Week 52 (n=4,1)	0.000 (± 0.1871)	0.010 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Laboratory Parameter: Chloride

End point title	Change from Baseline in Clinical Laboratory Parameter: Chloride

End point description:

Change from baseline in chemistry parameter: chloride was reported. SAS population. Here 'n' (number analysed) signifies number of subjects evaluable at specified timepoints. Here 'N' (number of subjects analysed) signifies to number of subjects with available data for this endpoint. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint. Here '9999' signifies that mean SD was not evaluated because only 1 subject was available for analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Week 24, and Week 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	16		
Units: mmol/L				
arithmetic mean (standard deviation)				
Week 24 (n=14,16)	0.1 (± 4.50)	0.7 (± 0.0958)		
Week 52 (n=4,1)	2.0 (± 4.83)	2.0 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Laboratory Parameter: Bilirubin

End point title	Change from Baseline in Clinical Laboratory Parameter: Bilirubin

End point description:

Change from baseline in chemistry parameter: bilirubin was reported. SAS population. Here 'n' (number analysed) signifies number of subjects evaluable at specified timepoints. Here 'N' (number of subjects analysed) signifies to number of subjects with available data for this endpoint. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint. Here '9999' signifies that mean and SD was not evaluated because only one subject was available for analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Week 24, and Week 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	16		
Units: micromole per liter				
arithmetic mean (standard deviation)				
Week 24 (n=14,16)	0.1 (± 1.98)	0.3 (± 2.46)		
Week 52 (n=4,1)	-0.3 (± 2.06)	4.0 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Laboratory Parameter: Creatine Kinase

End point title	Change from Baseline in Clinical Laboratory Parameter: Creatine Kinase

End point description:

Change from baseline in chemistry parameter: creatine kinase was reported. mean and SD was not evaluated because no subject was available for the analysis. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint. Here '9999' signifies that SD was not evaluated because only 1 subject was available for analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Week 24, and Week 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	16		
Units: Enzyme U/L				
arithmetic mean (standard deviation)				
Week 24 (n=14,16)	3.3 (± 42.22)	-0.5 (± 53.94)		
Week 52 (n=4,1)	-8.8 (± 36.65)	-2.0 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Laboratory Parameters: Cholesterol

End point title	Change from Baseline in Clinical Laboratory Parameters: Cholesterol

End point description:

Change from baseline in chemistry parameter: cholesterol was reported. mean and SD was not evaluated because no subject was available for the analysis. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint. Here '9999' signifies that SD was not evaluated because only 1 subject was available for analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Week 24, and Week 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	15		
Units: mmol/L				
arithmetic mean (standard deviation)				
Week 24 (n=14,15)	-1.325 (± 1.3026)	0.017 (± 0.7818)		
Week 52 (n=4,1)	-2.235 (± 1.6588)	0.210 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Laboratory Parameter: Activated Partial Thromboplastin Time

End point title	Change from Baseline in Clinical Laboratory Parameter:

	Activated Partial Thromboplastin Time

End point description:

Change from baseline in hematology parameter: activated partial thromboplastin time was reported. SAS population. Here 'n' (number analysed) signifies number of subjects evaluable at specified timepoints. Here 'N' (number of subjects analysed) signifies to number of subjects with available data for this endpoint. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint.9999=signifies that mean and SD was not evaluated because no subject was available for the analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Week 24, and Week 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	13		
Units: Seconds				
arithmetic mean (standard deviation)				
Week 24 (n=12,13) Week 52 (n=4,0)	0.78 (± 1.734) 0.88 (± 1.387)	0.96 (± 3.869) 99999 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved CRR at Week 52

End point title	Percentage of Subjects who Achieved CRR at Week 52

End point description:

CRR was defined as UPCR less than (<) 0.5 mg/mg, eGFR >= 60 mL/min/1.73m^2 or no confirmed decrease >=20% from baseline and prednisone dose <= 10 mg/d. Subject was considered as achieved CRR who did not discontinue study intervention for any reason excluding COVID-19 related discontinuations or met the medication intercurrent event (exceeded baseline glucocorticoid dose, increase above 10 mg/d prednisone equivalent after Week 12, use of new or increased dose of concomitant medication related to LN or other immunosuppressive agents, within 8 weeks prior to the endpoint time point (Week 52) or initiation of prohibited medications at any time prior to the endpoint time point (Week 52). The Full Analyses Set for Week 52 (FASC52) includes all randomized subjects who received at least 1 dose of any study intervention and have the opportunity to complete the Week 52 visit prior to study termination. Here 'N' (number of subjects analyzed) signifies subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Week 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	11		
Units: percentage of subjects				
number (not applicable)	25.0	9.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Laboratory Parameter: Basophils

End point title	Change from Baseline in Clinical Laboratory Parameter: Basophils

End point description:

Change from baseline in hematology parameter: basophils was reported. mean and SD was not evaluated because no subject was available for the analysis. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint. Here '9999' signifies that mean and SD was not evaluated because no subjects were available for analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Week 24, and Week 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	12		
Units: 10*9 cells per liter				
arithmetic mean (standard deviation)				
Week 24 (n=13,12)	-0.009 (± 0.0512)	-0.009 (± 0.0502)		
Week 52 (n=2,0)	-0.070 (± 0.0990)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Laboratory Parameter: Creatinine

End point title	Change from Baseline in Clinical Laboratory Parameter: Creatinine

End point description:

Change from baseline in clinical laboratory parameter: creatinine was reported. mean and SD was not evaluated because no subject was available for the analysis. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint. Here '9999' signifies that SD was not evaluated because only 1 subject was available for analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Week 24, and Week 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	16		
Units: micromole per liter				
arithmetic mean (standard deviation)				
Week 24 (n=14,16)	0.6 (± 18.30)	6.7 (± 16.78)		
Week 52 (n=4,1)	-3.3 (± 7.54)	-5.0 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Laboratory Parameter: Protein

End point title	Change from Baseline in Clinical Laboratory Parameter: Protein

End point description:

Change from baseline in clinical laboratory parameter: protein was reported. mean and SD was not evaluated because no subject was available for the analysis. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint. Here '9999' signifies that SD was not evaluated because only 1 subject was available for analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Week 24, and Week 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	16		
Units: g/L				
arithmetic mean (standard deviation)				
Week 24 (n=14,16)	3.0 (± 8.83)	2.9 (± 16.78)		
Week 52 (n=4,1)	7.0 (± 7.39)	1.0 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Laboratory Parameter: Phosphate

End point title	Change from Baseline in Clinical Laboratory Parameter: Phosphate

End point description:

Change from baseline in clinical laboratory parameter: phosphate was reported. mean and SD was not evaluated because no subject was available for the analysis. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint. Here '9999' signifies that SD was not evaluated because only 1 subject was available for analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Week 24, and Week 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	16		
Units: mmol/L				
arithmetic mean (standard deviation)				
Week 24 (n=14,16)	0.060 (± 0.1498)	0.030 (± 0.2916)		
Week 52 (n=4,1)	-0.035 (± 0.2213)	0.220 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Laboratory Parameter: Sodium

End point title	Change from Baseline in Clinical Laboratory Parameter: Sodium

End point description:

Change from baseline in clinical laboratory parameter: sodium was reported. mean and SD was not evaluated because no subject was available for the analysis. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint. Here '9999' signifies that SD was not evaluated because only 1 subject was available for analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Week 24, and Week 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	16		
Units: mmol/L				
arithmetic mean (standard deviation)				
Week 24 (n=14,16)	-0.7 (± 2.30)	0.4 (± 4.24)		
Week 52 (n=4,1)	1.0 (± 1.41)	3.0 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Laboratory Parameter: Erythrocytes

End point title	Change from Baseline in Clinical Laboratory Parameter: Erythrocytes

End point description:

Change from baseline in clinical laboratory parameter: erythrocytes was reported. mean and SD was not evaluated because no subject was available for the analysis. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint. Here '9999' signifies that mean and SD was not evaluated because no subjects were available for analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Week 24, and Week 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	12		
Units: 10*12 cells per liter				
arithmetic mean (standard deviation)				
Week 24 (n=13,12)	-0.16 (± 0.582)	0.12 (± 0.577)		
Week 52 (n=2,0)	-0.40 (± 0.566)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Laboratiory Parameters: Potassium

End point title	Change from Baseline in Clinical Laboratiory Parameters: Potassium

End point description:

Change from baseline in clinical laboratory parameter: potassium was reported. mean and SD was not evaluated because no subject was available for the analysis. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint. Here '9999' signifies that SD was not evaluated because only 1 subject was available for analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Week 24, and Week 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	16		
Units: mmol/L				
arithmetic mean (standard deviation)				
Week 24 (n=14,16)	0.19 (± 0.704)	0.13 (± 0.402)		
Week 52 (n=4,1)	0.03 (± 0.457)	0.00 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Laboratory Parameter: Gamma Glutamyl and Transferase Lactate Dehydrogenase

End point title	Change from Baseline in Clinical Laboratory Parameter: Gamma Glutamyl and Transferase Lactate Dehydrogenase

End point description:

Change from baseline in clinical laboratory parameter: gamma glutamyl transferase and lactate dehydrogenase were reported. mean and SD was not evaluated because no subject was available for the analysis. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint. Here '9999' signifies that SD was not evaluated because only 1 subject was available for analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Weeks 24 and 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	16		
Units: Enzyme units per liter (U/L)				
arithmetic mean (standard deviation)				
gamma glutamyl transferase: Week 24 (n=14,16)	-0.6 (± 15.01)	-3.0 (± 9.70)		
gamma glutamyl transferase: Week 52 (n=4,1)	1.0 (± 8.60)	-2.0 (± 99999)		
Lactate dehrdogenase: Week 24 (n=13,12)	-14.5 (± 47.90)	-2.5 (± 17.52)		
Lactate dehrdogenase: Week 24 (n=2,1)	-62.5 (± 40.31)	7.0 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Laboratory Parameter: Glomerular Filtration Rate (GFR) from Creatinine Adjusted for Body Surface Area (BSA)

End point title	Change from Baseline in Clinical Laboratory Parameter: Glomerular Filtration Rate (GFR) from Creatinine Adjusted for Body Surface Area (BSA)

End point description:

Change from baseline in clinical laboratory parameter: GFR from Creatinine Adjusted for BSA was reported. mean and SD was not evaluated because no subject was available for the analysis. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint. Here '9999' signifies that SD was not evaluated because only 1 subject was available for analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Weeks 24 and 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	16		
Units: millilter/minute/1.73 meter square				
arithmetic mean (standard deviation)				
Week 24 (n=14,16)	0.44 (± 21.639)	-5.87 (± 17.150)		
Week 52 (n=4,1)	6.75 (± 22.588)	5.60 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Laboratory Parameters: Urea Nitrogen

End point title	Change from Baseline in Clinical Laboratory Parameters: Urea Nitrogen

End point description:

Change from baseline in chemistry parameter: urea nitrogen was reported. mean and SD was not evaluated because no subject was available for the analysis. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint. Here '9999' signifies that SD was not evaluated because only 1 subject was available for analysis

End point type	Secondary

End point timeframe:

Baseline (Week 0), Week 24, and Week 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	16		
Units: mmol/L				
arithmetic mean (standard deviation)				
Week 24 (n=14,16)	-1.23 (± 3.106)	0.71 (± 2.177)		
Week 52 (n=4,1)	-1.60 (± 1.564)	0.50 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Laboratory Parameter: Glucose and Magnesium

End point title	Change from Baseline in Clinical Laboratory Parameter: Glucose and Magnesium

End point description:

Change from baseline in clinical laboratory parameter: glucose and magnesium werereported. mean and SD was not evaluated because no subject was available for the analysis. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint. Here '9999' signifies that SD was not evaluated because only 1 subject was available for analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Weeks 24 and 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	16		
Units: millimoles per liter (mmol/L)				
arithmetic mean (standard deviation)				
Glucose: Week 24 (n=14,16)	-0.23 (± 1.041)	-0.04 (± 0.908)		
Glucose:: Week 52 (n=4,1)	-0.03 (± 0.126)	0.20 (± 9999)		
Magnesium: Week 24 (n=14,16)	-0.024 (± 0.0696)	-0.022 (± 0.0607)		
Magnesium: Week 24 (n=4,1)	-0.068 (± 0.0842)	-0.010 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Laboratory Parameter:

Protein/Creatinine

End point title	Change from Baseline in Clinical Laboratory Parameter: Protein/Creatinine

End point description:

Change from baseline in clinical labpratory parameter: protein/creatinine was reported. mean and SD was not evaluated because no subject was available for the analysis. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Weeks 24 and 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	16		
Units: milligrams per milligram (mg/mg)				
arithmetic mean (standard deviation)				
Week 24 (n=15,16)	-1.509 (± 1.9494)	-0.821 (± 2.4250)		
Week 52 (n=6,7)	-1.586 (± 1.7966)	-0.352 (± 1.6960)		

Statistical analyses

No statistical analyses for this end point

Secondary: Double-blind Period: Change from Baseline in Clinical Laboratory Parameter: Urate

End point title	Double-blind Period: Change from Baseline in Clinical Laboratory Parameter: Urate

End point description:

Change from baseline in clinical laboratory parameter: urate was reported. mean and SD was not evaluated because no subject was available for the analysis. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint.Here '9999' signifies that SD was not evaluated because only 1 subject was available for analysis.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Weeks 24 and 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	16		
Units: micromole per liter				
arithmetic mean (standard deviation)				

Week 24 (n=14,16)	-73.4 (± 104.11)	8.4 (± 48.61)		
Week 52 (n=4,7)	-79.5 (± 79.38)	-2.0 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Double-blind Period: Change from Baseline in Clinical Laboratory Parameter: Urine Protein

End point title	Double-blind Period: Change from Baseline in Clinical Laboratory Parameter: Urine Protein

End point description:

Change from baseline in clinical labpratory parameter: urine protein was reported. mean and SD was not evaluated because no subject was available for the analysis. Since a small number of subjects only entered the LTE phase than the planned enrollment count, the planned analysis of change from baseline for the safety parameters was not performed for the LTE phase for this endpoint.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Weeks 24 and 52

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	16		
Units: milligrams per liter (mg/L)				
arithmetic mean (standard deviation)				
Week 24 (n=15,16)	-1322.1 (± 1865.82)	-310.3 (± 1494.58)		
Week 52 (n=6,7)	-1821.7 (± 2334.78)	-166.4 (± 1099.54)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Maximum US National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE) Toxicity Grade (Grade 4) in Clinical Laboratory Parameters: Hematology and Chemistry

End point title	Number of Subjects with Maximum US National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE) Toxicity Grade (Grade 4) in Clinical Laboratory Parameters: Hematology and Chemistry

End point description:

Number of subjects with maximum US NCI-CTCAE toxicity grade (Grade 4) in clinical laboratory parameters: hematology and chemistry were reported. Toxicity were graded as Grade 1: Mild, Grade 2: Moderate; Grade 3: Severe. Grade 4: Life-threatening and Grade 5: Death. SAS included all subjects who received at least one dose of study intervention. Since a small number of subjects only entered the

LTE period than the planned enrollment count, no separate adverse events analysis was performed for the LTE phase subjects and thus, data of both DB period and LTE phase were presented together for this endpoint under the arms: placebo and guselkumab.

End point type	Secondary

End point timeframe:

DB period: From Week 0 up to 12 week safety follow-up (i.e., up to Week 60); LTE phase: From Week 52 up to LTE phase termination (i.e., up to Week 96)

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	17		
Units: subjects				
number (not applicable)				
Alanine Aminotransferase Increased	0	0		
Alkaline Phosphatase Increased	0	0		
Aspartate Aminotransferase Increased	0	0		
Blood Bilirubin Increased	0	0		
CPK Increased	0	0		
Cholesterol High	0	0		
Creatinine Increase	0	0		
Gamma-glutamyl transferase (GGT) Increased	0	0		
Hypermagnesemia	0	0		
Hypernatremia	0	0		
Hypertriglyceridemia	0	0		
Hypoalbuminemia	0	0		
Hypoglycemia	0	0		
Hypokalemia	0	0		
Hypomagnesemia	0	0		
Hyponatremia	0	0		
Activated Partial Thromboplastin Time Prolonged	0	0		
Anemia	0	0		
Hemoglobin Increased	0	0		
Leukocytosis	0	0		
Lymphocyte Count Decreased	0	0		
Lymphocyte Count Increased	0	0		
Neutrophil Count Decreased	0	0		
Platelet Count Decreased	0	0		
White Blood Cell Decreased	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

DB period: From Week 0 up to 12 week safety follow-up (i.e., up to Week 60); LTE phase: From Week 52 up to LTE phase termination (i.e., up to Week 96)

Adverse event reporting additional description:

SAS: all subjects who received at least 1 dose of study drug. Since small number of subjects only entered LTE period than planned enrollment, no separate AEs analysis was performed for LTE phase subjects and thus, data of both DB and LTE period were presented together for AEs (SAEs and non-SAEs) and death data under arms: placebo and guselkumab.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.1

Reporting groups

Reporting group title	Guselkumab

Reporting group description:

In double-blind period subjects received guselkumab 400 mg IV infusion at Weeks 0, 4 and 8 and guselkumab 200 mg SC injection q4w from Week 12 through Week 48 along with standard-of-care treatment of MMF/MPA and glucocorticoids. Subjects who achieved CRR at Week 48 and 52, and completed the Week 52 assessments entered LTE phase and continued to receive guselkumab 200 mg SC injection q4w from Week 52 through Week 84 (that is., up to LTE phase treatment termination).

Reporting group title	Placebo

Reporting group description:

In double-blind period, subjects received placebo matched to guselkumab (400 milligrams [mg]) intravenous (IV) infusion at Weeks 0, 4 and 8 and placebo matched to guselkumab (200 mg) subcutaneous (SC) injection every 4 weeks (q4w) from Week 12 through Week 48 along with standard-of-care treatment of mycophenolate mofetil (MMF)/mycophenolic acid (MPA) and glucocorticoids. Subjects who achieved complete renal response (CRR) at Week 48 and 52, and completed the Week 52 assessments entered the long-term extension (LTE) phase and continued to receive placebo matched to guselkumab SC injection q4w from Week 52 through Week 84 (that is., up to LTE phase treatment termination)

Serious adverse events	Guselkumab	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 17 (5.88%)	1 / 16 (6.25%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Nervous system disorders			
Basal Ganglia Stroke			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Lupus Nephritis			

subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Guselkumab	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 17 (70.59%)	12 / 16 (75.00%)	
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	0	
Hypertension			
subjects affected / exposed	2 / 17 (11.76%)	2 / 16 (12.50%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	0	
Injection Site Erythema			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	0	
Fatigue			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	0	
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	
occurrences (all)	0	0	
White Blood Cell Count Increased			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	
occurrences (all)	0	0	
Liver Function Test Increased			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	
occurrences (all)	0	0	

Heart Rate Increased			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	
occurrences (all)	0	0	
Blood Pressure Increased			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	
occurrences (all)	0	0	
Blood Creatine Phosphokinase Increased			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	0	
Blood Bicarbonate Decreased			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
Skin Laceration			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	0	
Medication Error			
subjects affected / exposed	2 / 17 (11.76%)	0 / 16 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
Left Ventricular Hypertrophy			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Tension Headache			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	0	
Sciatica			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	0	
Post Herpetic Neuralgia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	
occurrences (all)	0	0	
Hypoaesthesia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	0	

Headache			
subjects affected / exposed	2 / 17 (11.76%)	0 / 16 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 17 (17.65%)	1 / 16 (6.25%)	
occurrences (all)	0	0	
Iron Deficiency Anaemia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	0	
Leukopenia			
subjects affected / exposed	0 / 17 (0.00%)	2 / 16 (12.50%)	
occurrences (all)	0	0	
Lymphopenia			
subjects affected / exposed	0 / 17 (0.00%)	3 / 16 (18.75%)	
occurrences (all)	0	0	
Thrombocytopenia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	0	
Eye disorders			
Ocular Myasthenia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Toothache			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	0	
Nausea			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	0	
Gastrooesophageal Reflux Disease			
subjects affected / exposed	2 / 17 (11.76%)	0 / 16 (0.00%)	
occurrences (all)	0	0	
Diarrhoea			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	0	
Chronic Gastritis			

subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	
occurrences (all)	0	0	
Abdominal Pain Upper			
subjects affected / exposed	0 / 17 (0.00%)	2 / 16 (12.50%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Urticaria			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	
occurrences (all)	0	0	
Skin Striae			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	
occurrences (all)	0	0	
Dry Skin			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Lupus Nephritis			
subjects affected / exposed	5 / 17 (29.41%)	2 / 16 (12.50%)	
occurrences (all)	0	0	
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	0	
Back Pain			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	0	
Muscular Weakness			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	0	
Systemic Lupus Erythematosus			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	
occurrences (all)	0	0	

Sle Arthritis			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	0	
Pain in Extremity			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	0	
Muscle Spasms			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	0	
Infections and infestations			
Bacterial Vaginosis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	
occurrences (all)	0	0	
Bronchitis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	
occurrences (all)	0	0	
Urinary Tract Infection			
subjects affected / exposed	2 / 17 (11.76%)	2 / 16 (12.50%)	
occurrences (all)	0	0	
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	0	
Pyelonephritis Chronic			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	
occurrences (all)	0	0	
Pneumonia Bacterial			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	0	
Influenza			
subjects affected / exposed	2 / 17 (11.76%)	0 / 16 (0.00%)	
occurrences (all)	0	0	
Herpes Zoster			
subjects affected / exposed	1 / 17 (5.88%)	2 / 16 (12.50%)	
occurrences (all)	0	0	
Gastroenteritis			

subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	0	
Covid-19			
subjects affected / exposed	0 / 17 (0.00%)	3 / 16 (18.75%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Vitamin D Deficiency			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	0	
Hypokalaemia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	0	
Hyperuricaemia			
subjects affected / exposed	1 / 17 (5.88%)	2 / 16 (12.50%)	
occurrences (all)	0	0	
Hyperlipidaemia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	
occurrences (all)	0	0	
Hyperkalaemia			
subjects affected / exposed	1 / 17 (5.88%)	1 / 16 (6.25%)	
occurrences (all)	0	0	
Dyslipidaemia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 16 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 May 2020	It was recognized that the Coronavirus Disease 2019 (COVID-19) pandemic may have an impact on the conduct of this clinical study. In alignment with recent health authority guidance, the Sponsor was providing options for study related subject management in the event of COVID-19 related disruption to the conduct of the study.
20 May 2021	Added a LTE to the study for an additional 2 years in order to evaluate long-term efficacy and safety of guselkumab treatment in lupus nephritis. Eligible subjects must have achieved complete renal response (CRR) at Weeks 48 and 52. This amendment also addressesed the use of oral contraceptives (using oral contraceptives with a second method of contraception) with concomitant mycophenolate mofetil (MMF)/mycophenolic acid (MPA) due to changes in their label.
29 March 2022	Revised the inclusion and exclusion criteria on the use of glucocorticoids and cyclophosphamide to better align with standard of care treatment for lupus nephritis and to enhance enrollment in the study without affecting the Sponsor's ability to fulfill the objectives of the study. The requirement for collection of plasma biomarkers samples in the long-term extension (LTE) was removed. In addition, Cystatin C testing was now required. Additional changes are also listed in the amendment table below.
24 May 2022	Revised the protocol to reflect the sponsor's decision to stop screening of new subjects and terminate the study early, as a result of enrollment challenges.

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.

Due to enrollment challenges,Sponsor decided to stop screening of new subjects and stop study early. Since small number of subjects entered LTE phase than planned enrollment, some of planned safety analyses were not performed for LTE phase subjects.

Notes: