Clinical trial results:
A Multi-Center, Open-Label Trial to Evaluate the Pharmacokinetics, Safety, and Pharmacodynamics of Subcutaneously Administered Belimumab, a Human Monoclonal Anti-BLyS Antibody, Plus Standard Therapy in Pediatric Participants with Systemic Lupus Erythematosus (SLE)

Summary

EudraCT number	2018-004645-16
Trial protocol	DE NL ES
Global end of trial date	

Results information

Result version number	v1
This version publication date	01 February 2024
First version publication date	01 February 2024

Trial information

Trial identification

Sponsor protocol code	200908

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04179032
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)	Yes
EMA paediatric investigation plan number(s)	EMEA-000313-PIP20-20
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	Interim
Date of interim/final analysis	16 January 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	16 January 2023
Global end of trial reached?	No

Notes:

General information about the trial

Main objective of the trial:

To characterize the PK profile of belimumab 200 mg SC in pediatric SLE participants.

Protection of trial subjects:

None

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 November 2019
Long term follow-up planned	Yes
Long term follow-up rationale	Scientific research, Efficacy, Safety
Long term follow-up duration	3 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 4
Country: Number of subjects enrolled	Germany: 4
Country: Number of subjects enrolled	Japan: 2
Country: Number of subjects enrolled	Mexico: 3
Country: Number of subjects enrolled	Netherlands: 2
Country: Number of subjects enrolled	Spain: 6
Country: Number of subjects enrolled	United States: 4
Worldwide total number of subjects	25
EEA total number of subjects	12

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)	3
Adolescents (12-17 years)	22
Adults (18-64 years)	0

From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The primary study included Part A which is an open label 12-week treatment phase and Part B an optional 40-week open-label continuation phase, open to all participants who have completed Part A. An optional access extension phase is ongoing and additional data will be provided after study completion date is achieved.

Pre-assignment

Screening details:

A total of 28 participants were screened and 25 were enrolled to the study.

Period 1

Period 1 title	Part A (Up to Week 12)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Belimumab 200 mg

Arm description:

Participants with Systemic Lupus Erythematosus were administered with Belimumab 200 milligram per milliliter (mg/mL) subcutaneous (SC) injection. The dosing frequency was based on body weight. Participants who weigh more than or equal to 50 kilograms were administered every week, who weigh between 30 to less than 50 kg were administered every 10 days and who weigh less than 30 kg were administered every 2 weeks.

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

Dosage and administration details:

Cohort 1 (≥50 kg): 200 mg weekly

Investigational medicinal product name	Belimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Cohort 3 (<30 kg): 200 mg every 2 weeks

Investigational medicinal product name	Belimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Cohort 2 (≥ 30 kg - <50 kg): 200 mg every 10 days

Number of subjects in period 1	Belimumab 200 mg
Started	25
Completed	25

Period 2

Period 2 title	Part B (Up to Week 52)
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Belimumab 200 mg

Arm description:

Participants with Systemic Lupus Erythematosus were administered with Belimumab 200 milligram per milliliter (mg/mL) subcutaneous (SC) injection. The dosing frequency was based on body weight. Participants who weigh more than or equal to 50 kilograms were administered every week, who weigh between 30 to less than 50 kg were administered every 10 days and who weigh less than 30 kg were administered every 2 weeks.

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

Dosage and administration details:

Cohort 1 (≥50 kg): 200 mg weekly

Investigational medicinal product name	Belimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Cohort 3 (<30 kg): 200 mg every 2 weeks

Investigational medicinal product name	Belimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Cohort 2 (≥ 30 kg - <50 kg): 200 mg every 10 days

Number of subjects in period 2	Belimumab 200 mg
Started	25
Completed	23
Not completed	2
Adverse event, non-fatal	1
INVESTIGATOR DISCRETION	1

Period 3	
Period 3 title	Access Extension Phase
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Belimumab 200 mg

Arm description:

Participants with Systemic Lupus Erythematosus were administered with Belimumab 200 milligram per milliliter (mg/mL) subcutaneous (SC) injection. The dosing frequency was based on body weight. Participants who weigh more than or equal to 50 kilograms were administered every week, who weigh between 30 to less than 50 kg were administered every 10 days and who weigh less than 30 kg were administered every 2 weeks.

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

Dosage and administration details:

Cohort 1 (≥50 kg): 200 mg weekly

Investigational medicinal product name	Belimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Cohort 2 (≥ 30 kg - <50 kg): 200 mg every 10 days

Investigational medicinal product name	Belimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Cohort 3 (<30 kg): 200 mg every 2 weeks

Number of subjects in period 3[1]	Belimumab 200 mg
Started	11
Completed	0
Not completed	11
Ongoing	11

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: The study is still ongoing, and we are reporting the interim results.

Baseline characteristics

Reporting groups	
Reporting group title	Belimumab 200 mg
Reporting group description:	
Participants with Systemic Lupus Erythematosus were administered with Belimumab 200 milligram per milliliter (mg/mL) subcutaneous (SC) injection. The dosing frequency was based on body weight. Participants who weigh more than or equal to 50 kilograms were administered every week, who weigh between 30 to less than 50 kg were administered every 10 days and who weigh less than 30 kg were administered every 2 weeks.	

Reporting group values	Belimumab 200 mg	Total	
Number of subjects	25	25	
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)	3	3	
Adolescents (12-17 years)	22	22	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Sex: Female, Male Units: Participants			
Female	21	21	
Male	4	4	
Race/Ethnicity, Customized Units: Subjects			
AMERICAN INDIAN OR ALASKA NATIVE	3	3	
ASIAN	4	4	
BLACK OR AFRICAN AMERICAN	1	1	
WHITE	16	16	
MIXED RACE	1	1	
Age, Continuous Units: YEARS			
arithmetic mean	14.0		
standard deviation	± 2.09	-	

End points

End points reporting groups

Reporting group title	Belimumab 200 mg

Reporting group description:

Participants with Systemic Lupus Erythematosus were administered with Belimumab 200 milligram per milliliter (mg/mL) subcutaneous (SC) injection. The dosing frequency was based on body weight. Participants who weigh more than or equal to 50 kilograms were administered every week, who weigh between 30 to less than 50 kg were administered every 10 days and who weigh less than 30 kg were administered every 2 weeks.

Reporting group title	Belimumab 200 mg

Reporting group description:

Participants with Systemic Lupus Erythematosus were administered with Belimumab 200 milligram per milliliter (mg/mL) subcutaneous (SC) injection. The dosing frequency was based on body weight. Participants who weigh more than or equal to 50 kilograms were administered every week, who weigh between 30 to less than 50 kg were administered every 10 days and who weigh less than 30 kg were administered every 2 weeks.

Reporting group title	Belimumab 200 mg

Reporting group description:

Participants with Systemic Lupus Erythematosus were administered with Belimumab 200 milligram per milliliter (mg/mL) subcutaneous (SC) injection. The dosing frequency was based on body weight. Participants who weigh more than or equal to 50 kilograms were administered every week, who weigh between 30 to less than 50 kg were administered every 10 days and who weigh less than 30 kg were administered every 2 weeks.

Subject analysis set title	Belimumab 200 mg
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants with Systemic Lupus Erythematosus were administered with Belimumab 200 milligram per milliliter (mg/mL) subcutaneous (SC) injection. The dosing frequency was based on body weight. Participants who weigh more than or equal to 50 kilograms were administered every week, who weigh between 30 to less than 50 kg were administered every 10 days and who weigh less than 30 kg were administered every 2 weeks.

Primary: Observed belimumab concentrations at Week 12

End point title	Observed belimumab concentrations at Week 12[1]

End point description:

Blood samples were collected for analysis of belimumab concentration. The analysis was performed on the pharmacokinetic (PK) Set that 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:

At Week 12

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			
Subject group type	Subject analysis set			
Number of subjects analysed	25			
Units: microgram per milliliter (ug/ml)				
geometric mean (confidence interval 95%)	106.42 (87.80 to 128.99)			

Statistical analyses

No statistical analyses for this end point

Primary: Estimated maximum concentration (Cmax) of belimumab at steady state

End point title	Estimated maximum concentration (Cmax) of belimumab at steady state[2]

End point description:

Blood samples were collected for measurement of serum concentrations of belimumab at steady state. Cmax was analyzed and reported for all time-points from Week 1 through Week 60The analysis was performed on the PK Set that 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 Week 1, Week 2, Week 4, Week 8, Week 12, Week 16, Week 24, Week 36, Week 52, and Week 60

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			
Subject group type	Subject analysis set			
Number of subjects analysed	25			
Units: ug/ml				
geometric mean (geometric coefficient of variation)	131 (± 34.9)			

Statistical analyses

No statistical analyses for this end point

Primary: Estimated average concentration (Cavg) of belimumab at steady state

End point title	Estimated average concentration (Cavg) of belimumab at steady state[3]

End point description:

Blood samples were collected for measurement of serum concentrations of belimumab at steady state. Average concentrations were analyzed and reported for all time-points from Week 1 through Week 60. The analysis was performed on the PK Set that 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 Week 1, Week 2, Week 4, Week 8, Week 12, Week 16, Week 24, Week 36, Week 52, and Week 60

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			
Subject group type	Subject analysis set			
Number of subjects analysed	25			
Units: ug/ml				
geometric mean (geometric coefficient of variation)	124 (± 37.3)			

Statistical analyses

No statistical analyses for this end point

Primary: Estimated minimum concentration (Cmin) of belimumab at steady state

End point title	Estimated minimum concentration (Cmin) of belimumab at steady state[4]

End point description:

Blood samples were collected for measurement of serum concentrations of belimumab at steady state. Cmin was analyzed and reported for all time-points from Week 1 through Week 60 The analysis was performed on the PK Set that 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 Week 1, Week 2, Week 4, Week 8, Week 12, Week 16, Week 24, Week 36, Week 52, and Week 60

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			
Subject group type	Subject analysis set			
Number of subjects analysed	25			
Units: ug/ml				
geometric mean (geometric coefficient of variation)	112 (± 41.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with serious adverse events (SAEs)

End point title	Number of participants with serious adverse events (SAEs)

End point description:

A SAE is any untoward medical occurrence that, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent disability/incapacity and/or can result in death. The safety analysis was performed on the Intent-To-Treat (ITT) set that included all participants assigned treatment who received at least one dose of study treatment.

End point type	Secondary

End point timeframe:

Up to Week 68

End point values	Belimumab 200 mg			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: Participants	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with adverse events (AEs)

End point title	Number of participants with adverse events (AEs)

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. The safety analysis was performed on the Intent-To-Treat (ITT) set that included all participants assigned treatment who received at least one dose of study treatment.

End point type	Secondary

End point timeframe:

Up to Week 68

End point values	Belimumab 200 mg			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: Participants	22			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with adverse events of special interest (AESIs)

End point title	Number of participants with adverse events of special interest (AESIs)

End point description:

AESI included post-injection systemic reactions and hypersensitivity reactions, infections, malignancies, and depression/suicidality/self-injury. AESIs were followed until the event is resolved, stabilized, otherwise explained, or the participant is lost to follow-up. The safety analysis was performed on the Intent-To-Treat (ITT) set that included all participants assigned treatment who received at least one dose of study treatment.

End point type	Secondary

End point timeframe:

Up to Week 68

End point values	Belimumab 200 mg			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: Participants				
Malignancies	0			
Post-Injection Systemic Reactions	3			
Infections	0			
Depression/Suicide/Self-injury	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline in anti-double stranded deoxyribonucleic acid (dsDNA) Antibodies at Week 12 and Week 52

End point title	Percent Change from Baseline in anti-double stranded deoxyribonucleic acid (dsDNA) Antibodies at Week 12 and Week 52

End point description:

Blood samples were collected for anti-dsDNA- antibody biomarker analysis. Baseline status are defined as positive (Anti-dsDNA antibody >= 30 International Units Per Milliliter (IU/mL)) or negative (Anti-dsDNA antibody< 30 IU/mL). Percent change from Baseline was calculated by subtracting the Baseline value from value at Week 12 and 52 divided by the Baseline value X 100. The analysis was performed on the ITT set that included all participants assigned treatment who received at least one dose of study treatment. Participants who had positive anti-dsDNA antibody levels at baseline were included in the analysis.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 12 and Week 52

End point values	Belimumab 200 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	15			
Units: IU/mL				
median (full range (min-max))				

Week 12	-17.74 (-68.0 to 40.0)			
Week 52	-58.88 (-85.3 to -2.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline in Complement C3 and Complement C4 at Week 12 and Week 52

End point title	Percent Change from Baseline in Complement C3 and Complement C4 at Week 12 and Week 52

End point description:

Blood samples were collected from participants to assess complement C3 and complement C4 levels. Baseline status are defined as low complement [C3 less than (<) 90 milligrams per deciliter (mg/dL)] or normal/high (C3 >= 90 mg/dL) and low (C4 < 13 mg/dL) or normal/high (C4 >= 13 mg/dL) respectively. Percent change from Baseline was calculated by subtracting the Baseline value from value at Week 12 and 52 divided by the Baseline value X 100. The analysis was performed on the ITT set that included all participants assigned treatment who received at least one dose of study treatment. Participants who had low baseline C3 and C4 levels were included in the respective analysis. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 12 and Week 52

End point values	Belimumab 200 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	15			
Units: Milligram per deciliter				
median (full range (min-max))				
Complement C3 (Week 12)	8.26 (2.0 to 24.8)			
Complement C3 (Week 52)	23.46 (-7.6 to 61.6)			
Complement C4 (Week 12)	31.03 (-3.5 to 67.3)			
Complement C4 (Week 52)	67.52 (21.8 to 443.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline in CD19+ Total B cells and CD20+ B Cells at Week 12 and Week 52

End point title	Percent Change from Baseline in CD19+ Total B cells and CD20+ B Cells at Week 12 and Week 52

End point description:

Blood samples were collected for biomarker analysis. B cell subsets included CD19+ total B cells and CD 20+ B cells. Percent change from Baseline was calculated by subtracting the Baseline value from value at Week 12 and 52 divided by the Baseline value X 100. The analysis was performed on the ITT set that included all participants assigned treatment who received at least one dose of study treatment. Number of participants analyzed signifies those participants who were evaluable for this outcome measure.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 12 and Week 52

End point values	Belimumab 200 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	15			
Units: cells per milliliter (cells/mL)				
median (full range (min-max))				
CD19+ Total B cells (Week 12)	-42.97 (-74.4 to 68.8)			
CD19+ Total B cells (Week 52)	-61.32 (-89.4 to 95.5)			
CD20+ B cells (Week 12)	-41.85 (-75.8 to 92.1)			
CD20+ B cells (Week 52)	-61.65 (-89.9 to 92.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline in Naïve B Cells and Memory B Cells at Week 12 and Week 52

End point title	Percent Change from Baseline in Naïve B Cells and Memory B Cells at Week 12 and Week 52

End point description:

Blood samples were collected for biomarker analysis and included CD20+ CD27- Naïve B cells and CD20+ CD27+ memory B cells. Percent change from Baseline was calculated by subtracting the Baseline value from value at Week 12 and 52 divided by the Baseline value X 100. The analysis was performed on the ITT set that included all participants assigned treatment who received at least one dose of study treatment.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 12 and Week 52

End point values	Belimumab 200 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	15			
Units: cells/mL				
median (full range (min-max))				
Naïve B Cells (Week 12)	-53.19 (-81.5 to 21.0)			
Naïve B Cells (Week 52)	-72.13 (-94.5 to 20.3)			
Memory B Cells (Week 12)	69.06 (-36.7 to 531.8)			
Memory B Cells (Week 52)	27.10 (-63.2 to 402.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline in Immunoglobulin A (IgA), Immunoglobulin G (IgG) and Immunoglobulin M (IgM) at Week 52

End point title	Percent Change from Baseline in Immunoglobulin A (IgA), Immunoglobulin G (IgG) and Immunoglobulin M (IgM) at Week 52

End point description:

Blood samples were collected for analysis of immunoglobulins: Immunoglobulin A (IgA), Immunoglobulin A (IgG), and Immunoglobulin M (IgM). Percent change from Baseline was calculated by subtracting the Baseline value from value at Week 52 divided by the Baseline value X 100. The analysis was performed on the ITT set that included all participants assigned treatment who received at least one dose of study treatment.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Week 52

End point values	Belimumab 200 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	21			
Units: Gram per liter (g/L)				
median (full range (min-max))				
Immunoglobulin A (IgA)	-13.06 (-37.5 to 41.0)			
Immunoglobulin G (IgG)	-12.29 (-34.0 to 10.6)			
Immunoglobulin M (IgM)	-30.79 (-56.7 to -8.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline in in CD27bright CD38bright Plasma blasts at Week 12 and Week 52

End point title	Percent Change from Baseline in in CD27bright CD38bright Plasma blasts at Week 12 and Week 52

End point description:

Blood samples were collected for CD27bright CD38bright Plasma blasts biomarker analysis. Percent change from Baseline was calculated by subtracting the Baseline value from value at Week 12 and 52 divided by the Baseline value X 100. The analysis was performed on the ITT set that included all participants assigned treatment who received at least one dose of study treatment.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 12 and Week 52

End point values	Belimumab 200 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	15			
Units: cells/mL				
median (full range (min-max))				
Week 12 Week 52	9.40 (-81.8 to 428.1) -70.07 (-88.9 to 193.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline in Immunoglobulin A (IgA), Immunoglobulin G (IgG) and Immunoglobulin M (IgM) at Week 12

End point title	Percent Change from Baseline in Immunoglobulin A (IgA), Immunoglobulin G (IgG) and Immunoglobulin M (IgM) at Week 12

End point description:

Blood samples were collected for analysis of immunoglobulins: Immunoglobulin A (IgA), Immunoglobulin G (IgG), and Immunoglobulin M (IgM). Percent change from Baseline was calculated by subtracting the Baseline value from value at Week 12 divided by the Baseline value X 100. The analysis was performed on the ITT set that included all participants assigned treatment who received at least one dose of study treatment.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Week 12

End point values	Belimumab 200 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	25			
Units: Gram per liter (g/L)				
median (full range (min-max))				
Immunoglobulin A (IgA)	-3.13 (-35.2 to 8.0)			
Immunoglobulin G (IgG)	-3.40 (-30.7 to 12.7)			
Immunoglobulin M (IgM)	-10.41 (-49.2 to 4.3)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to Week 68 (treatment: up to 52 weeks [12 weeks Part A plus 40 weeks Part B extension phase] and follow-up: 16 weeks)

Adverse event reporting additional description:

The safety analysis was based on the Intent-To-Treat set that comprised of all participants assigned treatment who received at least one dose of study treatment.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.1

Reporting groups

Reporting group title	Belimumab 200 mg

Reporting group description:

Participants with Systemic Lupus Erythematosus were administered with Belimumab 200 milligram per milliliter (mg/mL) subcutaneous (SC) injection. The dosing frequency was based on body weight. Participants who weigh more than or equal to 50 kilograms were administered every week, who weigh between 30 to less than 50 kg were administered every 10 days and who weigh less than 30 kg were administered every 2 weeks.

Serious adverse events	Belimumab 200 mg		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 25 (4.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Infections and infestations			
COVID-19			
alternative dictionary used: v25.1 25.1			
subjects affected / exposed	1 / 25 (4.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	Belimumab 200 mg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 25 (76.00%)		
Investigations			

White blood cell count decreased			
alternative dictionary used: v25.1 25.1			
subjects affected / exposed	2 / 25 (8.00%)		
occurrences (all)	2		
Urine protein/creatinine ratio increased			
alternative dictionary used: v25.1 25.1			
subjects affected / exposed	2 / 25 (8.00%)		
occurrences (all)	2		
Neutrophil count decreased			
alternative dictionary used: v25.1 25.1			
subjects affected / exposed	2 / 25 (8.00%)		
occurrences (all)	2		
Blood and lymphatic system disorders			
Anaemia			
alternative dictionary used: v25.1 25.1			
subjects affected / exposed	2 / 25 (8.00%)		
occurrences (all)	3		
Leukopenia			
alternative dictionary used: v25.1 25.1			
subjects affected / exposed	4 / 25 (16.00%)		
occurrences (all)	4		
Lymphopenia			
alternative dictionary used: v25.1 25.1			
subjects affected / exposed	3 / 25 (12.00%)		
occurrences (all)	3		
Neutropenia			
alternative dictionary used: v25.1 25.1			
subjects affected / exposed	4 / 25 (16.00%)		
occurrences (all)	5		
General disorders and administration site conditions			
Injection site erythema			
alternative dictionary used: v25.1 25.1			
subjects affected / exposed	2 / 25 (8.00%)		
occurrences (all)	3		

Injection site pain alternative dictionary used: v25.1 25.1 subjects affected / exposed occurrences (all)	 4 / 25 (16.00%) 9		
Skin and subcutaneous tissue disorders Erythema alternative dictionary used: v25.1 25.1 subjects affected / exposed occurrences (all)	 2 / 25 (8.00%) 2		
Musculoskeletal and connective tissue disorders Myalgia alternative dictionary used: v25.1 25.1 subjects affected / exposed occurrences (all)	 2 / 25 (8.00%) 2		
Infections and infestations Viral infection alternative dictionary used: v25.1 25.1 subjects affected / exposed occurrences (all) Upper respiratory tract infection alternative dictionary used: v25.1 25.1 subjects affected / exposed occurrences (all) Nasopharyngitis alternative dictionary used: v25.1 25.1 subjects affected / exposed occurrences (all) COVID-19 alternative dictionary used: v25.1 25.1 subjects affected / exposed occurrences (all)	 2 / 25 (8.00%) 2 3 / 25 (12.00%) 3 3 / 25 (12.00%) 3 8 / 25 (32.00%) 8		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
29 April 2019	Original protocol (00)
24 July 2019	Amendment 1
24 April 2020	Amendment 2
14 July 2021	Amendment 3
14 December 2022	Amendment 4

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported