Clinical trial results:
A Multi-Centre, Open-Label Study to Evaluate the Pharmacokinetics and Safety of Subcutaneously Administered Belimumab Plus Standard Therapy in Chinese Paediatric Participants with Systemic Lupus Erythematosus (SLE)

Summary

EudraCT number	2025-000142-26
Trial protocol	Outside EU/EEA
Global end of trial date	30 October 2024

Results information

Result version number	v1 (current)
This version publication date	14 November 2025
First version publication date	14 November 2025

Trial information

Trial identification

Sponsor protocol code	217091

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05917288
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	980 Great West Road, Brentford,Middlesex, United Kingdom, TW8 9GS
Public contact	GSK Response Center, GlaxoSmithKline, 1 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, GlaxoSmithKline, 1 8664357343, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	29 November 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	30 October 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To characterize belimumab exposure following belimumab 200 mg SC in Chinese paediatric systemic lupus erythematosus (SLE) participants who have previously been treated with IV belimumab.

Protection of trial subjects:

NA

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 July 2023
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	China: 16
Worldwide total number of subjects	16
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)	4
Adolescents (12-17 years)	12
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 16 participants were enrolled in this study.

Pre-assignment

Screening details:

Participants who had completed 48 weeks of intravenous (IV) belimumab treatment in study 213560 (NCT04908865) were enrolled in this study.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Belimumab 200 mg/mL

Arm description:

Participants with systemic lupus erythematosus (SLE), who had completed 48 weeks of IV belimumab treatment in study 213560 (NCT04908865), received belimumab 200 milligrams per milliliter (mg/mL) as a subcutaneous (SC) injection over 12 weeks along with standard of care (SOC) therapy. The dosing frequency of belimumab was based on the body weight of the participants. Participants weighing greater than or equal to (>=) 50 kilograms (kg) received belimumab every week, participants weighing between 30 kg and less than (<) 50 kg received belimumab every 10 days, and participants weighing between 15 kg and < 30 kg received belimumab every 2 weeks.

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

Dosage and administration details:

200 mg/mL SC injection according to the baseline body weight plus SOC

Number of subjects in period 1	Belimumab 200 mg/mL
Started	16
Completed	16

Baseline characteristics

Reporting groups	
Reporting group title	Belimumab 200 mg/mL

Reporting group description:

Participants with systemic lupus erythematosus (SLE), who had completed 48 weeks of IV belimumab treatment in study 213560 (NCT04908865), received belimumab 200 milligrams per milliliter (mg/mL) as a subcutaneous (SC) injection over 12 weeks along with standard of care (SOC) therapy. The dosing frequency of belimumab was based on the body weight of the participants. Participants weighing greater than or equal to (>=) 50 kilograms (kg) received belimumab every week, participants weighing between 30 kg and less than (<) 50 kg received belimumab every 10 days, and participants weighing between 15 kg and < 30 kg received belimumab every 2 weeks.

Reporting group values	Belimumab 200 mg/mL	Total	
Number of subjects	16	16	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	4	4	
Adolescents (12-17 years)	12	12	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Sex: Female, Male Units: Participants			
Male	5	5	
Female	11	11	
Race/Ethnicity, Customized Units: Subjects			
Asian - East Asian Heritage	16	16	
Age, Continuous Units: YEARS			
arithmetic mean	12.9		
standard deviation	± 2.55	-	

Subject analysis sets	
Subject analysis set title	Belimumab 200 mg/mL Every Week
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants with SLE, who had completed 48 weeks of IV belimumab treatment in study 213560 (NCT04908865) and weighed >= 50 kg, received belimumab 200 mg/mL as an SC injection every week over 12 weeks along with SOC therapy.

Subject analysis set title	Belimumab 200 mg/mL Every 10 Days
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants with SLE, who had completed 48 weeks of IV belimumab treatment in study 213560 (NCT04908865) and weighed between 30 kg and < 50 kg, received belimumab 200 mg/mL as an SC injection every 10 days over 12 weeks along with SOC therapy.

Subject analysis set title	Belimumab 200 mg/mL Every 2 Weeks
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants with SLE, who had completed 48 weeks of IV belimumab treatment in study 213560 (NCT04908865) and weighed between 15 kg and < 30 kg, received belimumab 200 mg/mL as an SC injection every 2 weeks over 12 weeks along with SOC therapy.

Reporting group values	Belimumab 200 mg/mL Every Week	Belimumab 200 mg/mL Every 10 Days	Belimumab 200 mg/mL Every 2 Weeks
Number of subjects	10	5	1
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Sex: Female, Male Units: Participants			
Male Female			
Race/Ethnicity, Customized Units: Subjects			
Asian - East Asian Heritage	10	5	1
Age, Continuous Units: YEARS arithmetic mean standard deviation	±	±	±

End points

End points reporting groups

Reporting group title	Belimumab 200 mg/mL

Reporting group description:

Participants with systemic lupus erythematosus (SLE), who had completed 48 weeks of IV belimumab treatment in study 213560 (NCT04908865), received belimumab 200 milligrams per milliliter (mg/mL) as a subcutaneous (SC) injection over 12 weeks along with standard of care (SOC) therapy. The dosing frequency of belimumab was based on the body weight of the participants. Participants weighing greater than or equal to (>=) 50 kilograms (kg) received belimumab every week, participants weighing between 30 kg and less than (<) 50 kg received belimumab every 10 days, and participants weighing between 15 kg and < 30 kg received belimumab every 2 weeks.

Subject analysis set title	Belimumab 200 mg/mL Every Week
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants with SLE, who had completed 48 weeks of IV belimumab treatment in study 213560 (NCT04908865) and weighed >= 50 kg, received belimumab 200 mg/mL as an SC injection every week over 12 weeks along with SOC therapy.

Subject analysis set title	Belimumab 200 mg/mL Every 10 Days
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants with SLE, who had completed 48 weeks of IV belimumab treatment in study 213560 (NCT04908865) and weighed between 30 kg and < 50 kg, received belimumab 200 mg/mL as an SC injection every 10 days over 12 weeks along with SOC therapy.

Subject analysis set title	Belimumab 200 mg/mL Every 2 Weeks
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants with SLE, who had completed 48 weeks of IV belimumab treatment in study 213560 (NCT04908865) and weighed between 15 kg and < 30 kg, received belimumab 200 mg/mL as an SC injection every 2 weeks over 12 weeks along with SOC therapy.

Primary: Area Under the Curve at Steady-state to the End of the Dosing Period (AUCss,0-tau) of Belimumab for Participants Weighing Between 30 kg and Less Than (<) 50 kg

End point title	Area Under the Curve at Steady-state to the End of the Dosing Period (AUCss,0-tau) of Belimumab for Participants Weighing Between 30 kg and Less Than (<) 50 kg[1]

End point description:

Blood samples were collected at indicated time points for PK analysis of belimumab. AUCss,0-tau of belimumab for participants weighing between 30 kg and < 50 kg has been reported. PK Analysis Set included all participants assigned treatment who received at least one dose of study treatment and for whom at least one post belimumab treatment PK sample was obtained and analyzed.

End point type	Primary

End point timeframe:

Pre-dose on Days 1, 11, and 71, and post-dose on Days 4, 74, and 81

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: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Belimumab 200 mg/mL Every 10 Days			
Subject group type	Subject analysis set			
Number of subjects analysed	5			
Units: Days*micrograms per milliliter				
geometric mean (geometric coefficient of variation)	807.57 (± 17.44)			

Statistical analyses

No statistical analyses for this end point

Primary: Area Under the Curve at Steady-state to the End of the Dosing Period (AUCss,0-tau) of Belimumab for Participants Weighing Greater than or Equal to (>=) 50 kilograms (kg)

End point title	Area Under the Curve at Steady-state to the End of the Dosing Period (AUCss,0-tau) of Belimumab for Participants Weighing Greater than or Equal to (>=) 50 kilograms (kg)[2]

End point description:

Blood samples were collected at indicated time points for pharmacokinetic (PK) analysis of belimumab. AUCss,0-tau of belimumab for participants weighing >= 50 kg has been reported. As the first dose of belimumab was administered on Day 1, Week 12 post-dose correlates to Day 1 plus 84 days, i.e., Day 85. PK Analysis Set included all participants assigned treatment who received at least one dose of study treatment and for whom at least one post belimumab treatment PK sample was obtained and analyzed.

End point type	Primary

End point timeframe:

Pre-dose on Days 1, 8, and 78, and post-dose on Days 4, 81, and 85

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Belimumab 200 mg/mL Every Week			
Subject group type	Subject analysis set			
Number of subjects analysed	10			
Units: Days*micrograms per milliliter				
geometric mean (geometric coefficient of variation)	633.26 (± 27.50)			

Statistical analyses

No statistical analyses for this end point

Primary: Average Serum Concentration at Steady State (Cavg,ss) of Belimumab for Participants Weighing Between 15 kg and < 30 kg

End point title	Average Serum Concentration at Steady State (Cavg,ss) of Belimumab for Participants Weighing Between 15 kg and < 30 kg[3]

End point description:

Blood samples were collected at indicated time points for PK analysis of belimumab. Cavg,ss of belimumab for participants weighing between 15 kg and < 30 kg has been reported. As the first dose of belimumab was administered on Day 1, Week 12 post-dose correlates to Day 1 plus 84 days, i.e., Day 85. PK Analysis Set included all participants assigned treatment who received at least one dose of study treatment and for whom at least one post belimumab treatment PK sample was obtained and analyzed. '99999' indicates that geometric coefficient of variation could not be calculated as only 1 participant was analyzed.

End point type	Primary

End point timeframe:

Pre-dose on Days 1, 15, and 71, and post-dose on Days 4, 74, and 85

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Belimumab 200 mg/mL Every 2 Weeks			
Subject group type	Subject analysis set			
Number of subjects analysed	1			
Units: Micrograms per milliliter				
geometric mean (geometric coefficient of variation)	97.52 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Primary: Minimum Serum Concentration at Steady State (Cmin,ss) of Belimumab for Participants Weighing >= 50 kg

End point title	Minimum Serum Concentration at Steady State (Cmin,ss) of Belimumab for Participants Weighing >= 50 kg[4]

End point description:

Blood samples were collected at indicated time points for PK analysis of belimumab. Cmin,ss of belimumab for participants weighing >= 50 kg has been reported. As the first dose of belimumab was administered on Day 1, Week 12 post-dose correlates to Day 1 plus 84 days, i.e., Day 85. PK Analysis Set included all participants assigned treatment who received at least one dose of study treatment and for whom at least one post belimumab treatment PK sample was obtained and analyzed.

End point type	Primary

End point timeframe:

Pre-dose on Days 1, 8, and 78, and post-dose on Days 4, 81, and 85

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Belimumab 200 mg/mL Every Week			
Subject group type	Subject analysis set			
Number of subjects analysed	10			
Units: Micrograms per milliliter				
geometric mean (geometric coefficient of variation)	82.63 (± 28.69)			

Statistical analyses

No statistical analyses for this end point

Primary: Average Serum Concentration at Steady State (Cavg,ss) of Belimumab for Participants Weighing Between 30 kg and < 50 kg

End point title	Average Serum Concentration at Steady State (Cavg,ss) of Belimumab for Participants Weighing Between 30 kg and < 50 kg[5]

End point description:

Blood samples were collected at indicated time points for PK analysis of belimumab. Cavg,ss of belimumab for participants weighing between 30 kg and < 50 kg has been reported. PK Analysis Set included all participants assigned treatment who received at least one dose of study treatment and for whom at least one post belimumab treatment PK sample was obtained and analyzed.

End point type	Primary

End point timeframe:

Pre-dose on Days 1, 11, and 71, and post-dose on Days 4, 74, and 81

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Belimumab 200 mg/mL Every 10 Days			
Subject group type	Subject analysis set			
Number of subjects analysed	5			
Units: Micrograms per milliliter				
geometric mean (geometric coefficient of variation)	80.76 (± 17.44)			

Statistical analyses

No statistical analyses for this end point

Primary: Average Serum Concentration at Steady State (Cavg,ss) of Belimumab for Participants Weighing >= 50 kg

End point title	Average Serum Concentration at Steady State (Cavg,ss) of Belimumab for Participants Weighing >= 50 kg[6]

End point description:

Blood samples were collected at indicated time points for PK analysis of belimumab. Cavg,ss of belimumab for participants weighing >= 50 kg has been reported. As the first dose of belimumab was administered on Day 1, Week 12 post-dose correlates to Day 1 plus 84 days, i.e., Day 85. PK Analysis Set included all participants assigned treatment who received at least one dose of study treatment and for whom at least one post belimumab treatment PK sample was obtained and analyzed.

End point type	Primary

End point timeframe:

Pre-dose on Days 1, 8, and 78, and post-dose on Days 4, 81, and 85

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Belimumab 200 mg/mL Every Week			
Subject group type	Subject analysis set			
Number of subjects analysed	10			
Units: Micrograms per milliliter				
geometric mean (geometric coefficient of variation)	90.47 (± 27.50)			

Statistical analyses

No statistical analyses for this end point

Primary: Area Under the Curve at Steady-state to the End of the Dosing Period (AUCss,0-tau) of Belimumab for Participants Weighing Between 15 kg and < 30 kg

End point title	Area Under the Curve at Steady-state to the End of the Dosing Period (AUCss,0-tau) of Belimumab for Participants Weighing Between 15 kg and < 30 kg[7]

End point description:

Blood samples were collected at indicated time points for PK analysis of belimumab. AUCss,0-tau of belimumab for participants weighing between 15 kg and < 30 kg has been reported. As the first dose of belimumab was administered on Day 1, Week 12 post-dose correlates to Day 1 plus 84 days, i.e., Day 85. PK Analysis Set included all participants assigned treatment who received at least one dose of study treatment and for whom at least one post belimumab treatment PK sample was obtained and analyzed. '99999' indicates that geometric coefficient of variation could not be calculated as only 1 participant was analyzed.

End point type	Primary

End point timeframe:

Pre-dose on Days 1, 15, and 71, and post-dose on Days 4, 74, and 85

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Belimumab 200 mg/mL Every 2 Weeks			
Subject group type	Subject analysis set			
Number of subjects analysed	1			
Units: Days*micrograms per milliliter				
geometric mean (geometric coefficient of variation)	1365.23 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Primary: Maximum Serum Concentration during the Dosing Interval at Steady State (Cmax,ss) of Belimumab for Participants Weighing Between 30 kg and < 50 kg

End point title	Maximum Serum Concentration during the Dosing Interval at Steady State (Cmax,ss) of Belimumab for Participants Weighing Between 30 kg and < 50 kg[8]

End point description:

Blood samples were collected at indicated time points for PK analysis of belimumab. Cmax,ss of belimumab for participants weighing between 30 kg and < 50 kg has been reported. PK Analysis Set included all participants assigned treatment who received at least one dose of study treatment and for whom at least one post belimumab treatment PK sample was obtained and analyzed.

End point type	Primary

End point timeframe:

Pre-dose on Days 1, 11, and 71, and post-dose on Days 4, 74, and 81

Notes:

[8] - 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: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Belimumab 200 mg/mL Every 10 Days			
Subject group type	Subject analysis set			
Number of subjects analysed	5			
Units: Micrograms per milliliter				
geometric mean (geometric coefficient of variation)	87.15 (± 15.91)			

Statistical analyses

No statistical analyses for this end point

Primary: Maximum Serum Concentration during the Dosing Interval at Steady State (Cmax,ss) of Belimumab for Participants Weighing >= 50 kg

End point title	Maximum Serum Concentration during the Dosing Interval at Steady State (Cmax,ss) of Belimumab for Participants Weighing >= 50 kg[9]

End point description:

Blood samples were collected at indicated time points for PK analysis of belimumab. Cmax,ss of belimumab for participants weighing >= 50 kg has been reported. As the first dose of belimumab was administered on Day 1, Week 12 post-dose correlates to Day 1 plus 84 days, i.e., Day 85. PK Analysis Set included all participants assigned treatment who received at least one dose of study treatment and for whom at least one post belimumab treatment PK sample was obtained and analyzed.

End point type	Primary

End point timeframe:

Pre-dose on Days 1, 8, and 78, and post-dose on Days 4, 81, and 85

Notes:

[9] - 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: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Belimumab 200 mg/mL Every Week			
Subject group type	Subject analysis set			
Number of subjects analysed	10			
Units: Micrograms per milliliter				
geometric mean (geometric coefficient of variation)	93.36 (± 25.80)			

Statistical analyses

No statistical analyses for this end point

Primary: Minimum Serum Concentration at Steady State (Cmin,ss) of Belimumab for Participants Weighing Between 15 kg and < 30 kg

End point title	Minimum Serum Concentration at Steady State (Cmin,ss) of Belimumab for Participants Weighing Between 15 kg and < 30 kg[10]

End point description:

Blood samples were collected at indicated time points for PK analysis of belimumab. Cmin,ss of belimumab for participants weighing 15 kg and < 30 kg has been reported. As the first dose of belimumab was administered on Day 1, Week 12 post-dose correlates to Day 1 plus 84 days, i.e., Day 85. PK Analysis Set included all participants assigned treatment who received at least one dose of study treatment and for whom at least one post belimumab treatment PK sample was obtained and analyzed. '99999' indicates that geometric coefficient of variation could not be calculated as only 1 participant was analyzed.

End point type	Primary

End point timeframe:

Pre-dose on Days 1, 15, and 71, and post-dose on Days 4, 74, and 85

Notes:

[10] - 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: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Belimumab 200 mg/mL Every 2 Weeks			
Subject group type	Subject analysis set			
Number of subjects analysed	1			
Units: Micrograms per milliliter				
geometric mean (geometric coefficient of variation)	80.95 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Primary: Minimum Serum Concentration at Steady State (Cmin,ss) of Belimumab for Participants Weighing Between 30 kg and < 50 kg

End point title	Minimum Serum Concentration at Steady State (Cmin,ss) of Belimumab for Participants Weighing Between 30 kg and < 50 kg[11]

End point description:

Blood samples were collected at indicated time points for PK analysis of belimumab. Cmin,ss of belimumab for participants weighing 30 kg and < 50 kg has been reported. PK Analysis Set included all participants assigned treatment who received at least one dose of study treatment and for whom at least one post belimumab treatment PK sample was obtained and analyzed.

End point type	Primary

End point timeframe:

Pre-dose on Days 1, 11, and 71, and post-dose on Days 4, 74, and 81

Notes:

[11] - 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: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Belimumab 200 mg/mL Every 10 Days			
Subject group type	Subject analysis set			
Number of subjects analysed	5			
Units: Micrograms per milliliter				
geometric mean (geometric coefficient of variation)	70.71 (± 20.14)			

Statistical analyses

No statistical analyses for this end point

Primary: Maximum Serum Concentration during the Dosing Interval at Steady State (Cmax,ss) of Belimumab for Participants Weighing Between 15 kg and < 30 kg

End point title	Maximum Serum Concentration during the Dosing Interval at Steady State (Cmax,ss) of Belimumab for Participants Weighing Between 15 kg and < 30 kg[12]

End point description:

Blood samples were collected at indicated time points for PK analysis of belimumab. Cmax,ss of belimumab for participants weighing between 15 kg and < 30 kg has been reported. As the first dose of belimumab was administered on Day 1, Week 12 post-dose correlates to Day 1 plus 84 days, i.e., Day 85. PK Analysis Set included all participants assigned treatment who received at least one dose of study treatment and for whom at least one post belimumab treatment PK sample was obtained and analyzed. '99999' indicates that geometric coefficient of variation could not be calculated as only 1 participant was analyzed.

End point type	Primary

End point timeframe:

Pre-dose on Days 1, 15, and 71, and post-dose on Days 4, 74, and 85

Notes:

[12] - 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: This endpoint was descriptive; hence no statistical analysis to report.

End point values	Belimumab 200 mg/mL Every 2 Weeks			
Subject group type	Subject analysis set			
Number of subjects analysed	1			
Units: Micrograms per milliliter				
geometric mean (geometric coefficient of variation)	109.59 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Adverse Events (AEs), Serious AEs (SAEs), and AEs of Special Interest (AESIs) Through Week 12

End point title	Number of Participants with Adverse Events (AEs), Serious AEs (SAEs), and AEs of Special Interest (AESIs) Through Week 12

End point description:

An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a study intervention, whether or not considered related to the study intervention. An SAE is defined as any untoward medical occurrence that, at any dose: results in death; is life-threatening; requires inpatient hospitalization or prolongation of existing hospitalization; results in persistent or significant disability/incapacity; is a congenital anomaly/birth defect in the offspring of a study participant; or other situations as per medical and scientific judgement of the Investigator. AESIs defined in the protocol included post-injection systemic reactions and hypersensitivity reactions, infections of special interest, malignancies, and depression, suicidality, or self-injury. Intent-to-Treat (ITT) Analysis Set included all participants assigned treatment who received at least one dose of study treatment.

End point type	Secondary

End point timeframe:

Up to Week 12

End point values	Belimumab 200 mg/mL			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: Participants				
AEs	13			
SAEs	0			
AESIs	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality, SAEs, and non-SAEs were collected up to 28 weeks (treatment: up to 12 weeks and follow-up: up to 16 weeks)

Adverse event reporting additional description:

All-cause mortality, SAEs, and non-SAEs were analyzed for ITT Analysis Set that included all participants assigned treatment who received at least one dose of study treatment.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.1

Reporting groups

Reporting group title	Belimumab 200 mg/mL

Reporting group description:

Participants with SLE, who had completed 48 weeks of IV belimumab treatment in study 213560 (NCT04908865), received belimumab 200 mg/mL as an SC injection over 12 weeks along with SOC therapy. The dosing frequency of belimumab was based on the body weight of the participants. Participants weighing >= 50 kg received belimumab every week, participants weighing between 30 kg and < 50 kg received belimumab every 10 days, and participants weighing between 15 kg and < 30 kg received belimumab every 2 weeks.

Serious adverse events	Belimumab 200 mg/mL		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 16 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Belimumab 200 mg/mL		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 16 (81.25%)		
Investigations			
White blood cell count decreased			
subjects affected / exposed	1 / 16 (6.25%)		
occurrences (all)	2		
Gastrointestinal disorders			
Diarrhoea			

subjects affected / exposed occurrences (all) Noninfective gingivitis subjects affected / exposed occurrences (all) Lip swelling subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1 1 / 16 (6.25%) 1 1 / 16 (6.25%) 1		
Hepatobiliary disorders Hepatic function abnormal subjects affected / exposed occurrences (all)	 2 / 16 (12.50%) 3		
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) Rhinitis allergic subjects affected / exposed occurrences (all)	 1 / 16 (6.25%) 1 1 / 16 (6.25%) 1		
Skin and subcutaneous tissue disorders Acne subjects affected / exposed occurrences (all) Rash subjects affected / exposed occurrences (all)	 1 / 16 (6.25%) 1 1 / 16 (6.25%) 1		
Musculoskeletal and connective tissue disorders Growth retardation subjects affected / exposed occurrences (all)	 1 / 16 (6.25%) 1		
Infections and infestations Bronchitis subjects affected / exposed occurrences (all) Upper respiratory tract infection	 3 / 16 (18.75%) 3 		

subjects affected / exposed	9 / 16 (56.25%)		
occurrences (all)	17		
Mycoplasma infection			
subjects affected / exposed	1 / 16 (6.25%)		
occurrences (all)	1		
Tinea versicolour			
subjects affected / exposed	1 / 16 (6.25%)		
occurrences (all)	1		
Tonsillitis			
subjects affected / exposed	1 / 16 (6.25%)		
occurrences (all)	1		
Viral infection			
subjects affected / exposed	1 / 16 (6.25%)		
occurrences (all)	1		
Conjunctivitis			
subjects affected / exposed	1 / 16 (6.25%)		
occurrences (all)	1		
Bacterial infection			
subjects affected / exposed	1 / 16 (6.25%)		
occurrences (all)	1		
Metabolism and nutrition disorders			
Weight fluctuation			
subjects affected / exposed	1 / 16 (6.25%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
03 January 2023	Protocol Amendment 01

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported