Clinical trial results:
A Multi-Center, Continuation Trial of Belimumab (HGS1006, LymphoStat-B™), a Fully Human Monoclonal Anti-BLyS Antibody, in Subjects with Systemic Lupus Erythematosus (SLE) who Completed the Phase 3 Protocol HGS1006-C1056 or HGS1006-C1057

Summary

EudraCT number	2007-007648-85
Trial protocol	DE AT NL BE GB CZ ES IT SE SK FR
Global end of trial date	09 December 2016

Results information

Result version number	v2 (current)
This version publication date	31 December 2017
First version publication date	24 November 2017
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	112234

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	980 Great West Road, Brentford, Middlesex, United Kingdom,
Public contact	GSK Response Center, GlaxoSmithKline, 1 866-435-7343,
Scientific contact	GSK Response Center, GlaxoSmithKline, 1 866-435-7343,

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	23 February 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	09 December 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To provide continuing treatment to subjects with SLE who complete HGS1006-C1056 or HGS1006-C1057. To evaluate the long-term safety and tolerability of belimumab in subjects with SLE.

Protection of trial subjects:

The study protocol, any amendments, the informed consent, and other information that required pre-approval were reviewed and approved by a national, regional, or investigational center ethics committee or institutional review board, in accordance with the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) and applicable country-specific requirements, including US 21 Code of Federal Regulations (CFR) 312.3(b) for constitution of independent ethics committees. Ethics committee or institutional review board approvals are maintained in the Sponsor’s study file.

Investigators were trained to conduct the study in accordance with GCPs and the study protocol, as defined in ICH E3, Section 9.6. Written commitments were obtained from investigators to conduct the study in accordance with ICH GCP and all applicable subject privacy requirements, and the ethical principles that are outlined in the Declaration of Helsinki, and to conduct the study in accordance with the protocol.

The study was monitored in accordance with ICH E6, Section 5.18. At the time of this report, no GCP noncompliance issues were identified by monitoring or audit.

Written informed consent was obtained from each subject prior to the performance of any study-specific procedures. The investigator agreed to provide the subject as much time as necessary to review the document, to inquire about details of the trial, and to decide whether or not to participate in the study. The informed consent was signed and dated by the study subject and by the person who conducted the informed consent.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 May 2008
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	8 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 55
Country: Number of subjects enrolled	Austria: 23
Country: Number of subjects enrolled	Belgium: 3
Country: Number of subjects enrolled	Brazil: 44

Country: Number of subjects enrolled	Canada: 11
Country: Number of subjects enrolled	Chile: 25
Country: Number of subjects enrolled	Colombia: 137
Country: Number of subjects enrolled	Czech Republic: 25
Country: Number of subjects enrolled	France: 1
Country: Number of subjects enrolled	Germany: 44
Country: Number of subjects enrolled	Hong Kong: 6
Country: Number of subjects enrolled	India: 37
Country: Number of subjects enrolled	Israel: 20
Country: Number of subjects enrolled	Italy: 2
Country: Number of subjects enrolled	Korea, Republic of: 38
Country: Number of subjects enrolled	Mexico: 26
Country: Number of subjects enrolled	Netherlands: 7
Country: Number of subjects enrolled	Peru: 24
Country: Number of subjects enrolled	Philippines: 52
Country: Number of subjects enrolled	Poland: 5
Country: Number of subjects enrolled	Puerto Rico: 5
Country: Number of subjects enrolled	Romania: 11
Country: Number of subjects enrolled	Russian Federation: 46
Country: Number of subjects enrolled	Slovakia: 4
Country: Number of subjects enrolled	Spain: 2
Country: Number of subjects enrolled	Sweden: 1
Country: Number of subjects enrolled	Taiwan: 77
Country: Number of subjects enrolled	United Kingdom: 4
Worldwide total number of subjects	735
EEA total number of subjects	132

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	726
From 65 to 84 years	9
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This was a multi-center, continuation trial of belimumab and was conducted at 115 centers in 28 countries. Participants with Systemic Lupus Erythematosus (SLE), who had completed the Phase 3 HGS1006-C1056 or HGS1006-C1057 trial or participants who had previously received subcutaneous belimumab in Protocol HGS1006-C1070 were included in this trail.

Pre-assignment

Screening details:

738 participants were enrolled in the study and 735 received at least one dose of belimumab.Out of 735 participants, 368 completed the study and 370 withdrew from 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 10mg/kg IV

Arm description:

Participants received belimumab every 28 days by intravenous (IV) infusion at 1 milligram per kilogram (mg/kg) or 10 mg/kg body weight. Participants who received either 1 mg/kg or 10 mg/kg belimumab in their parent studies continued to receive the same dose of belimumab. Participants randomized to receive placebo in the parent studies received 10 mg/kg beliumamb. Subsequently, the dose of belimumab for participants receiving 1 mg/kg was increased to 10 mg/kg .All participants also received SoC SLE therapy while participating in this trial.

Arm type	Experimental
Investigational medicinal product name	Belimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Belimumab was administered every 28 days by IV infusion at 1 mg/kg or 10 mg/kg body weight.

Number of subjects in period 1	Belimumab 10mg/kg IV
Started	735
Completed	368
Not completed	367
Adverse event, serious fatal	8
Other Hip replacement surgery	1
Other Involved in Clinical research	3
Physician decision	36
Other Physician decision	1
Other Non-compliance with study drug	13

Other Participant travelled overseas	2
Other Not committed to contraception	1
Other Death of patient	1
Other Participant received medication	1
Consent withdrawn by subject	151
Adverse event, non-fatal	61
Other Pregnancy	37
Other Participant hospitalized	1
Lost to follow-up	22
Other Sponsor decision	14
Other Withdrew consent	4
Lack of efficacy	6
Protocol deviation	4

Baseline characteristics

Reporting groups	
Reporting group title	Belimumab 10mg/kg IV
Reporting group description:	
Participants received belimumab every 28 days by intravenous (IV) infusion at 1 milligram per kilogram (mg/kg) or 10 mg/kg body weight. Participants who received either 1 mg/kg or 10 mg/kg belimumab in their parent studies continued to receive the same dose of belimumab. Participants randomized to receive placebo in the parent studies received 10 mg/kg beliumamb. Subsequently, the dose of belimumab for participants receiving 1 mg/kg was increased to 10 mg/kg .All participants also received SoC SLE therapy while participating in this trial.	

Reporting group values	Belimumab 10mg/kg IV	Total	
Number of subjects	735	735	
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	37.2		
standard deviation	± 11.17	-	
Gender categorical Units: Subjects			
Female	695	695	
Male	40	40	
Race/Ethnicity, Customized Units: Subjects			
Black or African American/African Heritage	18	18	
American Indian or Alaska Native	225	225	
East Asian Heritage	118	118	
South Asian Heritage	38	38	
Southeast Asian Heritage	58	58	
Middle East/North African Heritage	22	22	
White/Caucasian/European Heritage	256	256	

End points

End points reporting groups

Reporting group title	Belimumab 10mg/kg IV
Reporting group description:	
Participants received belimumab every 28 days by intravenous (IV) infusion at 1 milligram per kilogram (mg/kg) or 10 mg/kg body weight. Participants who received either 1 mg/kg or 10 mg/kg belimumab in their parent studies continued to receive the same dose of belimumab. Participants randomized to receive placebo in the parent studies received 10 mg/kg beliumamb. Subsequently, the dose of belimumab for participants receiving 1 mg/kg was increased to 10 mg/kg .All participants also received SoC SLE therapy while participating in this trial.	
Subject analysis set title	participants with no prednisone and other steroids at baseline
Subject analysis set type	Modified intention-to-treat
Subject analysis set description:	
Participants were not receiving prednisone and other steroids at Baseline.	
Subject analysis set title	participants with baseline daily dose of >0 to <=7.5 mg
Subject analysis set type	Modified intention-to-treat
Subject analysis set description:	
Participants were receiving a daily dose of >0 to <=7.5 mg of prednisone and other steroids at Baseline.	
Subject analysis set title	participants with baseline daily dose of >7.5 to <=40 mg
Subject analysis set type	Modified intention-to-treat
Subject analysis set description:	
Participants were receiving a daily dose of >7.5 to <=40 mg of prednisone and other steroids at Baseline.	
Subject analysis set title	participants with baseline daily dose of >40 mg
Subject analysis set type	Modified intention-to-treat
Subject analysis set description:	
Participants were receiving a daily dose of >40 mg of prednisone and other steroids at Baseline.	

Primary: Number of participants with Adverse events (AE)

End point title	Number of participants with Adverse events (AE)[1]
End point description:	
An adverse event is defined as any unfavorable or unintended sign, symptom, or disease that is temporally associated with the use of a study agent but is not necessarily caused by the study agent. This includes worsening (example: increase in frequency or severity) of preexisting conditions. Participants with incidences of any event at any time post-baseline are presented by yearly interval. Only treatment-emergent AEs are summarized.	
End point type	Primary
End point timeframe:	
Up to 9 years	

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: There are no statistical data to report.

End point values	Belimumab 10mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	735			
Units: Participants				
Any-time post Baseline,n=735	706			
Year 0-1,n=735	617			
Year 1-2 ,n =701	502			
Year 2-3, n= 620	441			

Year 3-4,n= 514	344			
Year 4-5,n= 442	261			
Year 5-6, n =345	181			
Year 6-7, n= 219	92			
Year 7-8, n = 65	26			
Year 8 plus,n = 6	3			

Statistical analyses

No statistical analyses for this end point

Primary: AE rates by System Organ Class (SOC) During the Study

End point title	AE rates by System Organ Class (SOC) During the Study[2]

End point description:

AE rates by SOC adjusting for participant-years on study drug anytime post Baseline are summarized, which included the follow up visits. Only treatment-emergent AEs are summarized. The event rate of an AE was calculated as the number of events per 100 participant years. Participant years were calculated as sum across all participants ([last visit of interval day - first visit of interval day + 1] divided by365). Participant years excluded between study gaps if participant had not started extension study on date of last visit of parent study.

End point type	Primary

End point timeframe:

Up to 9 years

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: There are no statistical data to report.

End point values	Belimumab 10mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	735			
Units: Adverse events per 100 participant years				
number (not applicable)				
Infections and infestations	101.8			
Gastrointestinal disorders	32.8			
Musculoskeletal and connective tissuedisorder	32.8			
Nervous system disorders	22.6			
Skin and subcutaneous and tissue disorders	22.5			
Respiratory,thoracic and mediastinal disorder	14.9			
Vascular disorders	13.3			
General disorders and administration sitecondition	11.8			
Injury, poisoning andprocedural complications	11.5			
Blood and lymphatic system disorders	7.5			
Eye disorders	6.6			
Reproductive system and breast disorders	6.4			
Investigations	5.8			

Psychiatric disorders	5.6			
Renal and urinary and disorder	5.3			
Metabolism and nutrition disorder	3.6			
Cardiac disorders	3.0			
Ear and labyrinth disorder	2.4			
Neoplasms benign,malignant andunspecified	2.2			
Hepatobiliary disorders	1.8			
Immune system disorder	1.2			
Endocrine disorders	1.0			
Social circumstances	0.7			
Congenital, familial and genetic disorders	0.1			
Pregnancy, puerperium and perinatal conditions	0.1			
Product Issues	0.1			

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with Serious Adverse events (SAE)

End point title	Number of participants with Serious Adverse events (SAE)[3]

End point description:

An adverse event resulting in death, is life threatening (ie, an immediate threat to life), inpatient hospitalization, prolongation of existing hospitalization, persistent or significant disability/incapacity, congenital anomaly/birth defect or any other situation which is medically important is categorized as SAE. Only treatment-emergent AEs are summarized.

End point type	Primary

End point timeframe:

Up to 9 years

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: There are no statistical data to report.

End point values	Belimumab 10mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	735			
Units: Participants				
Any post-Baseline,n=735	231			
Year 0-1,n=735	78			
Year 1-2,n = 701	58			
Year 2-3,n = 620	66			
Year 3-4,n= 514	44			
Year 4-5 ,n= 442	27			
Year 5-6,n=345	16			
Year 6-7,n= 219	11			
Year 7-8,n= 65	1			
Year 8 plus,n= 6	0			

Statistical analyses

No statistical analyses for this end point

Primary: SAE rates by SOC During the Study

End point title	SAE rates by SOC During the Study[4]

End point description:

SAE rates by SOC adjusting for participants-years on study drug anytime post Baseline are summarized, which included the follow up visits. Only treatment-emergent SAEs are summarized. The event rate of an SAE was calculated as the number of events per 100 participant years. Participants years were calculated as = sum across all participants ([last visit of interval day - first visit of interval day + 1] divided by 365). Participants years excluded between study gaps if participant had not started extension study on date of last visit of parent study.

End point type	Primary

End point timeframe:

Up to 9 years

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: There are no statistical data to report.

End point values	Belimumab 10mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	735			
Units: Adverse events per 100 participant years				
number (not applicable)				
Infections and infestations	5.1			
Blood and lymphatic system disorders	1.0			
Musculoskeletal and connective tissue disorder	1.0			
Gastrointestinal disorders	1.0			
Renal and urinary disorders	0.8			
Vascular disorders	0.8			
Injury, poisoning andprocedural complications	0.8			
General disorders and administration sitecondition	0.6			
Nervous system disorders	0.6			
Respiratory, thoracic and mediastinal disorder	0.5			
Cardiac disorders	0.5			
Skin and subcutaneous tissue disorders	0.5			
Neoplasms benign, malignant and unspecified	0.4			
Reproductive system and breast disorder	0.4			
Psychiatric disorders	0.4			

Hepatobiliary disorders	0.3			
Metabolism and nutrition disorders	0.1			
Pregnancy, puerperium and perinatal condition	0.1			
Endocrine disorders	0.1			
Immune system disorders	0.1			
Ear and labyrinth disorders	0.1			
Eye disorders	0.1			

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Activated Partial Thromboplastin Time (APTT) and Prothrombin Time (PT) at the Indicated Time Points

End point title	Change From Baseline in Activated Partial Thromboplastin Time (APTT) and Prothrombin Time (PT) at the Indicated Time Points[5]

End point description:

Hematology parameters were assessed at Baseline, Week 4,12,24,36, and 48 during Year 1. From Year 2-9 hematology parameters were assessed at Week 24 and 48 ; Exit visit and at follow-up (up to 8 weeks post infusion). Change from Baseline in APTT and PT is summarized. The Baseline is defined as For Year 1, Day 0 values for MITT participants who were treated with placebo in the parent study, and the last pre-treatment value in the parent study for MITT participants who were treated with belimumab in the parent study. Change from Baseline is defined as the difference between the post-dose post-Baseline visit value and the Baseline value. Only those participants available at the specified time points (represented by n=X in the category titles) were analyzed. 99999 indicates standard deviation was not calculable for a single data point.

End point type	Primary

End point timeframe:

Baseline and up to 9 years

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: There are no statistical data to report.

End point values	Belimumab 10mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	735			
Units: Seconds				
arithmetic mean (standard deviation)				
Year1,Week4,APTT,n=208	0.7 (± 5.27)			
Year1,Week12,APTT,n=208	2.1 (± 12.31)			
Year1,Week24,APTT,n=686	0.1 (± 9.10)			
Year1,Week36,APTT,n=193	2.5 (± 5.75)			
Year1,Week48,APTT,n=666	0.8 (± 9.48)			
Year2,Week24,APTT,n=625	2.7 (± 9.74)			
Year2,Week48,APTT,n=572	2.7 (± 9.66)			
Year3,Week24,APTT,n=521	3.4 (± 10.01)			
Year3,Week48,APTT,n=470	3.9 (± 11.41)			
Year4,Week24,APTT,n=422	3.5 (± 10.70)			
Year4,Week48,APTT,n=412	4.2 (± 6.63)			

Year5,Week24,APTT,n=383	4.1 (± 10.71)			
Year5,Week48,APTT,n=349	3.5 (± 6.35)			
Year6,Week24,APTT,n=292	3.8 (± 6.58)			
Year6,Week48,APTT,n=277	4.3 (± 7.91)			
Year7,Week24,APTT,n=177	6.4 (± 14.52)			
Year7,Week48,APTT,n=131	4.1 (± 6.23)			
Year8,Week24,APTT,n=52	5.6 (± 7.54)			
Year8,Week48,APTT,n=13	4.2 (± 3.98)			
Year9,Week24,APTT,n=6	5.0 (± 6.39)			
Year9,Week48,APTT,n=1	9.0 (± 99999)			
Exit, APTT,n=586	3.2 (± 10.71)			
8 Week,Follow up,n=524	3.4 (± 8.14)			
Year1,Week4,PT,n=205	-0.22 (± 5.139)			
Year1,Week12,PT,n=206	1.71 (± 19.533)			
Year1,Week24,PT,n=686	-0.43 (± 8.267)			
Year1,Week36,PT,n=193	0.13 (± 3.357)			
Year1,Week48,PT,n=666	-0.45 (± 8.174)			
Year2,Week24,PT,n=626	0.15 (± 11.528)			
Year2,Week48,PT,n=572	-0.26 (± 8.925)			
Year3,Week24,PT,n=521	0.12 (± 9.609)			
Year3,Week48,PT,n=469	0.63 (± 14.334)			
Year4,Week24,PT,n=422	0.06 (± 10.458)			
Year4,Week48,PT,n=412	0.40 (± 4.228)			
Year5,Week24,PT,n=384	-0.14 (± 10.810)			
Year5,Week48,PT,n=349	0.61 (± 11.276)			
Year6,Week24,PT,n=292	0.64 (± 8.023)			
Year6,Week48,PT,n=278	0.85 (± 12.414)			
Year7,Week24,PT,n=177	1.76 (± 14.272)			
Year7,Week48,PT,n=131	0.36 (± 2.290)			
Year8,Week24,PT,n=52	1.21 (± 6.716)			
Year8,Week48,PT,n=13	0.52 (± 0.600)			
Year9,Week24,PT,n=6	0.50 (± 0.657)			
Year9,Week48,PT,n=1	1.00 (± 99999)			
Exit,PT, n=587	0.25 (± 9.973)			
8 Week, Follow up,n=524	0.50 (± 4.965)			

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Platelets (Plt), Lymphocytes (Lymp), Leukocytes

(Leu), Eosinophils (Eos), Basophils (Baso), Monocytes (Mono), Neutrophils (Neu), Neutrophils Band Form (NeuBF), Neutrophils Segmented (NeuS) at the Indicated Time Points

End point title	Change From Baseline in Platelets (Plt), Lymphocytes (Lymp), Leukocytes (Leu), Eosinophils (Eos), Basophils (Baso), Monocytes (Mono), Neutrophils (Neu), Neutrophils Band Form (NeuBF), Neutrophils Segmented (NeuS) at the Indicated Time Points[6]

End point description:

Hematology parameters were assessed at Baseline, Week 4,12,24,36, and 48 during Year 1. From Year 2-9 hematology parameters were assessed at Week 24 and 48 ; Exit visit and at follow-up (up to 8 weeks post infusion). Change from Baseline in Plt, Lymp, Leu, Eos, Baso, Mono, Neu, NeuBF, and NueS are summarized. The Baseline is defined as For Year 1, Day 0 values for MITT participants who were treated with placebo in the parent study, and the last pre-treatment value in the parent study for MITT participants who were treated with belimumab in the parent study. Change from Baseline is defined as the difference between the post-dose post-Baseline visit value and the Baseline value. Only those participants available at the specified time points (represented by n=X in the category titles) were analyzed. 99999 indicates standard deviation was not calculable for a single data point.

End point type	Primary

End point timeframe:

Baseline and up to 9 years

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: There are no statistical data to report.

End point values	Belimumab 10mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	735			
Units: Billion cells per liter				
arithmetic mean (standard deviation)				
Baso,Year1,Week4,n=693	0.002 (± 0.0172)			
Baso,Year1,Week12,n=694	0.002 (± 0.0187)			
Baso,Year1,Week24,n=696	0.002 (± 0.0176)			
Baso,Year1,Week36,n=682	0.002 (± 0.0179)			
Baso,Year1,Week48,n=684	0.003 (± 0.0183)			
Baso,Year2,Week24,n=629	0.004 (± 0.0190)			
Baso,Year2,Week48,n=589	0.004 (± 0.0200)			
Baso,Year3,Week24,n=533	0.005 (± 0.0165)			
Baso,Year3,Week48,n=476	0.008 (± 0.0194)			
Baso,Year4,Week24,n=446	0.007 (± 0.0192)			
Baso,Year4,Week48,n=423	0.008 (± 0.0202)			
Baso,Year5,Week24,n=389	0.007 (± 0.0191)			
Baso,Year5,Week48,n=360	0.005 (± 0.0191)			
Baso,Year6,Week24,n=306	0.006 (± 0.0184)			

Baso,Year6,Week48,n=282	0.007 (± 0.0198)			
Baso,Year7,Week24,n=181	0.007 (± 0.0211)			
Baso,Year7,Week48,n=130	0.012 (± 0.0259)			
Baso,Year8,Week24,n=52	0.014 (± 0.0187)			
Baso,Year8,Week48,n=13	0.001 (± 0.0166)			
Baso,Year9,Week24,n=6	0.003 (± 0.0082)			
Baso,Year9,Week48,n=1	0.010 (± 99999)			
Baso,Exit,n=614	0.005 (± 0.0204)			
Baso,8 Week,Follow up,n=532	0.009 (± 0.0253)			
Eos,Year1,Week4,n=693	0.007 (± 0.1597)			
Eos,Year1,Week12,n=694	0.003 (± 0.1595)			
Eos,Year1,Week24,n=696	0.000 (± 0.1614)			
Eos,Year1,Week36,n=682	0.020 (± 0.1866)			
Eos,Year1,Week48,n=684	0.001 (± 0.1763)			
Eos,Year2,Week24,n=629	0.004 (± 0.1605)			
Eos,Year2,Week48,n=589	-0.004 (± 0.1858)			
Eos,Year3,Week24,n=533	-0.011 (± 0.2074)			
Eos,Year3,Week48,n=476	-0.026 (± 0.2053)			
Eos,Year4,Week24,n=446	-0.041 (± 0.1792)			
Eos,Year4,Week48,n=423	-0.047 (± 0.1676)			
Eos,Year5,Week24,n=389	-0.035 (± 0.1949)			
Eos,Year5,Week48,n=360	-0.045 (± 0.1807)			
Eos,Year6,Week24,n=306	-0.046 (± 0.1801)			
Eos,Year6,Week48,n=282	-0.037 (± 0.1976)			
Eos,Year7,Week24,n=181	-0.046 (± 0.1710)			
Eos,Year7,Week48,n=130	-0.020 (± 0.2276)			
Eos,Year8,Week24,n=52	-0.017 (± 0.1753)			
Eos,Year8,Week48,n=13	-0.041 (± 0.1130)			
Eos,Year9,Week24,n=6	-0.088 (± 0.1078)			
Eos,Year9,Week48,n=1	-0.040 (± 99999)			
Eos, Exit, n=614	-0.026 (± 0.1754)			

Eso, 8 Week Follow up, n=532	-0.030 (± 0.1920)			
Leu,Year1,Week4,n=696	0.16 (± 1.928)			
Leu,Year1,Week12,n=697	0.19 (± 2.106)			
Leu,Year1,Week24,n=697	0.04 (± 2.142)			
Leu,Year1,Week36,n=682	0.05 (± 2.190)			
Leu,Year1,Week48,n=684	0.02 (± 2.274)			
Leu,Year2,Week24,n=630	-0.19 (± 2.287)			
Leu,Year2,Week48,n=589	-0.11 (± 2.449)			
Leu,Year3,Week24,n=533	-0.03 (± 2.544)			
Leu,Year3,Week24,n=476	0.06 (± 2.393)			
Leu,Year4,Week24,n=446	-0.01 (± 2.520)			
Leu,Year4,Week48,n=423	-0.06 (± 2.661)			
Leu,Year5,Week24,n=389	0.05 (± 2.430)			
Leu,Year5,Week48,n=360	-0.06 (± 2.463)			
Leu,Year6,Week24,n=306	0.04 (± 2.449)			
Leu,Year6,Week48,n=282	0.17 (± 2.579)			
Leu,Year7,Week24,n=181	0.12 (± 2.395)			
Leu,Year7,Week48,n=130	0.48 (± 2.354)			
Leu,Year8,Week24,n=52	0.38 (± 2.761)			
Leu,Year8,Week48,n=13	-0.65 (± 3.136)			
Leu,Year9,Week24,n=6	-0.35 (± 3.422)			
Leu,Year9,Week48,n=1	-3.90 (± 99999)			
Leu, Exit, n=614	0.18 (± 2.650)			
Leu, 8 Week Follow up,n=532	0.21 (± 2.496)			
Lymp,Year1,Week4,n=693	0.093 (± 0.5986)			
Lymp,Year1,Week12,n=694	0.107 (± 0.6607)			
Lymp,Year1,Week24,n=696	0.066 (± 0.6544)			
Lymp,Year1,Week36,n=682	0.119 (± 0.6583)			
Lymp,Year1,Week48,n=684	0.048 (± 0.6361)			
Lymp,Year2,Week24,n=629	0.051 (± 0.6898)			
Lymp,Year2,Week48,n=589	0.067 (± 0.6971)			
Lymp,Year3,Week24,n=533	0.057 (± 0.6717)			
Lymp,Year3,Week48,n=476	0.038 (± 0.6676)			
Lymp,Year4,Week24,n=446	0.054 (± 0.6858)			
Lymp,Year4,Week48,n=423	0.067 (± 0.7186)			
Lymp,Year5,Week24,n=389	0.023 (± 0.6810)			

Lymp,Year5,Week48,n=360	0.078 (± 0.7485)			
Lymp,Year6,Week24,n=306	0.147 (± 0.7251)			
Lymp,Year6,Week48,n=282	0.168 (± 0.7523)			
Lymp,Year7,Week24,n=181	0.175 (± 0.7670)			
Lymp,Year7,Week48,n=130	0.169 (± 0.6639)			
Lymp,Year8,Week24,n=52	0.300 (± 0.7553)			
Lymp,Year8,Week48,n=13	0.052 (± 0.5252)			
Lymp,Year9,Week24,n=6	-0.032 (± 0.6156)			
Lymp,Year9,Week48,n=1	-0.460 (± 99999)			
Lymp,Exit,n=614	0.128 (± 0.7808)			
Lymp,8 Week Follow up,n=532	0.140 (± 0.7453)			
Mono,Year1,Week4,n=693	0.025 (± 0.2108)			
Mono,Year1,Week12,n=694	0.036 (± 0.2043)			
Mono,Year1,Week24,n=696	0.028 (± 0.2127)			
Mono,Year1,Week36,n=682	0.053 (± 0.2053)			
Mono,Year1,Week48,n=684	0.050 (± 0.2069)			
Mono,Year2,Week24,n=629	0.034 (± 0.1992)			
Mono,Year2,Week48,n=589	0.050 (± 0.2172)			
Mono,Year3,Week24,n=533	0.053 (± 0.2314)			
Mono,Year3,Week48,n=476	0.084 (± 0.1994)			
Mono,Year4,Week24,n=446	0.071 (± 0.2085)			
Mono,Year4,Week48,n=423	0.076 (± 0.2040)			
Mono,Year5,Week24,n=389	0.089 (± 0.2015)			
Mono,Year5,Week48,n=360	0.088 (± 0.2044)			
Mono,Year6,Week24,n=306	0.087 (± 0.2043)			
Mono,Year6,Week48,n=282	0.086 (± 0.2063)			
Mono,Year7,Week24,n=181	0.113 (± 0.2155)			
Mono,Year7,Week48,n=130	0.134 (± 0.2090)			
Mono,Year8,Week24,n=52	0.173 (± 0.2014)			
Mono,Year8,Week48,n=13	0.021 (± 0.1503)			
Mono,Year9,Week24,n=6	0.022 (± 0.1931)			

Mono,Year9,Week48,n=1	-0.120 (± 99999)			
Mono, Exit,n=614	0.083 (± 0.2157)			
Mono, 8 Week Follow up, n=532	0.084 (± 0.2189)			
Neu,Yaer1,Week4,n=688	0.024 (± 2.0482)			
Neru,Year1,Week12,n=690	0.047 (± 2.1575)			
Neu,Year1,Week24,n=691	-0.059 (± 2.1845)			
Neu,Year1,Week36,n=677	-0.141 (± 2.1907)			
Neu,Year1,Week48,n=679	-0.078 (± 2.3164)			
Neu,Year2,Week24,n=624	-0.286 (± 2.2746)			
Neu,Year2,Week48,n=584	-0.230 (± 2.3963)			
Neu,Year3,Week24,n=528	-0.135 (± 2.4914)			
Neu,Year3,Week48,n=471	-0.049 (± 2.3683)			
Neu,Year4,Week24,n=446	-0.104 (± 2.3846)			
Neu,Year4,Week48,n=423	-0.160 (± 2.5563)			
Neu,Year5,Week24,n=384	-0.031 (± 2.3060)			
Neu,Year5,Week48,n=356	-0.198 (± 2.3952)			
Neu,Year6,Week24,n=306	-0.151 (± 2.3083)			
Neu,Year6,Week48,n=282	-0.060 (± 2.4314)			
Neu,Year7,Week24,n=181	-0.129 (± 2.3908)			
Neu,Year7,Week48,n=130	-0.687 (± 3.0412)			
Neu,Year8,Week24,n=52	-0.092 (± 2.3908)			
Neu,Year8,Week48,n=13	-0.687 (± 3.0412)			
Neu,Year9,Week24,n=6	-0.257 (± 2.9192)			
Neu,Year9,Week48,n=1	-3.300 (± 99999)			
Neu, Exit, n=609	-0.006 (± 2.5612)			
Neu,8 Week Follow up,n=528	0.001 (± 2.3935)			
NeuBF,Year1,Week4,n=4	0.013 (± 0.1473)			
NeuBF,Year1,Week12,n=4	0.073 (± 0.1106)			
NeuBF,Year1,Week24,n=5	0.000 (± 0.2699)			
NeuBF,Year1,Week36,n=4	0.045 (± 0.0465)			
NeuBF,Year1,Week48,n=2	0.105 (± 0.1909)			

NeuBF,Year2,Week24,n=1	0.120 (± 99999)			
NeuBF,Year2,Week48,n=0	99999 (± 99999)			
NeuBF,Year3,Week24,n=1	0.070 (± 99999)			
NeuBF,Year3,Week48,n=0	99999 (± 99999)			
NeuBF,Year7,Week24,n=0	99999 (± 99999)			
NeuBF,Exit,n=2	0.465 (± 0.6435)			
NeuS,Year1,Week4,n=693	0.021 (± 2.0450)			
NeuS,Year1,Week12,n=694	0.051 (± 2.1519)			
NeuS,Year1,Week24,n=696	-0.055 (± 2.1757)			
NeuS,Year1,Week36,n=682	-0.139 (± 2.1819)			
NeuS,Year1,Week48,n=684	-0.079 (± 2.3128)			
NeuS,Year2,Week24,n=629	-0.289 (± 2.2609)			
NeuS,Year2,Week48,n=589	-0.226 (± 2.3846)			
NeuS,Year3,Week24,n=533	-0.130 (± 2.4736)			
NeuS,Year3,Week48,n=476	-0.041 (± 2.3547)			
NeuS,Year4,Week24,n=446	-0.097 (± 2.3804)			
NeuS,Year4,Week48,n=423	-0.158 (± 2.5542)			
NeuS,Year5,Week24,n=389	-0.024 (± 2.2893)			
NeuS,Year5,Week48,n=360	-0.184 (± 2.3831)			
NeuS,Year6,Week24,n=306	-0.147 (± 2.3029)			
NeuS,Year6,Week48,n=282	-0.058 (± 2.4310)			
NeuS,Year7,Week24,n=181	-0.151 (± 2.2248)			
NeuS,Year7,Week48,n=130	0.191 (± 2.2514)			
NeuS,Year8,Week24,n=52	-0.092 (± 2.3908)			
NeuS,Year8,Week48,n=13	-0.687 (± 3.0412)			
NeuS,Year9,Week24,n=6	-0.257 (± 2.9192)			
NeuS,Year9,Week48,n=1	-3.300 (± 99999)			
NeuS,Exit,n=614	-0.008 (± 2.5501)			
NeuS,8 Week Followup,n=532	0.007 (± 2.3824)			
Plt,Year1,Week4,n=683	8.1 (± 38.82)			
Plt,Year1,Week12,n=690	4.6 (± 43.63)			
Plt,Year1,Week24,n=687	-0.5 (± 47.73)			

Plt,Year1,Week36,n=680	-2.9 (± 50.25)			
Plt,Year1,Week48,n=677	-9.3 (± 50.81)			
Plt,Year2,Week24,n=631	-15.4 (± 53.80)			
Plt,Year2,Week48,n=583	-20.3 (± 56.39)			
Plt,Year3,Week24,n=526	-19.9 (± 57.88)			
Plt,Year3,Week48,n=476	-13.4 (± 65.16)			
Plt,Year4,Week24,n=441	-14.0 (± 59.05)			
Plt,Year4,Week48,n=420	-18.2 (± 63.80)			
Plt,Year5,Week24,n=388	-19.3 (± 61.49)			
Plt,Year5,Week48,n=360	-17.9 (± 63.36)			
Plt,Year6,Week24,n=305	-13.3 (± 61.54)			
Plt,Year6,Week48,n=282	-13.4 (± 60.89)			
Plt,Year7,Week24,n=181	-15.3 (± 63.95)			
Plt,Year7,Week48,n=130	-16.3 (± 70.75)			
Plt,Year8,Week24,n=52	-2.3 (± 80.69)			
Plt,Year8,Week48,n=13	-29.9 (± 88.66)			
Plt,Year9,Week24,n=6	-5.0 (± 82.67)			
Plt,Year9,Week48,n=1	57.0 (± 99999)			
Plt,Exit,n=613	-11.0 (± 64.36)			
Plt,8Week Followup,n=530	-11.2 (± 60.57)			

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Hemoglobin (Hg) at the Indicated Time Points

End point title	Change From Baseline in Hemoglobin (Hg) at the Indicated Time Points[7]

End point description:

Hematology parameters were assessed at Baseline, Week 4,12,24,36, and 48 during Year 1. From Year 2-9 hematology parameters were assessed at Week 24 and 48 ; Exit visit and at follow-up (up to 8 weeks post infusion). Change from Baseline in Hg is summarized. The Baseline is defined as For Year 1, Day 0 values for MITT participants who were treated with placebo in the parent study, and the last pre-treatment value in the parent study for MITT participants who were treated with belimumab in the parent study. Change from Baseline is defined as the difference between the post-dose post-Baseline visit value and the Baseline value. Only those participants available at the specified time points (represented by n=X in the category titles) were analyzed. 99999 indicates standard deviation was not calculable for a single data point.

End point type	Primary

End point timeframe:

Baseline and up to 9 years

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: There are no statistical data to report.

End point values	Belimumab 10mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	735			
Units: Gram per liter (g/L)				
arithmetic mean (standard deviation)				
Hg,Year1, Week 4,n=697	-0.3 (± 7.05)			
Hg,Year1,Week12,n=698	0.1 (± 8.75)			
Hg,Year1,Week24,n=699	0.1 (± 9.48)			
Hg,Year1,Week36,n=688	0.3 (± 9.90)			
Hg,Year1,Week48,n=686	1.0 (± 11.03)			
Hg,Year2,Week24,n=635	1.0 (± 11.31)			
Hg,Year2,Week48,n=591	1.3 (± 12.12)			
Hg,Year3,Week24,n=534	2.2 (± 12.79)			
Hg,Year3,Week48,n=478	2.9 (± 12.67)			
Hg,Year4,Week24,n=446	2.6 (± 12.93)			
Hg,Year,Week48,n=424	2.4 (± 13.59)			
Hg,Year5,Week24,n=390	2.9 (± 12.76)			
Hg,Year5,Week48,n=362	3.2 (± 13.26)			
Hg,Year6,Week24,n=306	2.7 (± 13.19)			
Hg,Year6,Week48,n=282	2.3 (± 13.83)			
Hg,Year7,Week24,n=181	2.9 (± 14.54)			
Hg,Year7,Week48,n=130	4.0 (± 14.66)			
Hg,Year8,Week24,n=52	1.5 (± 14.84)			
Hg,Year8,Week48,n=13	-0.2 (± 13.95)			
Hg,Year9,Week24,n=6	-0.7 (± 20.67)			
Hg,Year9,Week48,n=1	-29.0 (± 99999)			
Hg,Exit,n=619	3.2 (± 13.90)			
Hg,8 Week Follow up,n=534	2.8 (± 13.71)			

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Hematocrit at the Indicated Time Points

End point title	Change From Baseline in Hematocrit at the Indicated Time Points[8]

End point description:

Hematology parameters were assessed at Baseline, Week 4,12,24,36, and 48 during Year 1. From Year 2-9 hematology parameters were assessed at Week 24 and 48 ; Exit visit and at follow-up (up to 8 weeks). Change from Baseline in Hematocrit is summarized. The Baseline is defined as For Year 1, Day 0 values for MITT participants who were treated with placebo in the parent study, and the last pre-treatment value in the parent study for MITT participants who were treated with belimumab in the parent study. Change from Baseline is defined as the difference between the post-dose post-Baseline visit value and the Baseline value. Only those participants available at the specified time points (represented by n=X in the category titles) were analyzed. 99999 indicates standard deviation was not calculable for a single data point.

End point type	Primary

End point timeframe:

Baseline and up to 9 years

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: There are no statistical data to report.

End point values	Belimumab 10mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	735			
Units: Percentage of blood by volume				
arithmetic mean (standard deviation)				
Hematocrit,Year1,Week4,n=697	0.01 (± 2.250)			
Hematocrit,Year1,Week12,n=698	0.38 (± 2.729)			
Hematocrit,Year1,Week24,n=699	0.75 (± 2.928)			
Hematocrit,Year1,Week36,n=688	0.53 (± 2.954)			
Hematocrit,Year1,Week48,n=686	0.35 (± 3.286)			
Hematocrit,Year2,Week24,n=635	0.94 (± 3.427)			
Hematocrit,Year2,Week48,n=591	0.78 (± 3.584)			
Hematocrit,Year3,Week24,n=534	1.29 (± 3.828)			
Hematocrit,Year3,Week48,n=478	1.39 (± 3.800)			
Hematocrit,Year4,Week24,n=446	1.67 (± 3.834)			
Hematocrit,Year4,Week48,n=424	1.15 (± 3.998)			
Hematocrit,Year5,Week24,n=390	1.69 (± 3.776)			
Hematocrit,Year5,Week48,n=362	1.98 (± 3.842)			
Hematocrit,Year6,Week24,n=306	1.93 (± 3.939)			
Hematocrit,Year6,Week48,n=282	2.07 (± 4.023)			
Hematocrit,Year7,Week24,n=181	1.81 (± 4.251)			
Hematocrit,Year7,Week48,n=130	2.11 (± 4.238)			
Hematocrit,Year8,Week24,n=52	1.42 (± 4.390)			
Hematocrit,Year8,Week48,n=13	1.48 (± 4.234)			
Hematocrit,Year9,Week24,n=6	2.03 (± 6.001)			
Hematocrit,Year9,Week48,n=1	-6.00 (± 99999)			
Hematocrit,Exit,n=619	1.91 (± 4.202)			
Hematocrit,8 Week Follow up,n=534	1.85 (± 4.077)			

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Erythrocytes (Eryth) at the Indicated Time Points

End point title	Change From Baseline in Erythrocytes (Eryth) at the Indicated Time Points[9]

End point description:

Hematology parameters were assessed at Baseline, Week 4,12,24,36, and 48 during Year 1. From Year 2-9 hematology parameters were assessed at Week 24 and 48 ; Exit visit and at follow-up (up to 8 weeks post infusion). Change from Baseline in Erythrocytes is summarized. The Baseline is defined as For Year 1, Day 0 values for MITT participants who were treated with placebo in the parent study, and the last pre-treatment value in the parent study for MITT participants who were treated with belimumab

in the parent study. Change from Baseline is defined as the difference between the post-dose post-Baseline visit value and the Baseline value. Only those participants available at the specified time points (represented by n=X in the category titles) were analyzed. 99999 indicates standard deviation was not calculable for a single data point.

End point type	Primary

End point timeframe:

Baseline and up to 9 years

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: There are no statistical data to report.

End point values	Belimumab 10mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	735			
Units: Trillions cells per liter				
arithmetic mean (standard deviation)				
Eryth,Year1,Week4,n=697	0.00 (± 0.231)			
Eryth,Year1,Week12,n=698	0.04 (± 0.280)			
Eryth,Year1,Week24,n=699	0.06 (± 0.293)			
Eryth,Year1,Week36,n=688	0.06 (± 0.299)			
Eryth,Year1,Week48,n=686	0.06 (± 0.328)			
Eryth,Year2,Week24,n=635	0.07 (± 0.335)			
Eryth,Year2,Week48,n=591	0.04 (± 0.362)			
Eryth,Year3,Week24,n=534	0.04 (± 0.364)			
Eryth,Year3,Week48,n=478	0.05 (± 0.381)			
Eryth,Year4,Week24,n=446	0.06 (± 0.372)			
Eryth,Year,Week48,n=424	0.05 (± 0.379)			
Eryth,Year5,Week24,n=390	0.09 (± 0.375)			
Eryth,Year5,Week48,n=362	0.11 (± 0.383)			
Eryth,Year6,Week24,n=306	0.12 (± 0.396)			
Eryth,Year6,Week48,n=282	0.17 (± 0.408)			
Eryth,Year7,Week24,n=181	0.17 (± 0.415)			
Eryth,Year7,Week48,n=130	0.22 (± 0.387)			
Eryth,Year8,Week24,n=52	0.21 (± 0.375)			
Eryth,Year8,Week48,n=13	0.15 (± 0.207)			
Eryth,Year9,Week24,n=6	0.30 (± 0.374)			
Eryth,Year9,Week48,n=1	0.20 (± 99999)			
Eryth,Exit,n=619	0.14 (± 0.431)			
Eryth,8 Week Follow up,n=534	0.13 (± 0.411)			

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Calcium (Ca), Carbon dioxide (CO2), Chloride, Magnesium (Mg), Phosphate (Phos), Potassium (K), Sodium (Na) at the Indicated Time Points

End point title	Change From Baseline in Calcium (Ca), Carbon dioxide (CO2), Chloride, Magnesium (Mg), Phosphate (Phos), Potassium (K), Sodium (Na) at the Indicated Time Points[10]

End point description:

Electrolytes parameters were assessed at Baseline, Week 4,12,24,36, and 48 during Year 1. From Year 2-9 electrolytes parameters were assessed at Week 24 and 48 ; Exit visit and at follow-up (up to 8 weeks post infusion). Change from Baseline in Ca,CO2, Chloride, Mg, Phos, K and Na were summarized. The Baseline is defined as For Year 1, Day 0 values for MITT participants who were treated with placebo in the parent study, and the last pre-treatment value in the parent study for MITT participants who were treated with belimumab in the parent study. Change from Baseline is defined as the difference between the post-dose post-Baseline visit value and the Baseline value. Only those participants available at the specified time points (represented by n=X in the category titles) were analyzed. 99999 indicates standard deviation was not calculable for a single data point.

End point type	Primary

End point timeframe:

Baseline and up to 9 years

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: There are no statistical data to report.

End point values	Belimumab 10mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	735			
Units: Millimoles per liter (mmol/L)				
arithmetic mean (standard deviation)				
Ca,Year1,Week4,n=697	0.0030 (± 0.0763)			
Ca,Year1,Week12,n=696	0.0020 (± 0.0749)			
Ca,Year1,Week24,n=696	-0.0035 (± 0.0750)			
Ca,Year1,Week36,n=677	0.0024 (± 0.0836)			
Ca,Year1,Week48,n=687	-0.0065 (± 0.0778)			
Ca,Year2,Week24,n=636	-0.0075 (± 0.0764)			
Ca,Year2,Week48,n=587	-0.0091 (± 0.0837)			
Ca,Year3,Week24,n=526	-0.0047 (± 0.0810)			
Ca,Year3,Week48,n=481	-0.0123 (± 0.0800)			
Ca,Year4,Week24,n=438	-0.0056 (± 0.0771)			
Ca,Year,Week48,n=418	-0.0193 (± 0.0805)			
Ca,Year5,Week24,n=387	-0.0129 (± 0.0885)			
Ca,Year5,Week48,n=358	-0.0140 (± 0.0919)			
Ca,Year6,Week24,n=303	-0.0053 (± 0.0903)			
Ca,Year6,Week48,n=283	-0.0146 (± 0.0870)			
Ca,Year7,Week24,n=182	-0.0076 (± 0.0839)			
Ca,Year7,Week48,n=130	-0.0079 (± 0.1172)			
Ca,Year8,Week24,n=51	0.0003 (± 0.0806)			

Ca,Year8,Week48,n=13	-0.0395 (± 0.0611)			
Ca,Year9,Week24,n=6	-0.0402 (± 0.0336)			
Ca,Year9,Week48,n=1	-0.0642 (± 99999)			
Ca,Exit,n=619	0.0006 (± 0.0864)			
Ca,8 Week Follow up,n=534	-0.0014 (± 0.0909)			
CO2,Year1,Week4,n=701	0.0 (± 2.77)			
CO2,Year1,Week12,n=700	-0.1 (± 2.76)			
CO2,Year1,Week24,n=701	-0.1 (± 2.73)			
CO2,Year1,Week36,n=682	0.1 (± 2.73)			
CO2,Year1,Week48,n=692	-0.1 (± 2.78)			
CO2,Year2,Week24,n=641	-0.3 (± 2.94)			
CO2,Year2,Week48,n=692	-0.3 (± 2.87)			
CO2,Year3,Week24,n=531	-0.2 (± 2.90)			
CO2,Year3,Week48,n=486	-0.4 (± 2.75)			
CO2,Year4,Week24,n=438	0.0 (± 2.76)			
CO2,Year4,Week48,n=418	-0.5 (± 3.04)			
CO2,Year5,Week24,n=393	-0.2 (± 2.90)			
CO2,Year5,Week48,n=361	-0.8 (± 2.82)			
CO2,Year6,Week24,n=303	0.0 (± 2.86)			
CO2,Year6,Week48,n=284	-0.5 (± 2.76)			
CO2,Year7,Week24,n=182	0.2 (± 2.78)			
CO2,Year7,Week48,n=130	0.2 (± 2.67)			
CO2,Year8,Week24,n=52	1.0 (± 2.78)			
CO2,Year8,Week48,n=13	0.4 (± 3.38)			
CO2,Year9,Week24,n=6	-0.3 (± 0.82)			
CO2,Year9,Week48,n=1	-3.0 (± 99999)			
CO2,Exit,n=625	-0.3 (± 3.00)			
CO2,8 week Follow up,n=538	-0.2 (± 3.00)			
Chloride,Year1,Week4,n=707	0.3 (± 2.33)			
Chloride,Year1,Week12,n=704	0.6 (± 2.56)			
Chloride,Year1,Week24,n=703	0.6 (± 2.42)			
Chloride,Year1,Week36,n=684	0.6 (± 2.47)			
Chloride,Year1,Week48,n=693	0.4 (± 2.44)			
Chloride,Year2,Week24,n=643	0.5 (± 2.62)			
Chloride,Year2,Week48,n=598	0.5 (± 2.81)			
Chloride,Year3,Week24,n=535	0.7 (± 3.04)			
Chloride,Year3,Week48,n=488	0.6 (± 2.73)			
Chloride,Year4,Week24,n=439	0.5 (± 2.74)			
Chloride,Year4,Week48,n=421	0.7 (± 2.84)			
Chloride,Year5,Week24,n=392	0.6 (± 2.95)			
Chloride,Year5,Week48,n=362	0.6 (± 2.77)			
Chloride,Year6,Week24,n=304	1.0 (± 2.74)			
Chloride,Year6,Week48,n=286	0.8 (± 2.67)			
Chloride,Year7,Week24,n=183	0.7 (± 2.57)			
Chloride,Year7,Week48,n=130	1.1 (± 2.73)			
Chloride,Year8,Week24,n=52	1.3 (± 2.86)			
Chloride,Year8,Week48,n=13	1.2 (± 3.54)			
Chloride,Year9,Week24,n=6	3.2 (± 1.47)			

Chloride,Year9,Week48,n=1	1.0 (± 99999)			
Chloride,Exit,n=624	0.4 (± 3.06)			
Chloride,8 Week Follow up,n=538	0.4 (± 2.82)			
Mg,Year1,Week4,n=707	-0.003 (± 0.0583)			
Mg,Year1,Week 12,n=705	-0.006 (± 0.0647)			
Mg,Year1,Week 24,n=703	-0.003 (± 0.0604)			
Mg,Year1,Week 36,n=684	-0.004 (± 0.0616)			
Mg,Year1,Week 48,n=693	0.002 (± 0.0597)			
Mg,Year2,Week 24,n=643	0.002 (± 0.0694)			
Mg,Year2,Week 48,n=598	0.001 (± 0.0711)			
Mg,Year3,Week 24,n=535	0.010 (± 0.0668)			
Mg,Year3,Week 48,n=488	0.010 (± 0.0669)			
Mg,Year4,Week 24,n=439	0.016 (± 0.0700)			
Mg,Year4,Week 48,n=421	0.017 (± 0.0709)			
Mg,Year 5,Week 24,n=393	0.016 (± 0.0673)			
Mg,Year 5,Week 48,n=362	0.021 (± 0.0688)			
Mg,Year 6,Week 24,n=304	0.013 (± 0.0718)			
Mg,Year 6,Week 48,n=286	0.011 (± 0.0639)			
Mg,Year 7,Week 24,n=183	0.010 (± 0.0692)			
Mg,Year 7,Week 48,n=130	0.013 (± 0.0635)			
Mg,Year 8,Week 24,n=52	0.025 (± 0.0702)			
Mg,Year 8,Week 48,n=13	0.042 (± 0.0685)			
Mg,Year 9,Week 24,n=6	0.030 (± 0.0613)			
Mg,Year 9,Week 48,n=1	0.040 (± 99999)			
Mg, Exit,n=625	0.022 (± 0.0738)			
Mg,8 Week Follow up,n=539	0.021 (± 0.0729)			
Phos, Year1, Week4,n=707	0.0102 (± 0.1908)			
Phos, Year1, Week12,n=705	0.0004 (± 0.1999)			
Phos, Year1, Week24,n=703	-0.0126 (± 0.1964)			
Phos, Year1, Week 36,n=684	0.0101 (± 0.1976)			
Phos, Year1, Week48,n=693	-0.0110 (± 0.2086)			
Phos, Year2, Week24,n=643	-0.0026 (± 0.2138)			

Phos, Year2, Week48,n=598	-0.0044 (± 0.2062)			
Phos, Year3, Week24,n=535	-0.0109 (± 0.2028)			
Phos, Year3, Week48,n=488	-0.0185 (± 0.2138)			
Phos, Year4, Week24,n=439	-0.0072 (± 0.2067)			
Phos, Year4, Week48,n=421	-0.0143 (± 0.2118)			
Phos, Year5, Week24,n=393	-0.0199 (± 0.2751)			
Phos, Year5, Week48,n=362	-0.0320 (± 0.2145)			
Phos, Year6, Week24,n=304	-0.0238 (± 0.2214)			
Phos, Year6, Week48,n=286	-0.0123 (± 0.2113)			
Phos, Year 7, Week 24,n=183	-0.0196 (± 0.1970)			
Phos, Year 7, Week 48,n=130	-0.0101 (± 0.1912)			
Phos, Year 8, Week 24,n=52	-0.0041 (± 0.2038)			
Phos, Year 8, Week48,n=13	-0.0340 (± 0.1337)			
Phos, Year9, Week 24,n=6	-0.0803 (± 0.0823)			
Phos, Year 9, Week 48,n=1	0.0447 (± 99999)			
Phos, Exit, n=625	-0.0111 (± 0.2243)			
Phos, 8 Week Follow up,n=539	-0.0034 (± 0.2233)			
K, Year 1, Week 4, n=701	0.07 (± 0.411)			
K, Year 1, Week 12, n=700	0.03 (± 0.380)			
K, Year 1, Week 24, n=701	0.01 (± 0.377)			
K, Year 1, Week 36, n=682	0.04 (± 0.387)			
K, Year 1, Week 48, n=692	0.01 (± 0.377)			
K, Year 2, Week 24, n=641	0.01 (± 0.393)			
K, Year 2, Week 48, n=592	0.02 (± 0.372)			
K, Year 3, Week 24, n=531	0.05 (± 0.401)			
K, Year 3, Week 48, n=486	0.06 (± 0.421)			
K, Year 4, Week 24, n=438	0.06 (± 0.408)			
K, Year 4, Week 48, n=418	0.03 (± 0.397)			
K, Year 5, Week 24, n=393	0.08 (± 0.427)			
K, Year 5, Week 48, n=362	0.02 (± 0.404)			
K, Year 6, Week 24, n=303	0.06 (± 0.429)			
K, Year 6, Week 48, n=284	0.05 (± 0.437)			
K, Year 7, Week 24, n=182	0.05 (± 0.445)			
K, Year 7, Week 48, n=130	0.05 (± 0.413)			
K, Year 8, Week 24, n=52	-0.02 (± 0.418)			
K, Year 8, Week 48, n=13	-0.12 (± 0.300)			
K, Year 9, Week 24, n=6	0.05 (± 0.259)			
K, Year 9, Week 48, n=1	0.00 (± 99999)			
K, Exit, n=624	0.06 (± 0.435)			

K, 8 Week Follow up, n=537	0.07 (± 0.452)			
Na, Year 1, Week 4, n=707	0.1 (± 2.07)			
Na, Year 1, Week 12, n=705	0.3 (± 2.25)			
Na, Year 1, Week 24, n=703	0.4 (± 2.16)			
Na, Year 1, Week 36, n=684	0.4 (± 2.10)			
Na, Year 1, Week 48, n=693	0.1 (± 2.09)			
Na, Year 2, Week 24, n=643	0.0 (± 2.30)			
Na, Year 2, Week 48, n=598	0.1 (± 2.63)			
Na, Year 3, Week 24, n=535	0.2 (± 2.54)			
Na, Year 3, Week 48, n=488	0.3 (± 2.36)			
Na, Year 4, Week 24, n=439	0.1 (± 2.31)			
Na, Year 4, Week 48, n=421	0.3 (± 2.36)			
Na, Year 5, Week 24, n=393	0.3 (± 2.61)			
Na, Year 5, Week 48, n=362	0.3 (± 2.18)			
Na, Year 6, Week 24, n=304	0.3 (± 2.22)			
Na, Year 6, Week 48, n=286	0.4 (± 2.44)			
Na, Year 7, Week 24, n=183	0.1 (± 2.22)			
Na, Year 7, Week 48, n=130	0.1 (± 2.38)			
Na, Year 8, Week 24, n=52	0.2 (± 2.67)			
Na, Year 8, Week 48, n=13	0.1 (± 2.14)			
Na, Year 9, Week 24, n=6	1.0 (± 1.79)			
Na, Year 9, Week 48, n=1	-3.0 (± 99999)			
Na, Exist, n=624	0.1 (± 2.55)			
Na, 8 Week Follow up, n=538	0.3 (± 2.36)			

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Blood urea nitrogen/Creatinine (BUN/Cr) at the Indicated Time Points

End point title	Change From Baseline in Blood urea nitrogen/Creatinine (BUN/Cr) at the Indicated Time Points[11]

End point description:

Other chemistries parameters were assessed at Baseline, Week 4,12,24,36, and 48 during Year 1. From Year 2-9 other chemistries parameters were assessed at Week 24 and 48 ; Exit visit and at follow-up (up to 8 weeks post infusion). Change from Baseline in BUN/Cr is summarized. The Baseline is defined as For Year 1, Day 0 values for MITT participants who were treated with placebo in the parent study, and the last pre-treatment value in the parent study for MITT participants who were treated with belimumab in the parent study. Change from Baseline is defined as the difference between the post-dose post-Baseline visit value and the Baseline value. Only those participants available at the specified time points (represented by n=X in the category titles) were analyzed.

End point type	Primary

End point timeframe:

Baseline and up to 9 years

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: There are no statistical data to report.

End point values	Belimumab 10mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	735			
Units: Ratio				
arithmetic mean (standard deviation)				
BUN/Cr,Year1,Week4,n=707	-0.2 (± 4.66)			
BUN/Cr,Year1,Week12,n=705	-0.3 (± 4.88)			
BUN/CrYear1,Week24,n=703	-0.7 (± 5.02)			
BUN/Cr,Year1,Week36,n=683	-0.5 (± 5.61)			
BUN/Cr,Year1,Week48,n=693	-0.2 (± 5.26)			
BUN/Cr,Year2,Week24,n=643	-0.1 (± 5.68)			
BUN/Cr,Year2,Week48,n=598	0.5 (± 5.55)			
BUN/Cr,Year3,Week24,n=535	1.4 (± 5.48)			
BUN/Cr,Year3,Week48,n=488	1.2 (± 5.92)			
BUN/Cr,Year4,Week24,n=439	1.4 (± 5.65)			
BUN/Cr,Year 4,Week48,n=421	1.0 (± 5.85)			
BUN/Cr,Year5,Week24,n=393	0.7 (± 5.51)			
BUN/Cr,Year5,Week48,n=362	1.0 (± 5.62)			
BUN/Cr,Year6,Week24,n=304	1.0 (± 5.35)			
BUN/Cr,Year6,Week48,n=286	1.3 (± 5.74)			
BUN/Cr,Year7,Week24,n=183	0.8 (± 5.68)			
BUN/Cr,Year7,Week48,n=130	1.2 (± 5.47)			
BUN/Cr,Year8,Week24,n=52	3.3 (± 4.64)			
BUN/Cr,Year8,Week48,n=13	3.5 (± 6.04)			
BUN/Cr,Year9,Week24,n=6	3.5 (± 3.08)			
BUN/Cr,Year9,Week48,n=1	1 (± 2.0)			
BUN/Cr,Exit,n=625	0.9 (± 6.05)			
BUN/Cr,8 Week Follow up,n=539	0.9 (± 5.91)			

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Albumin (Alb) and Protein (Pro) at the Indicated Time Points

End point title	Change From Baseline in Albumin (Alb) and Protein (Pro) at the Indicated Time Points[12]

End point description:

Other chemistries parameters were assessed at Baseline, Week 4,12,24,36, and 48 during Year 1. From Year 2-9 other chemistries parameters were assessed at Week 24 and 48 ; Exit visit and at follow-up (up to 8 weeks post infusion). Change from Baseline in Alb and Protein were summarized. The Baseline is defined as For Year 1, Day 0 values for MITT participants who were treated with placebo in the parent study, and the last pre-treatment value in the parent study for MITT participants who were treated with belimumab in the parent study. Change from Baseline is defined as the difference between the post-dose post-Baseline visit value and the Baseline value. Only those participants available at the specified time points (represented by n=X in the category titles) were analyzed. 99999 indicates standard deviation was not calculable for a single data point.

End point type	Primary

End point timeframe:

Baseline and up to 9 years

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: There are no statistical data to report.

End point values	Belimumab 10mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	735			
Units: Grams per liter (g/L)				
arithmetic mean (standard deviation)				
Alb,Year1,Week4,n=707	-0.1 (± 2.36)			
Alb,Year1,Week12,n=705	0.2 (± 2.67)			
Alb,Year1,Week24,n=703	0.6 (± 3.03)			
Alb,Year1,Week36,n=684	0.7 (± 3.23)			
Alb,Year1,Week48,n=693	1.2 (± 3.52)			
Alb,Year2,Week24,n=643	1.2 (± 3.49)			
Alb,Year2,Week48,n=598	1.2 (± 3.67)			
Alb,Year3,Week24,n=535	1.2 (± 3.78)			
Alb,Year3,Week48,n=488	1.4 (± 4.02)			
Alb,Year4,Week24,n=439	1.7 (± 4.02)			
Alb,Year 4,Week48,n=421	1.9 (± 4.04)			
Alb,Year5,Week24,n=393	1.9 (± 3.85)			
Alb,Year5,Week48,n=362	2.3 (± 3.89)			
Alb,Year6,Week24,n=304	2.2 (± 3.78)			
Alb,Year6,Week48,n=286	2.1 (± 4.07)			
Alb,Year7,Week24,n=183	2.0 (± 3.60)			
Alb,Year7,Week48,n=130	2.3 (± 3.92)			
Alb,Year8,Week24,n=52	1.9 (± 4.16)			
Alb,Year8,Week48,n=13	1.1 (± 4.11)			
Alb,Year9,Week24,n=6	0.7 (± 3.01)			
Alb,Year9,Week48,n=1	1.0 (± 99999)			
Alb,Exit,n=625	1.8 (± 4.74)			
Alb,8 Week Follow up,n=539	1.7 (± 4.66)			
Pro,Year1,Week4,n=707	-1.4 (± 3.81)			
Pro,Year1,Week12,n=705	-2.0 (± 4.30)			
Pro,Year1,Week24,n=703	-1.9 (± 4.68)			
Pro,Year1,Week36,n=684	-2.3 (± 4.75)			
Pro,Year1,Week48,n=693	-1.8 (± 4.94)			
Pro,Year2,Week24,n=643	-2.3 (± 5.05)			
Pro,Year2,Week48,n=598	-2.7 (± 5.53)			
Pro,Year3,Week24,n=535	-3.1 (± 5.62)			
Pro,Year3,Week48,n=488	-3.5 (± 5.91)			
Pro,Year4,Week24,n=439	-3.2 (± 5.87)			
Pro,Year 4,Week48,n=421	-3.2 (± 6.07)			
Pro,Year5,Week24,n=393	-3.5 (± 5.75)			
Pro,Year5,Week48,n=362	-3.6 (± 5.78)			
Pro,Year6,Week24,n=304	-3.9 (± 5.57)			
Pro,Year6,Week48,n=286	-4.0 (± 5.79)			
Pro,Year7,Week24,n=183	-4.3 (± 5.36)			
Pro,Year7,Week48,n=130	-3.9 (± 5.32)			
Pro,Year8,Week24,n=52	-5.1 (± 6.38)			

Pro,Year8,Week48,n=13	-4.8 (± 5.02)			
Pro,Year9,Week24,n=6	-7.7 (± 7.03)			
Pro,Year9,Week48,n=1	0.0 (± 99999)			
Pro,Exit,n=625	-3.4 (± 6.45)			
Pro,8 Week Follow up,n=539	-3.7 (± 6.42)			

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in BUN and Glucose at the Indicated Time Points

End point title	Change From Baseline in BUN and Glucose at the Indicated Time Points[13]

End point description:

Other chemistries parameters were assessed at Baseline, Week 4,12,24,36, and 48 during Year 1. From Year 2-9 other chemistries were assessed at Week 24 and 48 ; Exit visit and at follow-up (up to 8 weeks post infusion). Change from Baseline in BUN and Glucose were summarized. The Baseline is defined as For Year 1, Day 0 values for MITT participants who were treated with placebo in the parent study, and the last pre-treatment value in the parent study for MITT participants who were treated with belimumab in the parent study. Change from Baseline is defined as the difference between the post-dose post-Baseline visit value and the Baseline value. Only those participants available at the specified time points (represented by n=X in the category titles) were analyzed. 99999 indicates standard deviation was not calculable for a single data point.

End point type	Primary

End point timeframe:

Baseline and up to 9 years

Notes:

[13] - 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: There are no statistical data to report.

End point values	Belimumab 10mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	735			
Units: mmol/L				
arithmetic mean (standard deviation)				
BUN,Year1,Week4,n=707	0.0299 (± 1.6783)			
BUN,Year1,Week12,n=705	0.0402 (± 1.9768)			
BUN,Year1,Week24,n=703	-0.1443 (± 1.3723)			
BUN,Year1,Week36,n=683	-0.0592 (± 1.6916)			
BUN,Year1,Week48,n=693	-0.0406 (± 1.5541)			
BUN,Year2,Week24,n=643	-0.0760 (± 1.6652)			
BUN,Year2,Week48,n=598	0.0631 (± 1.6429)			
BUN,Year3,Week24,n=535	0.0524 (± 1.6850)			
BUN,Year3,Week48,n=488	-0.1013 (± 1.6910)			

BUN,Year4,Week24,n=439	0.0967 (± 1.9398)			
BUN,Year 4,Week48,n=421	0.0672 (± 2.1393)			
BUN,Year5,Week24,n=393	-0.0291 (± 2.0169)			
BUN,Year5,Week48,n=362	0.0899 (± 2.0903)			
BUN,Year6,Week24,n=304	0.0959 (± 1.9852)			
BUN,Year6,Week48,n=286	0.2325 (± 2.2724)			
BUN,Year7,Week24,n=183	-0.0026 (± 1.6623)			
BUN,Year7,Week48,n=130	0.1455 (± 1.7145)			
BUN,Year8,Week24,n=52	0.5458 (± 1.7299)			
BUN,Year8,Week48,n=13	0.3883 (± 1.4603)			
BUN,Year9,Week24,n=6	0.1648 (± 1.0466)			
BUN,Year9,Week48,n=1	0.5700 (± 99999)			
BUN,Exit,n=625	0.2448 (± 2.4618)			
BUN,8 Week Follow up,n=539	0.0822 (± 2.5567)			
Glucose,Year1,Week4,n=707	-0.0031 (± 1.0221)			
Glucose,Year1,Week12,n=705	0.0333 (± 1.0627)			
Glucose,Year1,Week24,n=702	-0.0396 (± 1.2656)			
Glucose,Year1,Week36,n=684	0.0099 (± 1.0269)			
Glucose,Year1,Week48,n=693	0.0010 (± 1.1726)			
Glucose,Year2,Week24,n=643	0.0143 (± 1.3227)			
Glucose,Year2,Week48,n=598	-0.0082 (± 1.1352)			
Glucose,Year3,Week24,n=535	-0.0159 (± 1.3222)			
Glucose,Year3,Week48,n=488	0.0309 (± 1.1841)			
Glucose,Year4,Week24,n=439	-0.0160 (± 1.2213)			
Glucose,Year 4,Week48,n=421	-0.0259 (± 1.1936)			
Glucose,Year5,Week24,n=393	0.0554 (± 1.1255)			
Glucose,Year5,Week48,n=362	0.0655 (± 1.2946)			
Glucose,Year6,Week24,n=303	0.1290 (± 1.1163)			
Glucose,Year6,Week48,n=286	0.2001 (± 1.2411)			
Glucose,Year7,Week24,n=183	0.2303 (± 1.0514)			
Glucose,Year7,Week48,n=130	0.2335 (± 0.8346)			

Glucose,Year8,Week24,n=52	0.3301 (± 0.9052)			
Glucose,Year8,Week48,n=13	0.1431 (± 0.8115)			
Glucose,Year9,Week24,n=6	0.2128 (± 0.4914)			
Glucose,Year9,Week48,n=1	0.4739 (± 99999)			
Glucose,Exit,n=624	0.1842 (± 1.8723)			
Glucose,8 Week Follow up,n=539	0.0338 (± 1.4139)			

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Creatinine (Cr) and Urate at the Indicated Time Points

End point title	Change From Baseline in Creatinine (Cr) and Urate at the Indicated Time Points[14]

End point description:

Other chemistries parameters were assessed at Baseline, Week 4,12,24,36, and 48 during Year 1. From Year 2-9 other chemistries were assessed at Week 24 and 48 ; Exit visit and at follow-up (up to 8 weeks post infusion). Change from Baseline in Cr and Urate were summarized. The Baseline is defined as For Year 1, Day 0 values for MITT participants who were treated with placebo in the parent study, and the last pre-treatment value in the parent study for MITT participants who were treated with belimumab in the parent study. Change from Baseline is defined as the difference between the post-dose post-Baseline visit value and the Baseline value. Only those participants available at the specified time points (represented by n=X in the category titles) were analyzed. 99999 indicates standard deviation was not calculable for a single data point.

End point type	Primary

End point timeframe:

Baseline and up to 9 years

Notes:

[14] - 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: There are no statistical data to report.

End point values	Belimumab 10mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	735			
Units: Micromoles per liter (µmol/L)				
arithmetic mean (standard deviation)				
Urate,Year1,Week4,n=707	1.0332 (± 45.8504)			
Urate,Year1,Week12,n=704	0.4089 (± 54.3182)			
Urate,Year1,Week24,n=703	-0.0510 (± 49.2328)			
Urate,Year1,Week36,n=684	0.6713 (± 50.7341)			
Urate,Year1,Week48,n=693	-1.5147 (± 50.5928)			

Urate,Year2,Week24,n=643	2.7246 (± 55.7467)			
Urate,Year2,Week48,n=598	4.1255 (± 60.0251)			
Urate,Year3,Week24,n=535	6.7497 (± 60.4118)			
Urate,Year3,Week48,n=488	6.9744 (± 63.6876)			
Urate,Year4,Week24,n=439	5.9658 (± 66.6167)			
Urate,Year 4,Week48,n=421	4.0772 (± 67.9587)			
Urate,Year5,Week24,n=393	-0.5634 (± 66.9130)			
Urate,Year5,Week48,n=362	-0.8979 (± 67.3843)			
Urate,Year6,Week24,n=304	2.9530 (± 62.3168)			
Urate,Year6,Week48,n=286	1.1244 (± 67.3175)			
Urate,Year7,Week24,n=183	2.1521 (± 53.0854)			
Urate,Year7,Week48,n=130	4.0062 (± 58.3577)			
Urate,Year8,Week24,n=52	-1.1003 (± 51.8840)			
Urate,Year8,Week48,n=13	29.2043 (± 80.1811)			
Urate,Year9,Week24,n=6	0.2187 (± 45.1947)			
Urate,Year9,Week48,n=1	-69.6640 (± 99999)			
Urate,Exit,n=625	1.6479 (± 74.4078)			
Urate,8 Week Follow up,n=539	-2.7404 (± 75.5887)			
Cr,Year1,Week4,n=707	0.913 (± 14.2222)			
Cr,Year1,Week12,n=705	0.751 (± 14.0933)			
Cr,Year1,Week24,n=703	0.823 (± 9.5372)			
Cr,Year1,Week36,n=684	1.313 (± 13.1107)			
Cr,Year1,Week48,n=693	0.439 (± 11.1364)			
Cr,Year2,Week24,n=643	-0.217 (± 13.9502)			
Cr,Year2,Week48,n=598	-0.922 (± 13.6541)			
Cr,Year3,Week24,n=535	-3.870 (± 17.8146)			
Cr,Year3,Week48,n=488	-4.844 (± 17.7059)			
Crea,Year4,Week24,n=439	-3.196 (± 22.2874)			
Crea,Year 4,Week48,n=421	-2.145 (± 30.9370)			
Cr,Year5,Week24,n=393	-1.999 (± 32.6689)			
Cr,Year5,Week48,n=362	-1.918 (± 28.8788)			

Cr,Year6,Week24,n=304	-2.125 (± 24.2374)			
Cr,Year6,Week48,n=286	-1.534 (± 28.8012)			
Cr,Year7,Week24,n=183	-2.511 (± 15.6881)			
Cr,Year7,Week48,n=130	-2.586 (± 14.0864)			
Cr,Year8,Week24,n=52	-4.659 (± 16.3056)			
Cr,Year8,Week48,n=13	-6.175 (± 6.6311)			
Cr,Year9,Week24,n=6	-8.933 (± 5.6925)			
Cr,Year9,Week48,n=1	0.040 (± 99999)			
Cr,Exit,n=624	0.606 (± 35.9813)			
Cr,8 Week Follow up,n=539	-1.108 (± 39.0635)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in alanine aminotransferase (ALT), alkaline phosphatase (ALP), aspartate aminotransferase (AST), gamma-glutamyl transferase (GGT) and lactate dehydrogenase (LDH) levels

End point title	Change from Baseline in alanine aminotransferase (ALT), alkaline phosphatase (ALP), aspartate aminotransferase (AST), gamma-glutamyl transferase (GGT) and lactate dehydrogenase (LDH) levels[15]

End point description:

Liver function parameters were assessed at Baseline, Week 4,12,24,36, and 48 during Year 1. From Year 2-9 liver function parameters were assessed at Week 24 and 48 ; Exit visit and at follow-up (up to 8 weeks post infusion). Change from Baseline in ALT, ALP, AST, GGT and LDH were summarized. The Baseline is defined as For Year 1, Day 0 values for MITT participants who were treated with placebo in the parent study, and the last pre-treatment value in the parent study for MITT participants who were treated with belimumab in the parent study. Change from Baseline is defined as the difference between the post-dose post-Baseline visit value and the Baseline value. Only those participants available at the specified time points (represented by n=X in the category titles) were analyzed. 99999 indicates standard deviation was not calculable for a single data point.

End point type	Primary

End point timeframe:

Baseline and up to 9 years

Notes:

[15] - 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: There are no statistical data to report.

End point values	Belimumab 10mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	735			
Units: International Units/liter (IU/L)				
arithmetic mean (standard deviation)				
ALT, Year 1 Week 4, n=707	-0.4 (± 10.18)			

ALT, Year 1 Week 12, n=705	-0.9 (± 12.31)			
ALT, Year 1 Week 24, n=703	-0.9 (± 19.46)			
ALT, Year 1 Week 36, n=684	-1.0 (± 15.61)			
ALT, Year 1 Week 48, n=693	-0.7 (± 15.04)			
ALT, Year 2 Week 24, n=643	0.2 (± 23.56)			
ALT, Year 2 Week 48, n=598	2.7 (± 57.67)			
ALT, Year 3 Week 24, n=535	-1.3 (± 14.40)			
ALT, Year 3 Week 48, n=488	0.1 (± 21.21)			
ALT, Year 4 Week 24, n=439	-0.1 (± 18.72)			
ALT, Year 4 Week 48, n=421	-0.6 (± 17.59)			
ALT, Year 5 Week 24, n=393	-1.3 (± 18.74)			
ALT, Year 5 Week 48, n=362	-0.4 (± 22.72)			
ALT, Year 6 Week 24, n=304	-0.2 (± 20.54)			
ALT, Year 6 Week 48, n=286	0.9 (± 20.94)			
ALT, Year 7 Week 24, n=183	1.3 (± 19.46)			
ALT, Year 7 Week 48, n=130	-0.1 (± 16.79)			
ALT, Year 8 Week 24, n=52	2.7 (± 31.15)			
ALT, Year 8 Week 48, n=13	5.8 (± 33.54)			
ALT, Year 9 Week 24, n=6	9.3 (± 27.77)			
ALT, Year 9 Week 48, n=1	-6.0 (± 99999)			
ALT, Exit, n=624	-0.6 (± 17.03)			
ALT, 8 Week follow-up, n=539	-0.8 (± 17.06)			
ALP, Year 1 Week 4, n=707	0.0 (± 11.85)			
ALP, Year 1 Week 12, n=705	0.5 (± 13.31)			
ALP, Year 1 Week 24, n=703	2.1 (± 17.76)			
ALP, Year 1 Week 36, n=684	1.7 (± 22.81)			
ALP, Year 1 Week 48, n=693	4.6 (± 21.18)			
ALP, Year 2 Week 24, n=643	5.1 (± 21.58)			
ALP, Year 2 Week 48, n=598	6.1 (± 23.23)			
ALP, Year 3 Week 24, n=535	5.9 (± 18.95)			
ALP, Year 3 Week 48, n=488	7.3 (± 22.22)			
ALP, Year 4 Week 24, n=439	7.2 (± 21.56)			
ALP, Year 4 Week 48, n=421	8.1 (± 27.35)			
ALP, Year 5 Week 24, n=393	7.2 (± 21.01)			
ALP, Year 5 Week 48, n=362	8.5 (± 20.61)			
ALP, Year 6 Week 24, n=304	9.4 (± 23.28)			
ALP, Year 6 Week 48, n=286	11.5 (± 27.39)			
ALP, Year 7 Week 24, n=183	10.9 (± 28.08)			
ALP, Year 7 Week 48, n=130	7.5 (± 22.50)			
ALP, Year 8 Week 24, n=52	12.9 (± 26.64)			
ALP, Year 8 Week 48, n=13	6.1 (± 30.04)			
ALP, Year 9 Week 24, n=6	4.2 (± 35.43)			
ALP, Year 9 Week 48, n=1	12.0 (± 99999)			
ALP, Exit, n=625	7.5 (± 25.35)			
ALP, 8 Week follow-up, n=539	6.1 (± 23.00)			
AST, Year 1 Week 4, n=701	-0.6 (± 10.56)			
AST, Year 1 Week 12, n=700	-1.3 (± 14.12)			
AST, Year 1 Week 24, n=701	-1.0 (± 20.79)			
AST, Year 1 Week 36, n=682	-1.0 (± 17.88)			
AST, Year 1 Week 48, n=692	-0.9 (± 14.38)			
AST, Year 2 Week 24, n=641	-0.4 (± 22.22)			
AST, Year 2 Week 48, n=592	2.9 (± 57.25)			

AST, Year 3 Week 24, n=531	-1.4 (± 13.26)			
AST, Year 3 Week 48, n=486	-0.5 (± 17.23)			
AST, Year 4 Week 24, n=438	-0.9 (± 14.60)			
AST, Year 4 Week 48, n=418	-0.7 (± 15.32)			
AST, Year 5 Week 24, n=393	-1.3 (± 16.07)			
AST, Year 5 Week 48, n=362	-0.8 (± 18.57)			
AST, Year 6 Week 24, n=303	-0.5 (± 16.95)			
AST, Year 6 Week 48, n=284	-0.2 (± 19.00)			
AST, Year 7 Week 24, n=182	0.6 (± 13.43)			
AST, Year 7 Week 48, n=130	-0.3 (± 10.78)			
AST, Year 8 Week 24, n=52	3.0 (± 33.93)			
AST, Year 8 Week 48, n=13	5.8 (± 24.01)			
AST, Year 9 Week 24, n=6	7.7 (± 19.63)			
AST, Year 9 Week 48, n=1	0.0 (± 99999)			
AST, Exit, n=625	-0.6 (± 18.88)			
AST, 8 Week follow-up, n=539	-1.1 (± 16.58)			
GGT, Year 1 Week 4, n=707	-0.4 (± 23.39)			
GGT, Year 1 Week 12, n=705	-1.4 (± 23.12)			
GGT, Year 1 Week 24, n=703	-0.2 (± 39.50)			
GGT, Year 1 Week 36, n=684	1.0 (± 64.60)			
GGT, Year 1 Week 48, n=693	0.9 (± 35.99)			
GGT, Year 2 Week 24, n=643	-0.7 (± 34.81)			
GGT, Year 2 Week 48, n=598	0.1 (± 34.63)			
GGT, Year 3 Week 24, n=535	-1.6 (± 33.88)			
GGT, Year 3 Week 48, n=488	1.7 (± 45.42)			
GGT, Year 4 Week 24, n=439	0.1 (± 39.13)			
GGT, Year 4 Week 48, n=421	1.1 (± 54.41)			
GGT, Year 5 Week 24, n=393	-2.0 (± 37.17)			
GGT, Year 5 Week 48, n=362	-0.7 (± 43.39)			
GGT, Year 6 Week 24, n=304	-1.0 (± 42.04)			
GGT, Year 6 Week 48, n=286	1.3 (± 41.84)			
GGT, Year 7 Week 24, n=183	1.8 (± 37.06)			
GGT, Year 7 Week 48, n=130	-1.0 (± 27.86)			
GGT, Year 8 Week 24, n=52	2.7 (± 39.90)			
GGT, Year 8 Week 48, n=13	-0.3 (± 27.97)			
GGT, Year 9 Week 24, n=6	13.3 (± 26.96)			
GGT, Year 9 Week 48, n=1	-7.0 (± 99999)			
GGT, Exit, n=625	0.7 (± 41.40)			
GGT, 8 Week follow-up, n=539	0.2 (± 39.22)			
LDH, Year 1 Week 4, n=701	-4.1 (± 77.93)			
LDH, Year 1 Week 12, n=700	-6.0 (± 80.55)			
LDH, Year 1 Week 24, n=701	-6.6 (± 80.09)			
LDH, Year 1 Week 36, n=682	-8.8 (± 80.05)			
LDH, Year 1 Week 48, n=692	-7.3 (± 81.32)			
LDH, Year 2 Week 24, n=641	-9.4 (± 85.83)			
LDH, Year 2 Week 48, n=592	-9.6 (± 95.52)			
LDH, Year 3 Week 24, n=532	-11.8 (± 93.90)			
LDH, Year 3 Week 48, n=486	-15.1 (± 94.65)			
LDH, Year 4 Week 24, n=438	-16.5 (± 99.93)			

LDH, Year 4 Week 48, n=418	-16.9 (± 102.11)			
LDH, Year 5 Week 24, n=393	-17.5 (± 106.45)			
LDH, Year 5 Week 48, n=362	-19.8 (± 108.33)			
LDH, Year 6 Week 24, n=303	-21.7 (± 115.77)			
LDH, Year 6 Week 48, n=284	-21.3 (± 122.62)			
LDH, Year 7 Week 24, n=182	-15.2 (± 44.05)			
LDH, Year 7 Week 48, n=130	-16.3 (± 42.51)			
LDH, Year 8 Week 24, n=52	-14.3 (± 40.14)			
LDH, Year 8 Week 48, n=13	-31.5 (± 53.04)			
LDH, Year 9 Week 24, n=6	-27.2 (± 32.64)			
LDH, Year 9 Week 48, n=1	-65.0 (± 99999)			
LDH, Exit, n=624	-13.1 (± 90.39)			
LDH, 8 Week follow-up, n=538	-12.7 (± 95.65)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in bilirubin (bili) levels

End point title	Change from Baseline in bilirubin (bili) levels[16]

End point description:

Liver function parameters were assessed at Baseline, Week 4,12,24,36, and 48 during Year 1. From Year 2-9 liver function parameters were assessed at Week 24 and 48 ; Exit visit and at follow-up (up to 8 weeks post infusion). Change from Baseline in Bili were summarized. The Baseline is defined as For Year 1, Day 0 values for MITT participants who were treated with placebo in the parent study, and the last pre-treatment value in the parent study for MITT participants who were treated with belimumab in the parent study. Change from Baseline is defined as the difference between the post-dose post-Baseline visit value and the Baseline value. Only those participants available at the specified time points (represented by n=X in the category titles) were analyzed. 99999 indicates standard deviation was not calculable for a single data point.

End point type	Primary

End point timeframe:

Baseline and up to 9 years

Notes:

[16] - 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: There are no statistical data to report.

End point values	Belimumab 10mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	735			
Units: µmol/L				
arithmetic mean (standard deviation)				
Year 1 Week 4, n=707	0.142 (± 2.8398)			
Year 1 Week 12, n=705	0.008 (± 2.6383)			
Year 1 Week 24, n=703	0.217 (± 3.1280)			
Year 1 Week 36, n=684	0.173 (± 2.7566)			
Year 1 Week 48, n=693	0.367 (± 2.8441)			
Year 2 Week 24, n=643	0.488 (± 2.9346)			
Year 2 Week 48, n=598	0.540 (± 3.2181)			
Year 3 Week 24, n=535	0.606 (± 3.1612)			
Year 3 Week 48, n=488	0.637 (± 3.2474)			
Year 4 Week 24, n=439	0.548 (± 2.9773)			
Year 4 Week 48, n=421	0.629 (± 3.4680)			
Year 5 Week 24, n=393	0.410 (± 2.6931)			
Year 5 Week 48, n=362	0.788 (± 3.1324)			
Year 6 Week 24, n=304	0.801 (± 2.9946)			
Year 6 Week 48, n=285	0.638 (± 3.0669)			
Year 7 Week 24, n=183	0.938 (± 2.8158)			
Year 7 Week 48, n=130	1.129 (± 3.0314)			
Year 8 Week 24, n=52	1.280 (± 3.0707)			
Year 8 Week 48, n=13	0.768 (± 3.0434)			
Year 9 Week 24, n=6	0.028 (± 2.0182)			
Year 9 Week 48, n=1	-2.870 (± 99999)			
Exit, n=624	0.573 (± 3.3274)			
8 Week follow-up, n=539	0.572 (± 3.1052)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in immunoglobulin G (IgG) levels

End point title	Change from Baseline in immunoglobulin G (IgG) levels[17]

End point description:

Immunoglobulin (Ig) parameters were assessed at Baseline, Week 4,12,24,36, and 48 during Year 1. From Year 2-9 Ig parameters were assessed at Week 24 and 48 ; Exit visit and at follow-up (up to 8 weeks post infusion). Change from Baseline in Ig G were summarized. The Baseline is defined as For Year 1, Day 0 values for MITT participants who were treated with placebo in the parent study, and the last pre-treatment value in the parent study for MITT participants who were treated with belimumab in the parent study. Change from Baseline is defined as the difference between the post-dose post-Baseline visit value and the Baseline value. Only those participants available at the specified time points (represented by n=X in the category titles) were analyzed. 99999 indicates standard deviation was not calculable for a single data point.

End point type	Primary

End point timeframe:

Baseline and up to 9 years

Notes:

[17] - 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: There are no statistical data to report.

End point values	Belimumab 10mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	735			
Units: g/L				
arithmetic mean (standard deviation)				
Year 1 Week 12, n=213	-1.571 (± 2.2970)			
Year 1 Week 24, n=709	-1.963 (± 2.7334)			
Year 1 Week 48, n=695	-2.507 (± 3.1054)			
Year 2 Week 24, n=482	-3.058 (± 3.6147)			
Year 2 Week 48, n=605	-3.232 (± 3.7414)			
Year 3 Week 24, n=143	-3.453 (± 3.7073)			
Year 3 Week 48, n=405	-3.791 (± 4.0450)			
Year 4 Week 24, n=146	-3.839 (± 4.1411)			
Year 4 Week 48, n=362	-3.794 (± 3.8780)			
Year 5 Week 24, n=111	-4.356 (± 3.6399)			
Year 5 Week 48, n=322	-4.323 (± 4.0169)			
Year 6 Week 24, n=71	-5.111 (± 3.8846)			
Year 6 Week 48, n=268	-4.697 (± 3.9599)			
Year 7 Week 24, n=50	-4.803 (± 3.5908)			
Year 7 Week 48, n=115	-4.982 (± 4.0769)			
Year 8 Week 24, n=18	-6.016 (± 3.8450)			
Year 8 Week 48, n=12	-5.520 (± 5.1564)			

Year 9 Week 48, n=1	0.710 (± 99999)			
Exit, n=627	-4.138 (± 4.0025)			
8 Week Follow up, n=543	-4.325 (± 4.0246)			

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with immunogenic response by year

End point title	Number of participants with immunogenic response by year[18]

End point description:

Immunogenic response was analyzed using serum samples for anti-belimumab antibody measurements in MITT population. Categories of response are Negative, Transient Positive (+) means single + response that does not occur at the final assessment, and Persistent + means + response that occurs at least 2 consecutive assessments or a single result at the final assessment. Only those participants available at the specified time points (represented by n=X in the category titles) were analyzed.

End point type	Primary

End point timeframe:

Up to 9 years

Notes:

[18] - 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: There are no statistical data to report.

End point values	Belimumab 10mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	735			
Units: Participants				
Year 0-1 Negative, n=717	707			
Year 1-2 Negative, n=684	656			
Year 2-3 Negative, n=590	577			
Year 3-4, Negative, n=502	498			
Year 4-5 Negative, n=432	432			
Year 5-6 Negative, n=336	336			
Year 6-7 Negative, n=212	212			
Year 7-8 Negative, n=64	64			
Year 8 plus Negative, n=6	6			
Year 0-1 Transient +, n=717	10			
Year 1-2 Transient + n=684	18			
Year 2-3 Transient +, n=590	9			
Year 3-4 Transient +, n=502	4			
Year 4-5 Transient +, n=432	0			
Year 5-6 Transient +, n=336	0			
Year 6-7 Transient +, n=212	0			
Year 7-8 Transient +, n=64	0			
Year 8 plus Transient +, n=6	0			
Year 0-1 Persistent+,n=717	0			
Year 1-2 Persistent+,n=684	10			

Year 2-3 Persistent+,n=590	3			
Year 3-4 Persistent+,n=502	0			
Year 4-5 Persistent+,n=432	0			
Year 5-6 Persistent+,n=336	0			
Year 6-7 Persistent+,n=212	0			
Year 7-8 Persistent+,n=64	0			
Year 8 plus Persistent+,n=6	0			
Year 0-1 Unknown, n=717	0			
Year 1-2 Unknown, n=684	0			
Year 2-3 Unknown, n=590	1			
Year 3-4 Unknown, n=502	0			
Year 4-5 Unknown, n=432	0			
Year 5-6 Unknown, n=336	0			
Year 6-7 Unknown, n=212	0			
Year 7-8 Unknown, n=64	0			
Year 8 plus Unknown, n=6	0			

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with IgG values below the lower limit of normal by year

End point title	Number of participants with IgG values below the lower limit of normal by year[19]

End point description:

Blood samples were collected to evaluate IgG levels at Baseline and at Weeks 12, 24 and 48 during Year 1. From Year 2-9, IgG was evaluated at Week 24 and 48 ; Exit visit and at follow-up visit (up to 8 weeks post last infusion). Number of participants with IgG immunoglobulin values below the LLN at each one year interval are presented. Baseline includes Extension Year 1 Day 0 values for MITT participants treated with placebo in the parent study, and the last pre-treatment value in the parent study for MITT participants treated with Belimumab in the parent study. If a participant had more than one response within a year, then the last response within the year interval (usually the Week 48 assessment) was summarized. Only those participants available at the specified time points (represented by n=X in the category titles) were analyzed.

End point type	Primary

End point timeframe:

Up to 9 years

Notes:

[19] - 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: There are no statistical data to report.

End point values	Belimumab 10mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	735			
Units: Participants				
Baseline, n=735	6			
Any Time Post Baseline, n=735	64			
Year 0-1, n=735	22			
Year 1-2, n=701	24			
Year 2-3, n=620	22			

Year 3-4, n=514	19			
Year 4-5, n=442	15			
Year 5-6, n=345	10			
Year 6-7, n=219	8			
Year 7-8, n=65	2			
More than 8 Years, n=6	0			

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with shifts from Baseline in Prednisone and other steroids dose by visit

End point title	Number of participants with shifts from Baseline in Prednisone and other steroids dose by visit[20]

End point description:

Participants who had improving SLE disease activity for at least 8 weeks, at the investigator's discretion, the steroid dose was reduced by reduction to 7.5 mg/day. If the participant continued to have stable or improving disease activity after 4 weeks on a reduced dose, then the investigator considered reducing the dose again. Baseline includes extension Year 1 Day 0 values for MITT participants treated with placebo in the parent study, and the last pre-treatment value in the parent study for MITT participants treated with Belimumab in the parent study. Number of participants with shifts from Baseline total daily dose category by visit is summarized.

End point type	Primary

End point timeframe:

Up to 9 years

Notes:

[20] - 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: There are no statistical data to report.

End point values	participants with no prednisone and other steroids at baseline	participants with baseline daily dose of >0 to <=7.5 mg	participants with baseline daily dose of >7.5 to <=40 mg	participants with baseline daily dose of >40 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	227	462	1
Units: Participants				
Total daily dose=0, Year 1, Week 24	40	5	1	0
Total daily dose >0 to <=7.5, Year 1, Week 24	1	194	71	0
Total daily dose >7.5 to <=40, Year 1, Week 24	2	18	376	1
Total daily dose >40, Year 1, Week 24	0	0	1	0
Total daily dose=0, Year 1, Week 48	40	13	13	0
Total daily dose >0 to <=7.5, Year 1, Week 48	2	180	123	0
Total daily dose >7.5 to <=40, Year 1, Week 48	0	19	301	1
Total daily dose >40, Year 1, Week 48	1	0	4	0
Total daily dose=0, Year 2, Week 24	39	19	20	0
Total daily dose >0 to <=7.5, Year 2, Week 24	3	157	145	0

Total daily dose >7.5 to <=40, Year 2, Week 24	0	25	237	1
Total daily dose >40, Year 2, Week 24	0	0	5	0
Total daily dose=0, Year 2, Week 48	36	24	21	0
Total daily dose >0 to <=7.5, Year 2, Week 48	1	143	163	0
Total daily dose >7.5 to <=40, Year 2, Week 48	1	26	195	1
Total daily dose >40, Year 2, Week 48	0	0	1	0
Total daily dose=0, Year 3, Week 24	33	19	25	0
Total daily dose >0 to <=7.5, Year 3, Week 24	3	130	159	0
Total daily dose >7.5 to <=40, Year 3, Week 24	1	27	157	1
Total daily dose >40, Year 3, Week 24	0	0	0	0
Total daily dose=0, Year 3, Week 48	31	20	30	0
Total daily dose >0 to <=7.5, Year 3, Week 48	3	122	127	0
Total daily dose >7.5 to <=40, Year 3, Week 48	0	23	145	1
Total daily dose >40, Year 3, Week 48	0	0	2	0
Total daily dose=0, Year 4, Week 24	28	17	34	0
Total daily dose >0 to <=7.5, Year 4, Week 24	3	110	134	0
Total daily dose >7.5 to <=40, Year 4, Week 24	2	23	120	1
Total daily dose >40, Year 4, Week 24	0	0	2	0
Total daily dose=0, Year 4, Week 48	22	18	40	0
Total daily dose >0 to <=7.5, Year 4, Week 48	3	100	129	1
Total daily dose >7.5 to <=40, Year 4, Week 48	1	16	108	0
Total daily dose >40, Year 4, Week 48	0	1	0	0
Total daily dose=0, Year 5, Week 24	19	28	33	0
Total daily dose >0 to <=7.5, Year 5, Week 24	3	84	124	1
Total daily dose >7.5 to <=40, Year 5, Week 24	1	16	99	0
Total daily dose >40, Year 5, Week 24	0	0	2	0
Total daily dose=0, Year 5, Week 48	17	26	34	0
Total daily dose >0 to <=7.5, Year 5, Week 48	1	75	119	1
Total daily dose >7.5 to <=40, Year 5, Week 48	1	13	85	0
Total daily dose >40, Year 5, Week 48	0	0	0	0
Total daily dose=0, Year 6, Week 24	10	25	33	0
Total daily dose >0 to <=7.5, Year 6, Week 24	2	62	99	1
Total daily dose >7.5 to <=40, Year 6, Week 24	0	10	76	0
Total daily dose >40, Year 6, Week 24	0	0	2	0
Total daily dose=0, Year 6, Week 48	10	24	35	0
Total daily dose >0 to <=7.5, Year 6, Week 48	1	54	90	1
Total daily dose >7.5 to <=40, Year 6, Week 48	0	11	68	0
Total daily dose >40, Year 6, Week 48	0	0	0	0
Total daily dose=0, Year 7, Week 24	4	10	29	0

Total daily dose >0 to <=7.5, Year 7, Week 24	0	41	64	1
Total daily dose >7.5 to <=40, Year 7, Week 24	1	3	40	0
Total daily dose >40, Year 7, Week 24	0	0	0	0
Total daily dose=0, Year 7, Week 48	4	3	24	0
Total daily dose >0 to <=7.5, Year 7, Week 48	0	32	34	1
Total daily dose >7.5 to <=40, Year 7, Week 48	0	6	29	0
Total daily dose >40, Year 7, Week 48	0	0	0	0
Total daily dose=0, Year 8, Week 24	2	1	8	0
Total daily dose >0 to <=7.5, Year 8, Week 24	0	13	15	1
Total daily dose >7.5 to <=40, Year 8, Week 24	0	2	11	0
Total daily dose >40, Year 8, Week 24	0	0	0	0
Total daily dose=0, Year 8, Week 48	1	0	5	0
Total daily dose >0 to <=7.5, Year 8, Week 48	0	3	6	0
Total daily dose >7.5 to <=40, Year 8, Week 48	0	2	1	0
Total daily dose >40, Year 8, Week 48	0	0	0	0
Total daily dose=0, Year 9, Week 24	0	0	1	0
Total daily dose >0 to <=7.5, Year 9, Week 24	0	1	3	0
Total daily dose >7.5 to <=40, Year 9, Week 24	0	1	0	0
Total daily dose >40, Year 9, Week 24	0	0	0	0
Total daily dose=0, Year 9, Week 48	0	0	0	0
Total daily dose >0 to <=7.5, Year 9, Week 48	0	1	4	0
Total daily dose >7.5 to <=40, Year 9, Week 48	0	1	0	0
Total daily dose >40, Year 9, Week 48	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with any SLICC/ ACR Damage Index worsening (change > 0) from Baseline by visit

End point title	Number of participants with any SLICC/ ACR Damage Index worsening (change > 0) from Baseline by visit[21]

End point description:

The SLICC/ACR Damage Index was assessed every 48 weeks and at the exit visit as a measure of disease activity. It was developed to assess the accumulated damage since the onset of the disease. The number of participants with worsening in their SLICC/ACR Damage Index score compared with Baseline have been presented. Worsening was defined as a change in score (post-Baseline visit score – Baseline score) > 0. Baseline includes extension Year 1 Day 0 values for MITT participants treated with placebo in the parent study, and the last pre-treatment value in the parent study for MITT participants treated with Belimumab in the parent study. For years in which a participant was withdrawn from the study, the exit visit assessment was used in place of the Week 48 assessment for the year. This value was not carried forward through later years. Only those participants available at the specified time points (represented by n=X in the category titles) were analyzed.

End point type	Primary

End point timeframe:

Up to 9 years

Notes:

[21] - 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: There are no statistical data to report.

End point values	Belimumab 10mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	735			
Units: Participants				
Year 1,Week 48, n=716	39			
Year 2,Week 48, n=667	50			
Year 3,Week 48, n=580	56			
Year 4,Week 48, n=488	57			
Year 5,Week 48, n=423	51			
Year 6,Week 48, n=330	41			
Year 7,Week 48, n=213	28			
Year 8,Week 48, n=65	8			
Year 9,Week 48, n=6	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

On-treatment SAEs and non-serious adverse events (AEs) were collected from the start of investigational product and until 8 Weeks after the last infusion of trial medication (Approximately 8 years plus)

Adverse event reporting additional description:

The MITT consisted of all randomized participants who received at least one dose of trial medication.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.1

Reporting groups

Reporting group title	Belimumab 10mg/kg IV

Reporting group description:

Participants received belimumab every 28 days by intravenous (IV) infusion at 1 milligram per kilogram (mg/kg) or 10 mg/kg body weight. Participants who received either 1 mg/kg or 10 mg/kg belimumab in their parent studies continued to receive the same dose of belimumab. Participants randomized to receive placebo in the parent studies received 10 mg/kg beliumamb. Subsequently, the dose of belimumab for participants receiving 1 mg/kg was increased to 10 mg/kg .All participants also received SoC SLE therapy while participating in this trial.

Serious adverse events	Belimumab 10mg/kg IV		
Total subjects affected by serious adverse events			
subjects affected / exposed	231 / 735 (31.43%)		
number of deaths (all causes)	11		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cervix carcinoma stage 0			
subjects affected / exposed	2 / 735 (0.27%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Uterine leiomyoma			
subjects affected / exposed	2 / 735 (0.27%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Benign breast neoplasm			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

Benign neoplasm of skin			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bowen's disease			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Intraductal papilloma of breast			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Invasive ductal breast carcinoma			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Papillary thyroid cancer			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Rectal adenocarcinoma			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rectal cancer			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Vulval cancer stage 0			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			

Raynaud's phenomenon				
subjects affected / exposed	5 / 735 (0.68%)			
occurrences causally related to treatment / all	0 / 9			
deaths causally related to treatment / all	0 / 0			
Lupus vasculitis				
subjects affected / exposed	4 / 735 (0.54%)			
occurrences causally related to treatment / all	1 / 4			
deaths causally related to treatment / all	0 / 0			
Hypertension				
subjects affected / exposed	3 / 735 (0.41%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Deep vein thrombosis				
subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Vasculitis				
subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Aortic dissection				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Aortic stenosis				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypertensive crisis				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Peripheral arterial occlusive disease				

subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Peripheral ischaemia				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Peripheral artery stenosis				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Varicose vein				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pregnancy, puerperium and perinatal conditions				
Abortion spontaneous				
subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Gestational diabetes				
subjects affected / exposed	1 / 735 (0.14%)			
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	9 / 735 (1.22%)			
occurrences causally related to treatment / all	1 / 10			
deaths causally related to treatment / all	0 / 0			
Non-cardiac chest pain				
subjects affected / exposed	4 / 735 (0.54%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			

Complication associated with device			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cyst			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Face oedema			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fatigue			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oedema peripheral			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pain			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral swelling			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	2 / 735 (0.27%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast			

disorders				
Cervical dysplasia				
subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Ovarian cyst				
subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	0 / 0			
Dysfunctional uterine bleeding				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Endometriosis				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Haemorrhagic ovarian cyst				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ovarian cyst ruptured				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Ovarian cyst torsion				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Parovarian cyst				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Uterine haemorrhage				

subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Uterine polyp				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Pulmonary embolism				
subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Acute respiratory distress syndrome				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Acute respiratory failure				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Asthma				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Atelectasis				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Epistaxis				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haemoptysis				

subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haemothorax				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Interstitial lung disease				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lower respiratory tract inflammation				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lupus pneumonitis				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary congestion				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary haemorrhage				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Respiratory distress				

subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Rhinitis hypertrophic				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Anxiety				
subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Depression				
subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Suicide attempt				
subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Confusional state				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Mania				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Panic attack				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Suicidal ideation				

subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Foot fracture			
subjects affected / exposed	2 / 735 (0.27%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Humerus fracture			
subjects affected / exposed	2 / 735 (0.27%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pelvic fracture			
subjects affected / exposed	2 / 735 (0.27%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Radius fracture			
subjects affected / exposed	2 / 735 (0.27%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Ankle fracture			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Contusion			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Craniocerebral injury			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Femoral neck fracture			

subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Fibula fracture				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hip fracture				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Joint dislocation				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Laceration				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ligament sprain				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lower limb fracture				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Post procedural fistula				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Post procedural haemorrhage				

subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Spinal compression fracture				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Subdural haematoma				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tendon rupture				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tibia fracture				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ulna fracture				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Upper limb fracture				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Myocardial ischaemia				
subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Angina pectoris				

subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Angina unstable				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Aortic valve sclerosis				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Atrioventricular block second degree				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiac arrest				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Cardiac tamponade				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiogenic shock				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	1 / 1			
Coronary artery occlusion				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lupus myocarditis				

subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Myocardial infarction				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Pericardial effusion				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pericarditis				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pericarditis lupus				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sinus tachycardia				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Headache				
subjects affected / exposed	3 / 735 (0.41%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Syncope				
subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Cerebral infarction				

subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cerebral thrombosis				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Extrapyramidal disorder				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypoaesthesia				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	0 / 0			
Intracranial pressure increased				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ischaemic stroke				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Lacunar stroke				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Migraine				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Myasthenia gravis				

subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Neuropsychiatric lupus				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Paraesthesia				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Paraplegia				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tension headache				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Leukopenia				
subjects affected / exposed	8 / 735 (1.09%)			
occurrences causally related to treatment / all	3 / 9			
deaths causally related to treatment / all	0 / 0			
Anaemia				
subjects affected / exposed	7 / 735 (0.95%)			
occurrences causally related to treatment / all	1 / 7			
deaths causally related to treatment / all	0 / 0			
Thrombocytopenia				
subjects affected / exposed	6 / 735 (0.82%)			
occurrences causally related to treatment / all	1 / 7			
deaths causally related to treatment / all	0 / 0			
Haemolytic anaemia				

subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Lymphadenopathy				
subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Neutropenia				
subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	0 / 0			
Agranulocytosis				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Disseminated intravascular coagulation				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Febrile neutropenia				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Haemorrhagic disorder				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Thrombotic thrombocytopenic purpura				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Ear and labyrinth disorders				

Vertigo positional			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Maculopathy			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Gastritis			
subjects affected / exposed	5 / 735 (0.68%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Abdominal pain			
subjects affected / exposed	3 / 735 (0.41%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Pancreatitis acute			
subjects affected / exposed	3 / 735 (0.41%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
Haemorrhoids			
subjects affected / exposed	2 / 735 (0.27%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Oesophagitis			
subjects affected / exposed	2 / 735 (0.27%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	2 / 735 (0.27%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		

Abdominal adhesions			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal hernia			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal pain upper			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Duodenitis			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Food poisoning			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haematemesis			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haemorrhoidal haemorrhage			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ileus			

subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lupus enteritis				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Mouth ulceration				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Proctitis				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rectal ulcer				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Cholelithiasis				
subjects affected / exposed	5 / 735 (0.68%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Biliary dilatation				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cholangitis acute				

subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cholecystitis acute				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gallbladder non-functioning				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lupus hepatitis				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Portal vein thrombosis				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Systemic lupus erythematosus rash				
subjects affected / exposed	3 / 735 (0.41%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Urticaria				
subjects affected / exposed	3 / 735 (0.41%)			
occurrences causally related to treatment / all	3 / 3			
deaths causally related to treatment / all	0 / 0			
Alopecia				
subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Skin ulcer				

subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Drug eruption				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Erythema				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hyperhidrosis				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pemphigoid				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Pyoderma gangrenosum				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
Lupus nephritis				
subjects affected / exposed	12 / 735 (1.63%)			
occurrences causally related to treatment / all	0 / 14			
deaths causally related to treatment / all	0 / 0			
Acute kidney injury				
subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Nephrotic syndrome				

subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Proteinuria				
subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	1 / 3			
deaths causally related to treatment / all	0 / 0			
Bladder diverticulum				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cystitis haemorrhagic				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal colic				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal impairment				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal tubular acidosis				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal tubular necrosis				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Endocrine disorders				
Hyperthyroidism				

subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypothyroidism				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Back pain				
subjects affected / exposed	5 / 735 (0.68%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Osteonecrosis				
subjects affected / exposed	5 / 735 (0.68%)			
occurrences causally related to treatment / all	0 / 10			
deaths causally related to treatment / all	0 / 0			
Arthralgia				
subjects affected / exposed	4 / 735 (0.54%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
SLE arthritis				
subjects affected / exposed	3 / 735 (0.41%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Fibromyalgia				
subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Myalgia				
subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Arthritis				

subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intervertebral disc protrusion			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Kyphosis			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Neck pain			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Osteoarthritis			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Osteochondrosis			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pain in extremity			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pathological fracture			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Pneumonia bacterial			

subjects affected / exposed	14 / 735 (1.90%)			
occurrences causally related to treatment / all	9 / 16			
deaths causally related to treatment / all	0 / 1			
Cellulitis				
subjects affected / exposed	12 / 735 (1.63%)			
occurrences causally related to treatment / all	4 / 14			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	9 / 735 (1.22%)			
occurrences causally related to treatment / all	3 / 9			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection bacterial				
subjects affected / exposed	9 / 735 (1.22%)			
occurrences causally related to treatment / all	2 / 11			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	8 / 735 (1.09%)			
occurrences causally related to treatment / all	5 / 8			
deaths causally related to treatment / all	0 / 1			
Appendicitis				
subjects affected / exposed	6 / 735 (0.82%)			
occurrences causally related to treatment / all	2 / 6			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	5 / 735 (0.68%)			
occurrences causally related to treatment / all	1 / 5			
deaths causally related to treatment / all	0 / 0			
Herpes zoster				
subjects affected / exposed	5 / 735 (0.68%)			
occurrences causally related to treatment / all	5 / 5			
deaths causally related to treatment / all	0 / 0			
Bacterial pyelonephritis				

subjects affected / exposed	3 / 735 (0.41%)			
occurrences causally related to treatment / all	3 / 3			
deaths causally related to treatment / all	0 / 0			
Bacterial sepsis				
subjects affected / exposed	3 / 735 (0.41%)			
occurrences causally related to treatment / all	1 / 3			
deaths causally related to treatment / all	0 / 0			
Septic shock				
subjects affected / exposed	3 / 735 (0.41%)			
occurrences causally related to treatment / all	1 / 4			
deaths causally related to treatment / all	0 / 1			
Viral upper respiratory tract infection				
subjects affected / exposed	3 / 735 (0.41%)			
occurrences causally related to treatment / all	2 / 3			
deaths causally related to treatment / all	0 / 0			
Abscess soft tissue				
subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Acute sinusitis				
subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Bronchitis				
subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Bronchitis bacterial				
subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Cytomegalovirus infection				

subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Diarrhoea infectious				
subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Escherichia infection				
subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis viral				
subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis acute				
subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection viral				
subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	0 / 0			
Soft tissue infection				
subjects affected / exposed	2 / 735 (0.27%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Subcutaneous abscess				

subjects affected / exposed	2 / 735 (0.27%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Wound infection bacterial			
subjects affected / exposed	2 / 735 (0.27%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Abdominal infection			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abscess of salivary gland			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Acinetobacter bacteraemia			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Acinetobacter infection			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Amoebic dysentery			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anal abscess			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Bronchitis viral			

subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bursitis infective				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bursitis infective staphylococcal				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cellulitis staphylococcal				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Cutaneous tuberculosis				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Enterococcal bacteraemia				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Enterocolitis infectious				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Erysipelas				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Escherichia bacteraemia				

subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Escherichia sepsis			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Fungaemia			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis bacterial			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal fungal infection			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal infection			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal viral infection			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatitis A			
subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Herpes zoster cutaneous disseminated			

subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infectious colitis				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infectious pleural effusion				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	0 / 0			
Joint abscess				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Joint tuberculosis				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Kidney infection				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Latent tuberculosis				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Meningitis aseptic				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Osteomyelitis chronic				

subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Parasitic gastroenteritis				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Pelvic inflammatory disease				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Peritonitis				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Peritonitis bacterial				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Postoperative wound infection				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary tuberculosis				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary mycosis				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				

subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Salmonella bacteraemia				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Sialoadenitis				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Skin candida				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Staphylococcal abscess				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Streptococcal bacteraemia				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tracheitis				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tubo-ovarian abscess				

subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection bacterial				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection fungal				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urosepsis				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Dehydration				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypoalbuminaemia				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Hypokalaemia				
subjects affected / exposed	1 / 735 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Obesity				

subjects affected / exposed	1 / 735 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Belimumab 10mg/kg IV		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	614 / 735 (83.54%)		
Vascular disorders			
Hypertension			
subjects affected / exposed	67 / 735 (9.12%)		
occurrences (all)	111		
Hypotension			
subjects affected / exposed	39 / 735 (5.31%)		
occurrences (all)	192		
Nervous system disorders			
Headache			
subjects affected / exposed	205 / 735 (27.89%)		
occurrences (all)	407		
Dizziness			
subjects affected / exposed	61 / 735 (8.30%)		
occurrences (all)	82		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	73 / 735 (9.93%)		
occurrences (all)	92		
Fatigue			
subjects affected / exposed	56 / 735 (7.62%)		
occurrences (all)	61		
Oedema peripheral			
subjects affected / exposed	47 / 735 (6.39%)		
occurrences (all)	56		
Non-cardiac chest pain			

subjects affected / exposed occurrences (all)	38 / 735 (5.17%) 41		
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	 45 / 735 (6.12%) 56		
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all) Abdominal pain subjects affected / exposed occurrences (all) Abdominal pain upper subjects affected / exposed occurrences (all) Gastritis subjects affected / exposed occurrences (all) Vomiting subjects affected / exposed occurrences (all) Dyspepsia subjects affected / exposed occurrences (all)	 143 / 735 (19.46%) 235 64 / 735 (8.71%) 97 60 / 735 (8.16%) 78 60 / 735 (8.16%) 80 52 / 735 (7.07%) 59 50 / 735 (6.80%) 70 39 / 735 (5.31%) 50		
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) Rhinitis allergic subjects affected / exposed occurrences (all)	 120 / 735 (16.33%) 176 37 / 735 (5.03%) 47		
Skin and subcutaneous tissue disorders			

Rash			
subjects affected / exposed	56 / 735 (7.62%)		
occurrences (all)	77		
Alopecia			
subjects affected / exposed	48 / 735 (6.53%)		
occurrences (all)	62		
Pruritus			
subjects affected / exposed	44 / 735 (5.99%)		
occurrences (all)	55		
Psychiatric disorders			
Insomnia			
subjects affected / exposed	55 / 735 (7.48%)		
occurrences (all)	64		
Depression			
subjects affected / exposed	49 / 735 (6.67%)		
occurrences (all)	57		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	134 / 735 (18.23%)		
occurrences (all)	217		
Back pain			
subjects affected / exposed	102 / 735 (13.88%)		
occurrences (all)	141		
Myalgia			
subjects affected / exposed	64 / 735 (8.71%)		
occurrences (all)	77		
Pain in extremity			
subjects affected / exposed	49 / 735 (6.67%)		
occurrences (all)	73		
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	155 / 735 (21.09%)		
occurrences (all)	396		
Influenza			
subjects affected / exposed	132 / 735 (17.96%)		
occurrences (all)	274		

Urinary tract infection bacterial subjects affected / exposed occurrences (all)	87 / 735 (11.84%) 163		
Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	84 / 735 (11.43%) 196		
Upper respiratory tract infection subjects affected / exposed occurrences (all)	82 / 735 (11.16%) 151		
Urinary tract infection subjects affected / exposed occurrences (all)	68 / 735 (9.25%) 99		
Herpes zoster subjects affected / exposed occurrences (all)	55 / 735 (7.48%) 56		
Upper respiratory tract infection bacterial subjects affected / exposed occurrences (all)	54 / 735 (7.35%) 108		
Gastroenteritis subjects affected / exposed occurrences (all)	49 / 735 (6.67%) 59		
Bronchitis bacterial subjects affected / exposed occurrences (all)	48 / 735 (6.53%) 81		
Bronchitis subjects affected / exposed occurrences (all)	46 / 735 (6.26%) 64		
Oral herpes subjects affected / exposed occurrences (all)	45 / 735 (6.12%) 89		
Pharyngitis bacterial subjects affected / exposed occurrences (all)	39 / 735 (5.31%) 85		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
29 July 2011	Amendment 01 The main purposes of this amendment were to switch all subjects receiving 1 mg/kg belimumab to a 10 mg/kg dose of belimumab since that was the dose that has been approved for the treatment of systemic lupus erythematosus (SLE) in the United States, Canada, and Europe, and to define a list of serious adverse event terms that occurred in the study population of SLE patients irrespective of drug exposure that may not have been reported to regulatory authorities or participating investigators if the sponsor determines there was not a reasonable possibility that the drug caused the event. In addition, the requirement for contraceptive use in male study participants was eliminated, and the period after last dose of study agent during which a female study participant must agree to use adequate contraception and during which an investigator was asked to report any pregnancies in female subjects to the sponsor was increased to 16 weeks.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported