Clinical trial results:
Protocol Title: A Multi-Center, Open-Label Study to Evaluate Safety, Efficacy and Pharmacokinetics of Belimumab Plus Standard Therapy in Chinese Paediatric Patients with Active Systemic Lupus Erythematosus (SLE)

Summary

EudraCT number	2025-000106-42
Trial protocol	Outside EU/EEA
Global end of trial date	13 August 2024

Results information

Result version number	v1
This version publication date	17 August 2025
First version publication date	17 August 2025

Trial information

Trial identification

Sponsor protocol code	213560

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04908865
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	20 September 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	13 August 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety and efficacy of belimumab IV in Chinese pediatric participants with SLE.

Protection of trial subjects:

NA

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	21 October 2021
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: 67
Worldwide total number of subjects	67
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)	16
Adolescents (12-17 years)	51
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 67 participants were enrolled in the 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

Arm description:

Participants with active systemic lupus erythematosus (SLE) received belimumab at 10 milligrams per kilogram (mg/kg) body weight by intravenous (IV) infusion over a minimum of 1 hour on Days 0, 14, 28, and then every 28 days through Week 48 in combination with standard therapy.

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

Dosage and administration details:

10 milligrams per kilogram (mg/kg) on Days 0, 14, 28, and then every 28 days through Week 48

Number of subjects in period 1	Belimumab
Started	67
Pharmacokinetic (PK) Population	26 [1]
Completed	59
Not completed	8
Adverse event, non-fatal	2
Lost to follow-up	1
Lack of efficacy	5

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: PK population was added as a milestone because the study contains endpoints based on this population.

Baseline characteristics

Reporting groups	
Reporting group title	Belimumab
Reporting group description:	
Participants with active systemic lupus erythematosus (SLE) received belimumab at 10 milligrams per kilogram (mg/kg) body weight by intravenous (IV) infusion over a minimum of 1 hour on Days 0, 14, 28, and then every 28 days through Week 48 in combination with standard therapy.	

Reporting group values	Belimumab	Total	
Number of subjects	67	67	
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)	16	16	
Adolescents (12-17 years)	51	51	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	13.0		
standard deviation	± 2.22	-	
Sex: Female, Male Units: Participants			
Female	51	51	
Male	16	16	
Race/Ethnicity, Customized Units: Subjects			
Asian	67	67	

End points

End points reporting groups

Reporting group title	Belimumab

Reporting group description:

Participants with active systemic lupus erythematosus (SLE) received belimumab at 10 milligrams per kilogram (mg/kg) body weight by intravenous (IV) infusion over a minimum of 1 hour on Days 0, 14, 28, and then every 28 days through Week 48 in combination with standard therapy.

Primary: Number of Participants with Adverse Events of Special Interest (AESIs) Through Week 52

End point title	Number of Participants with Adverse Events of Special Interest (AESIs) Through Week 52[1]

End point description:

An adverse event (AE) is defined as 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. AESIs included malignancies, post-infusion systemic or hypersensitivity reactions, infections (including serious infections of special interest), and depression (including mood disorders and anxiety), suicide, or self-injury. Infections of special interest included opportunistic infections (OI), herpes zoster (HZ), tuberculosis (TB), and sepsis. Number of participants with AESIs as identified by custom Medical Dictionary for Regulatory Activities (MedDRA) query has been reported. Intent-to-Treat (ITT) population consisted of all participants who received at least one dose of study treatment.

End point type	Primary

End point timeframe:

Up to Week 52

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: As per the study protocol, no formal hypothesis testing was planned in the study. Hence, no statistical analyses have been specified for this endpoint.

End point values	Belimumab			
Subject group type	Reporting group			
Number of subjects analysed	67			
Units: Participants				
All malignancies	0			
Post-infusion systemic reactions (PISR)	0			
All infections of special interest	2			
Depression/suicide/self-injury	0			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Greater than Equal to (>=) 4 Points Reduction from Baseline to Week 52 in Safety of Estrogen in Lupus National Assessment - Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) Score

End point title	Number of Participants With Greater than Equal to (>=) 4 Points Reduction from Baseline to Week 52 in Safety of Estrogen in Lupus National Assessment - Systemic Lupus

	Erythematosus Disease Activity Index (SELENA-SLEDAI)

End point description:

SELENA-SLEDAI score is cumulative and weighted index for assessing SLE disease activity in participants with SLE. It consists of 24 disease descriptors across 9 organ systems. Each descriptor is assigned a weighted score (8 descriptors with a weight of 8 each, 6 descriptors with a weight of 4 each, 7 descriptors with a weight of 2 each, and 3 descriptors with a weight of 1 each) which is added up if the descriptor is observed during a visit or within the preceding 10 days. Total score ranges from 0 (no disease activity) to 105 (all 24 descriptors present simultaneously). Higher score indicates a more significant degree of disease activity. Baseline was defined as latest pre-dose assessment with non-missing value, including those from unscheduled visits. Number of participants with decrease of >= 4 points in score at Week 52 compared to Baseline is presented. ITT population. One participant with Baseline SELENA-SLEDAI score below (<) 4 was excluded.

End point type	Primary

End point timeframe:

Baseline (Day 0) and Week 52

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: As per the study protocol, no formal hypothesis testing was planned in the study. Hence, no statistical analyses have been specified for this endpoint.

End point values	Belimumab			
Subject group type	Reporting group			
Number of subjects analysed	66			
Units: Participants	44			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With AEs and Serious Adverse Events (SAEs) Through Week 52

End point title	Number of Participants With AEs and Serious Adverse Events (SAEs) Through Week 52

End point description:

An AE is defined as 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 or incapacity, is a birth defect or congenital anomaly, or other situations as per the medical or scientific judgment of the investigator. Number of participants with AEs and SAEs has been reported. ITT population consisted of all participants who received at least one dose of study treatment.

End point type	Secondary

End point timeframe:

Up to Week 52

End point values	Belimumab			
Subject group type	Reporting group			
Number of subjects analysed	67			
Units: Participants				
AEs	56			
SAEs	19			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With >=4 Points Reduction from Baseline in SELENA-SLEDAI Score by Each Visit

End point title	Percentage of Participants With >=4 Points Reduction from Baseline in SELENA-SLEDAI Score by Each Visit

End point description:

SELENA-SLEDAI score is used to assess SLE disease activity in participants with SLE. It consists of 24 disease descriptors across 9 organ systems. Each descriptor is assigned a weight (8 descriptors: each weighted 8; 6 descriptors: each weighted 4; 7 descriptors: each weighted 2; 3 descriptors: each weighted 1) which is summed if the descriptor is observed during a visit or within preceding 10 days. Total score ranges from 0 (no disease activity) to 105 (all 24 descriptors present together). Higher score means more significant degree of disease activity. Baseline was the latest pre-dose assessment with non-missing value, including those from unscheduled visits. ITT population. 1 participant with Baseline score < 4 was excluded. All 66 participants served as denominator to calculate percentages at each visit. Due to rounding off at Week 52 (as no data was missing) and use of multiple imputation for missing data for all other visits, percentages may not yield whole participants.

End point type	Secondary

End point timeframe:

Baseline (Day 0) and Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, and 52

End point values	Belimumab			
Subject group type	Reporting group			
Number of subjects analysed	66			
Units: Percentage of Participants				
number (not applicable)				
Week 4	39.8			
Week 8	51.8			
Week 12	68.9			
Week 16	69.0			
Week 20	65.4			
Week 24	68.1			
Week 28	65.7			
Week 32	67.7			
Week 36	69.1			
Week 40	75.1			
Week 44	74.2			
Week 48	71.3			
Week 52	66.7			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Week 52 in Physician Global Assessment (PGA)

End point title	Change from Baseline to Week 52 in Physician Global Assessment (PGA)

End point description:

The PGA is used to assess the participant's current disease activity by investigator. It is collected on a 10 centimeter (cm) visual analogue scale. The score ranges from 0 (no activity) to 3 (severe activity). Lower score means no disease activity, higher score means severe disease activity. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. ITT population consisted of all participants who received at least one dose of study treatment.

End point type	Secondary

End point timeframe:

Baseline (Day 0) and Week 52

End point values	Belimumab			
Subject group type	Reporting group			
Number of subjects analysed	67			
Units: Scores on scale				
arithmetic mean (standard deviation)	-0.931 (± 0.6046)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Week 52 in Parent Global Assessment (ParentGA)

End point title	Change from Baseline to Week 52 in Parent Global Assessment (ParentGA)

End point description:

The ParentGA is used to assess the participant's overall well-being at the moment rated on a 21-numbered circle visual analog scale by the parent. The score ranges from 0 (very well) to 10 (very poorly). Higher score indicates worse effect of the illness on the child. Baseline was defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. ITT population consisted of all participants who received at least one dose of study treatment.

End point type	Secondary

End point timeframe:

Baseline (Day 0) and Week 52

End point values	Belimumab			
Subject group type	Reporting group			
Number of subjects analysed	67			
Units: Scores on scale				
arithmetic mean (standard deviation)	-2.71 (± 2.713)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Average Daily Prednisone Equivalent Dose at Week 52

End point title	Change from Baseline in Average Daily Prednisone Equivalent Dose at Week 52

End point description:

Average daily prednisone equivalent dose included all steroids taken. All steroid dosages were converted to prednisone equivalent in mg at each visit. Daily prednisone equivalent dose was calculated as follows: dose of steroid in mg multiplied by (*) conversion factor * frequency factor. Baseline was defined as latest pre-dose assessment with non-missing value, including those from unscheduled visits. Baseline average daily prednisone equivalent dose was sum of all prednisone doses over 7 consecutive days up to but not including Day 0 divided by 7. Average daily prednisone dose at Week 52 visit was sum of all prednisone doses over 7 consecutive days up to and including Week 52 visit divided by 7. Average daily prednisone equivalent dose was expressed in mg per day. ITT population included all participants who received at least 1 dose of study treatment. 'Number of Subjects Analyzed' included only those participants who were analyzed (i.e., contributed data reported in table).

End point type	Secondary

End point timeframe:

Baseline (Day 0) and Week 52

End point values	Belimumab			
Subject group type	Reporting group			
Number of subjects analysed	59			
Units: milligrams per day				
arithmetic mean (standard deviation)	-6.020 (± 9.2970)			

Statistical analyses

No statistical analyses for this end point

Secondary: Time to First Flare Over 52 Weeks

End point title	Time to First Flare Over 52 Weeks

End point description:

SLE flare index (SFI) is used to categorize SLE flares as mild/moderate or severe. Mild/moderate SFI flare: SELENA-SLEDAI score increase of 3 to 12 (higher score - greater disease activity); SLE symptom development; prednisone dose increase (but not above [>] 0.5 milligrams per kilogram per day [mg/kg/day]); non-steroidal anti-inflammatory drugs (NSAIDs)/hydroxychloroquine addition; or PGA score increase by >= 1, but not to > 2.5 (higher score - greater disease activity). Severe SFI flare: SELENA-SLEDAI score increase > 12; onset or worsening of severe SLE symptoms; prednisone dose increase > 0.5 mg/kg/day; introduction of potent immunosuppressants; hospitalization; or PGA score reaching >= 2.5. Time to first SLE flare was number of days from treatment start date until the event. Time to first flare was defined as event date minus treatment start date plus 1. ITT population. 'Number of subjects analyzed' included participants with post-baseline SFI flare over 52 weeks.

End point type	Secondary

End point timeframe:

Up to Week 52

End point values	Belimumab			
Subject group type	Reporting group			
Number of subjects analysed	50			
Units: days				
median (inter-quartile range (Q1-Q3))	141.0 (58.0 to 333.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Time to First Severe Flare Over 52 Weeks

End point title	Time to First Severe Flare Over 52 Weeks

End point description:

SFI is used to categorize SLE flares as mild/moderate or severe. Severe SFI flare: SELENA-SLEDAI score increase > 12; onset or worsening of severe SLE symptoms; prednisone dose increase > 0.5 mg/kg/day; introduction of potent immunosuppressants; hospitalization; or PGA score reaching >= 2.5. Time to first SLE flare was number of days from treatment start date until the event. Time to first flare was defined as event date minus treatment start date plus 1. ITT population. 'Number of subjects analyzed' included participants with post-baseline severe SFI flare over 52 weeks. '99999’ indicates that the median time and/or interquartile range could not be estimated due to low number of events in the participants.

End point type	Secondary

End point timeframe:

Up to Week 52

End point values	Belimumab			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: days				
median (inter-quartile range (Q1-Q3))	99999 (289.0 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Median Belimumab Concentration Levels at Day 0, 7, and 14 Days Post First Dose, and Pre-infusion and Post-infusion at Day 84

End point title	Median Belimumab Concentration Levels at Day 0, 7, and 14 Days Post First Dose, and Pre-infusion and Post-infusion at Day 84

End point description:

Blood samples were collected at indicated time points for measurement of plasma concentrations of belimumab. Pharmacokinetic (PK) population consisted of all the participants who received at least one dose of study treatment and for whom at least one post belimumab treatment PK sample was obtained and analyzed. 'Number of subjects analyzed' included only those participants who were analyzed (i.e., contributed data reported in table). 'n' indicates participants evaluable for specified time points.

End point type	Secondary

End point timeframe:

Days 0, 7, and 14 days post first dose, and pre-infusion and post-infusion at Day 84

End point values	Belimumab			
Subject group type	Reporting group			
Number of subjects analysed	26			
Units: Micrograms per milliliter				
median (full range (min-max))				
Day 0 (n=24)	197.1173 (141.9326 to 257.3748)			
Day 7 (n=26)	71.3616 (35.9532 to 100.5913)			
Day 14 (n=26)	37.8585 (14.5944 to 74.1679)			
Day 84, pre-infusion (n=25)	28.2415 (2.3467 to 89.0718)			
Day 84, post-infusion (n=25)	238.5688 (139.1862 to 357.0316)			

Statistical analyses

No statistical analyses for this end point

Secondary: Apparent Total Clearance of Belimumab

End point title	Apparent Total Clearance of Belimumab

End point description:

Blood samples were collected at indicated time points for PK analysis of belimumab. '99999' indicates that data has not been disclosed for apparent total clearance of belimumab, as this analysis integrating data from Study 213560 and other studies, is still under discussion and review to fully understand the PK characteristics. The data for all pre-specified PK parameters will be disclosed by 30 June 2026.

End point type	Secondary

End point timeframe:

Days 0, 7, and 14 days post first dose, and pre-infusion and post-infusion at Day 84

End point values	Belimumab			
Subject group type	Reporting group			
Number of subjects analysed	26			
Units: Milliliters per day				
geometric mean (geometric coefficient of variation)	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Volume of Distribution of Belimumab

End point title	Volume of Distribution of Belimumab

End point description:

Blood samples were collected at indicated time points for PK analysis of belimumab. '99999' indicates that data has not been disclosed for volume of distribution of belimumab, as this analysis integrating data from Study 213560 and other studies, is still under discussion and review to fully understand the PK characteristics. The data for all pre-specified PK parameters will be disclosed by 30 June 2026.

End point type	Secondary

End point timeframe:

Days 0, 7, and 14 days post first dose, and pre-infusion and post-infusion at Day 84

End point values	Belimumab			
Subject group type	Reporting group			
Number of subjects analysed	26			
Units: Milliliters				
geometric mean (geometric coefficient of variation)	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Estimated Maximum Concentration (Cmax) of Belimumab at Steady State

End point title	Estimated Maximum Concentration (Cmax) of Belimumab at Steady State

End point description:

Blood samples were collected at indicated time points for PK analysis of belimumab. '99999' indicates that data has not been disclosed for estimated Cmax of belimumab at steady state, as this analysis integrating data from Study 213560 and other studies, is still under discussion and review to fully understand the PK characteristics. The data for all pre-specified PK parameters will be disclosed by 30 June 2026.

End point type	Secondary

End point timeframe:

Days 0, 7, and 14 days post first dose, and pre-infusion and post-infusion at Day 84

End point values	Belimumab			
Subject group type	Reporting group			
Number of subjects analysed	26			
Units: Micrograms per milliliter				
geometric mean (geometric coefficient of variation)	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Estimated Minimum Concentration (Cmin) of Belimumab at Steady State

End point title	Estimated Minimum Concentration (Cmin) of Belimumab at Steady State

End point description:

Blood samples were collected at indicated time points for PK analysis of belimumab. '99999' indicates that data has not been disclosed for estimated Cmin of belimumab at steady state, as this analysis integrating data from Study 213560 and other studies, is still under discussion and review to fully understand the PK characteristics. The data for all pre-specified PK parameters will be disclosed by 30 June 2026.

End point type	Secondary

End point timeframe:

Days 0, 7, and 14 days post first dose, and pre-infusion and post-infusion at Day 84

End point values	Belimumab			
Subject group type	Reporting group			
Number of subjects analysed	26			
Units: Micrograms per milliliter				
geometric mean (geometric coefficient of variation)	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Terminal Half-life (t1/2) of Belimumab

End point title	Terminal Half-life (t1/2) of Belimumab

End point description:

Blood samples were collected at indicated time points for PK analysis of belimumab. '99999' indicates that data has not been disclosed for t1/2 of belimumab, as this analysis integrating data from Study 213560 and other studies, is still under discussion and review to fully understand the PK characteristics. The data for all pre-specified PK parameters will be disclosed by 30 June 2026.

End point type	Secondary

End point timeframe:

Days 0, 7, and 14 days post first dose, and pre-infusion and post-infusion at Day 84

End point values	Belimumab			
Subject group type	Reporting group			
Number of subjects analysed	26			
Units: Days				
median (full range (min-max))	99999 (99999 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Estimated Average Concentration (Cavg) of Belimumab at Steady State

End point title	Estimated Average Concentration (Cavg) of Belimumab at Steady State

End point description:

Blood samples were collected at indicated time points for PK analysis of belimumab. '99999' indicates that data has not been disclosed for estimated Cavg of belimumab at steady state, as this analysis integrating data from Study 213560 and other studies, is still under discussion and review to fully understand the PK characteristics. The data for all pre-specified PK parameters will be disclosed by 30 June 2026.

End point type	Secondary

End point timeframe:

Days 0, 7, and 14 days post first dose, and pre-infusion and post-infusion at Day 84

End point values	Belimumab			
Subject group type	Reporting group			
Number of subjects analysed	26			
Units: Micrograms per milliliter				
geometric mean (geometric coefficient of variation)	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under Plasma Concentration-time Curve (AUC) of Belimumab at Steady State

End point title	Area Under Plasma Concentration-time Curve (AUC) of Belimumab at Steady State

End point description:

Blood samples were collected at indicated time points for PK analysis of belimumab. '99999' indicates that data has not been disclosed for AUC of belimumab at steady state, as this analysis integrating data from Study 213560 and other studies, is still under discussion and review to fully understand the PK characteristics. The data for all pre-specified PK parameters will be disclosed by 30 June 2026.

End point type	Secondary

End point timeframe:

Days 0, 7, and 14 days post first dose, and pre-infusion and post-infusion at Day 84

End point values	Belimumab			
Subject group type	Reporting group			
Number of subjects analysed	26			
Units: Micrograms-day per milliliter				
geometric mean (geometric coefficient of variation)	99999 (± 99999)			

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-serious adverse events (non-SAEs) were collected from the start of the study intervention (Day 0) up to the post-treatment follow-up visit at Week 64

Adverse event reporting additional description:

All-cause mortality, SAEs, and non-SAEs were reported for ITT population that comprised of all participants who received at least 1 dose of study treatment.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.0

Reporting groups

Reporting group title	Belimumab

Reporting group description:

Participants with active SLE received belimumab at 10 mg/kg body weight by IV infusion over a minimum of 1 hour on Days 0, 14, 28, and then every 28 days through Week 48 in combination with standard therapy.

Serious adverse events	Belimumab		
Total subjects affected by serious adverse events			
subjects affected / exposed	20 / 67 (29.85%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Cardiac disorders			
Myocarditis			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Cerebral infarction			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Headache			
subjects affected / exposed	2 / 67 (2.99%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Neuromyelitis optica spectrum disorder			

subjects affected / exposed	1 / 67 (1.49%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	2 / 67 (2.99%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Hypogammaglobulinaemia			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Eyelid oedema			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancreatitis necrotising			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Hepatic function abnormal			

subjects affected / exposed	1 / 67 (1.49%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Interstitial lung disease			
subjects affected / exposed	2 / 67 (2.99%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pulmonary arterial hypertension			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rash			
subjects affected / exposed	4 / 67 (5.97%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Systemic lupus erythematosus			
subjects affected / exposed	3 / 67 (4.48%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Bronchitis			
subjects affected / exposed	3 / 67 (4.48%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 0		
Pneumonia			

subjects affected / exposed	1 / 67 (1.49%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
H1N1 influenza			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
COVID-19			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Belimumab		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	57 / 67 (85.07%)		
Vascular disorders			
Venous thrombosis			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Hypertension			

subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Endocrine hypertension			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	7 / 67 (10.45%)		
occurrences (all)	9		
Peripheral swelling			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Fatigue			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Face oedema			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Chest pain			
subjects affected / exposed	2 / 67 (2.99%)		
occurrences (all)	2		
Immune system disorders			
Hypogammaglobulinaemia			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Drug hypersensitivity			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	9 / 67 (13.43%)		
occurrences (all)	13		
Rhinitis allergic			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Productive cough			

subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	2		
Oropharyngeal pain			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Epistaxis			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Dyspnoea			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Investigations			
Lymphocyte count decreased			
subjects affected / exposed	5 / 67 (7.46%)		
occurrences (all)	9		
White blood cell count decreased			
subjects affected / exposed	4 / 67 (5.97%)		
occurrences (all)	11		
Intraocular pressure increased			
subjects affected / exposed	3 / 67 (4.48%)		
occurrences (all)	3		
Neutrophil count increased			
subjects affected / exposed	2 / 67 (2.99%)		
occurrences (all)	3		
Blood bilirubin increased			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Blood immunoglobulin M decreased			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Blood phosphorus decreased			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Bone density decreased			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		

CD19 lymphocytes decreased subjects affected / exposed occurrences (all)	1 / 67 (1.49%) 1		
Neutrophil count decreased subjects affected / exposed occurrences (all)	1 / 67 (1.49%) 1		
Reticulocyte count increased subjects affected / exposed occurrences (all)	1 / 67 (1.49%) 1		
White blood cell count increased subjects affected / exposed occurrences (all)	1 / 67 (1.49%) 2		
Injury, poisoning and procedural complications Ligament sprain subjects affected / exposed occurrences (all)	1 / 67 (1.49%) 1		
Hand fracture subjects affected / exposed occurrences (all)	1 / 67 (1.49%) 1		
Contusion subjects affected / exposed occurrences (all)	1 / 67 (1.49%) 1		
Arthropod bite subjects affected / exposed occurrences (all)	1 / 67 (1.49%) 1		
Animal bite subjects affected / exposed occurrences (all)	1 / 67 (1.49%) 1		
Cardiac disorders Tachycardia subjects affected / exposed occurrences (all)	1 / 67 (1.49%) 1		
Sinus bradycardia subjects affected / exposed occurrences (all)	1 / 67 (1.49%) 1		
Pericardial effusion			

subjects affected / exposed occurrences (all)	1 / 67 (1.49%) 1		
Myocardial injury subjects affected / exposed occurrences (all)	1 / 67 (1.49%) 1		
Arrhythmia subjects affected / exposed occurrences (all)	1 / 67 (1.49%) 1		
Nervous system disorders Seizure subjects affected / exposed occurrences (all)	1 / 67 (1.49%) 1		
Headache subjects affected / exposed occurrences (all)	1 / 67 (1.49%) 1		
Blood and lymphatic system disorders Polycythaemia subjects affected / exposed occurrences (all)	1 / 67 (1.49%) 1		
Anaemia subjects affected / exposed occurrences (all)	3 / 67 (4.48%) 3		
Iron deficiency anaemia subjects affected / exposed occurrences (all)	1 / 67 (1.49%) 1		
Leukocytosis subjects affected / exposed occurrences (all)	1 / 67 (1.49%) 1		
Neutropenia subjects affected / exposed occurrences (all)	1 / 67 (1.49%) 1		
Ear and labyrinth disorders Cerumen impaction subjects affected / exposed occurrences (all)	1 / 67 (1.49%) 1		
Eye disorders			

Xerophthalmia subjects affected / exposed occurrences (all)	2 / 67 (2.99%) 2			
Conjunctivitis allergic subjects affected / exposed occurrences (all)	1 / 67 (1.49%) 1			
Eyelid oedema subjects affected / exposed occurrences (all)	1 / 67 (1.49%) 1			
Ocular hypertension subjects affected / exposed occurrences (all)	1 / 67 (1.49%) 1			
Retinal haemorrhage subjects affected / exposed occurrences (all)	1 / 67 (1.49%) 1			
Gastrointestinal disorders Mouth ulceration subjects affected / exposed occurrences (all)	2 / 67 (2.99%) 2			
Functional gastrointestinal disorder subjects affected / exposed occurrences (all)	2 / 67 (2.99%) 2			
Gastritis subjects affected / exposed occurrences (all)	3 / 67 (4.48%) 3			
Abdominal discomfort subjects affected / exposed occurrences (all)	1 / 67 (1.49%) 1			
Anal fissure subjects affected / exposed occurrences (all)	1 / 67 (1.49%) 1			
Cheilitis subjects affected / exposed occurrences (all)	1 / 67 (1.49%) 1			
Constipation				

subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Diarrhoea			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	2		
Pancreatitis acute			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Pancreatic pseudocyst			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Gastrointestinal disorder			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Faeces discoloured			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Dyspepsia			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Abdominal pain			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	9 / 67 (13.43%)		
occurrences (all)	13		
Cholestasis			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Hepatic steatosis			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Hepatomegaly			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		

Hepatic lesion subjects affected / exposed occurrences (all)	1 / 67 (1.49%) 1		
Skin and subcutaneous tissue disorders Rash subjects affected / exposed occurrences (all) Alopecia subjects affected / exposed occurrences (all) Dermatitis allergic subjects affected / exposed occurrences (all) Acne subjects affected / exposed occurrences (all) Cutaneous vasculitis subjects affected / exposed occurrences (all) Urticaria subjects affected / exposed occurrences (all)	 4 / 67 (5.97%) 4 2 / 67 (2.99%) 2 2 / 67 (2.99%) 2 1 / 67 (1.49%) 1 1 / 67 (1.49%) 1 1 / 67 (1.49%) 1		
Renal and urinary disorders Renal failure subjects affected / exposed occurrences (all)	 1 / 67 (1.49%) 1		
Endocrine disorders Autoimmune thyroiditis subjects affected / exposed occurrences (all)	 1 / 67 (1.49%) 1		
Musculoskeletal and connective tissue disorders Osteonecrosis subjects affected / exposed occurrences (all) Back pain	 1 / 67 (1.49%) 1 		

subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Arthralgia			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Arthritis			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	31 / 67 (46.27%)		
occurrences (all)	63		
COVID-19			
subjects affected / exposed	9 / 67 (13.43%)		
occurrences (all)	9		
Coronavirus pneumonia			
subjects affected / exposed	11 / 67 (16.42%)		
occurrences (all)	11		
Bronchitis			
subjects affected / exposed	4 / 67 (5.97%)		
occurrences (all)	5		
Conjunctivitis			
subjects affected / exposed	2 / 67 (2.99%)		
occurrences (all)	2		
Gastroenteritis			
subjects affected / exposed	3 / 67 (4.48%)		
occurrences (all)	3		
Respiratory tract infection			
subjects affected / exposed	2 / 67 (2.99%)		
occurrences (all)	2		
Pneumonia			
subjects affected / exposed	2 / 67 (2.99%)		
occurrences (all)	2		
Oral candidiasis			
subjects affected / exposed	2 / 67 (2.99%)		
occurrences (all)	2		

Influenza				
subjects affected / exposed	2 / 67 (2.99%)			
occurrences (all)	2			
Infection				
subjects affected / exposed	2 / 67 (2.99%)			
occurrences (all)	2			
Mumps				
subjects affected / exposed	1 / 67 (1.49%)			
occurrences (all)	1			
Nasopharyngitis				
subjects affected / exposed	1 / 67 (1.49%)			
occurrences (all)	1			
Oral herpes				
subjects affected / exposed	1 / 67 (1.49%)			
occurrences (all)	1			
Otitis media				
subjects affected / exposed	1 / 67 (1.49%)			
occurrences (all)	1			
Pharyngitis				
subjects affected / exposed	1 / 67 (1.49%)			
occurrences (all)	1			
Rhinovirus infection				
subjects affected / exposed	1 / 67 (1.49%)			
occurrences (all)	1			
Sepsis				
subjects affected / exposed	1 / 67 (1.49%)			
occurrences (all)	1			
Sinusitis				
subjects affected / exposed	1 / 67 (1.49%)			
occurrences (all)	1			
Tinea pedis				
subjects affected / exposed	1 / 67 (1.49%)			
occurrences (all)	1			
Herpangina				
subjects affected / exposed	1 / 67 (1.49%)			
occurrences (all)	1			

Helicobacter infection			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Varicella			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Adenovirus infection			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Abscess soft tissue			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Urinary tract infection			
subjects affected / exposed	2 / 67 (2.99%)		
occurrences (all)	2		
Tinea versicolour			
subjects affected / exposed	2 / 67 (2.99%)		
occurrences (all)	3		
Gingivitis			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Viral infection			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Gastroenteritis viral			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	2		
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Hyperglycaemia			

subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Hyperlipidaemia			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Hypertriglyceridaemia			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Hyperuricaemia			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Hypoalbuminaemia			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Hypocalcaemia			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Hypomagnesaemia			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	2		
Hypophosphataemia			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Hypoproteinaemia			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	1		
Hypokalaemia			
subjects affected / exposed	3 / 67 (4.48%)		
occurrences (all)	4		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
29 January 2021	Protocol Amendment 1
03 June 2022	Protocol Amendment 2
02 January 2023	Protocol Amendment 3

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.

Data for PK parameters derived from population PK analysis has not been disclosed as this analysis, integrating data from Study 213560 and others, is under ongoing review to understand PK characteristics. This data will be disclosed by 30 June 2026.

Notes: