Clinical trial results:
BEL116472. A 2 year mechanistic study of belimumab in Idiopathic Membranous Glomerulonephropathy

Summary

EudraCT number	2012-000385-38
Trial protocol	GB
Global end of trial date	14 September 2016

Results information

Result version number	v2 (current)
This version publication date	28 September 2017
First version publication date	28 May 2015
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	116472

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	10 April 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	14 September 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is: To evaluate whether belimumab can modulate proteinuria in IMGN. To evaluate whether belimumab can modulate anti-PLA2R autoantibodies in participants with detectable baseline levels of these antibodies.

Protection of trial subjects:

Not applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 July 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 14
Worldwide total number of subjects	14
EEA total number of subjects	14

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)	13
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Eligible participants were recruited from July 2012 until March 2014, into this 2 part study of a initial treatment phase, a long term treatment phase, and then followed up for a further 6 months. Results have previously been presented for the initial treatment phase, up to the Week 28 and are now presented for the completed study.

Pre-assignment

Screening details:

Screening occurred within 35 days and no less than 14 days before the first scheduled study treatment dose. Total 21 participants were screened; 14 were randomized and entered the initial treatment phase while 11 participants entered the long-term treatment phase. Common reasons for screen failures were insufficient, or improvements in proteinuria.

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 10 mg/kg IV

Arm description:

Participants received 10 milligrams per kilogram (mg/kg) belimumab intravenous (IV) infusion at Week 0 Week 2 and Week 4, then every 4 weeks over 24 weeks. Participants then entered the long-term phase of the study and received belimumab 10 mg/kg every 4 weeks up to Week 100 or until complete remission had been achieved.

Arm type	Experimental
Investigational medicinal product name	Belimumab ((GSK1550188)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of Belimumab 10 mg/kg was administered at Day 0, Week 2, Week 4 then ever 4 weeks up to 100 weeks.

Number of subjects in period 1	Belimumab 10 mg/kg IV
Started	14
Completed	8
Not completed	6
Other: Reached stopping criteria	1
Adverse event, non-fatal	1
Other:Treatment stopped due to remission	1
Lack of efficacy	3

Baseline characteristics

Reporting groups	
Reporting group title	Belimumab 10 mg/kg IV
Reporting group description:	
Participants received 10 milligrams per kilogram (mg/kg) belimumab intravenous (IV) infusion at Week 0 Week 2 and Week 4, then every 4 weeks over 24 weeks. Participants then entered the long-term phase of the study and received belimumab 10 mg/kg every 4 weeks up to Week 100 or until complete remission had been achieved.	

Reporting group values	Belimumab 10 mg/kg IV	Total	
Number of subjects	14	14	
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	46.1		
standard deviation	± 13.3	-	
Gender categorical			
Units: Subjects			
Female	3	3	
Male	11	11	
Race/Ethnicity, Customized			
Units: Subjects			
Asian - Central/South Asian Heritage	4	4	
White- White/Caucasian/European Heritage	9	9	
Unknown	1	1	

End points

End points reporting groups

Reporting group title	Belimumab 10 mg/kg IV

Reporting group description:

Participants received 10 milligrams per kilogram (mg/kg) belimumab intravenous (IV) infusion at Week 0 Week 2 and Week 4, then every 4 weeks over 24 weeks. Participants then entered the long-term phase of the study and received belimumab 10 mg/kg every 4 weeks up to Week 100 or until complete remission had been achieved.

Primary: Change from Baseline in proteinuria levels at Week 28

End point title	Change from Baseline in proteinuria levels at Week 28[1]

End point description:

Proteinuria based on urinary protein creatinine ratio (PCR) was measured from 2 consecutive 24 hour (h) urine collection pre and post dosing at Baseline and Week 28 and the mean PCR was determined at each time point. Baseline is defined as the mean of the pre and post dosing Day 0 values. The ratio is defined as the Week 28 value divided by the Baseline value. Ratio to Baseline: Estimated value = 0.76, 2-sided 95% confidence interval (CI)=0.57 to 1.01. The geometric mean method was used to calculate the CI. The analysis was performed on Intent-to-treat (ITT) Population which comprised of all eligible participants who received at least one dose of investigational drug. Only those participants available at the indicated time point (Week 28) were analyzed.

End point type	Primary

End point timeframe:

Baseline and Week 28

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 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	11[2]			
Units: Ratio				
geometric mean (geometric coefficient of variation)				
Ratio	0.7552 (± 45)			

Notes:

[2] - ITT Population

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in anti-phospholipase A2 receptor (PLA2R) autoantibody titers at Week 28

End point title	Change from Baseline in anti-phospholipase A2 receptor (PLA2R) autoantibody titers at Week 28[3]

End point description:

PLA2R autoantibody titers in serum were analyzed at Baseline and Week 28 by means of a validated anti- PLA2R enzyme linked immunosorbent assay (ELISA) from EuroImmun. Baseline is defined as the Day 0 value and change from Baseline was calculated as ratio to Baseline by dividing the Week 28 values with the Baseline values. Ratio to Baseline: Estimated value = 0.27, 2-sided 95% CI=0.12 to

0.58. The geometric mean method was used to calculate the CI.

End point type	Primary

End point timeframe:

Baseline and Week 28

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 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	11[4]			
Units: Ratio				
geometric mean (geometric coefficient of variation)				
Ratio	0.2666 (± 171)			

Notes:

[4] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Proteinuria levels at the indicated time points

End point title	Proteinuria levels at the indicated time points

End point description:

Proteinuria based on urinary protein creatinine ratio (PCR) measured from 2 consecutive 24h urine collections at Baseline and Week 28, from a pre-intervention spot urine sample and 24 hour urine collection after visit at Weeks 12, 52, 76 and 104, and from a spot urine sample at week 128. Mean PCR was calculated at each time point where there were 2 samples. Only those participants available at the specified time points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Baseline and Week 12, 28, 52, 76, 104 and 128/6 month follow-up

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[5]			
Units: milligrams per millimole (mg/mmol)				
geometric mean (geometric coefficient of variation)				
Baseline, n=14	724.3157 (± 40.2)			
Week 12, n=13	670.8655 (± 46.9)			
Week 28, n=11	498.1255 (± 40.9)			
Week 52, n=9	356.4209 (± 174.8)			

Week 76, n=8	274.9714 (± 70.4)			
Week 104, n=10	129.9761 (± 186)			
Week 128, n=9	75.2359 (± 136.4)			

Notes:

[5] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in proteinuria levels at the indicated time points

End point title	Change from Baseline in proteinuria levels at the indicated time points

End point description:

Proteinuria based on urinary protein creatinine ratio (PCR) measured from 2 consecutive 24h urine collections at Baseline and Week 28, from a pre-intervention spot urine sample and 24 hour urine collection after visit at Weeks 12, 52, 76 and 104, and from a spot urine sample at week 128. Mean PCR was calculated at each time point where there were 2 samples. Baseline is defined as Day 0 value and change from Baseline was calculated as ratio of post-Baseline value divided by the Baseline value. Only those participants available at the specified time points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Baseline and Week 12, 28, 52, 76, 104 and Week 128/6 month follow up

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[6]			
Units: Ratio				
geometric mean (geometric coefficient of variation)				
Week 12; n= 13	0.9437 (± 39.3)			
Week 28; n= 11	0.7552 (± 45)			
Week 52; n= 9	0.5297 (± 206.7)			
Week 76; n= 8	0.4177 (± 54.3)			
Week 104; n= 10	0.1874 (± 189.3)			
Week 128; n= 9	0.1118 (± 139.1)			

Notes:

[6] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-phospholipase A2 receptor (PLA2R) autoantibody levels at indicated time points

End point title	Anti-phospholipase A2 receptor (PLA2R) autoantibody levels at indicated time points

End point description:

Anti-PLA2R autoantibody titers in serum were analyzed by means of a validated anti-PLA2R enzyme linked immunosorbent assay (ELISA) assay from Euroimmun. Only those participants available at the specified time points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Baseline and Week 12, 28, 52, 76, 104 and 128/6 month follow-up

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[7]			
Units: relative units per milliliter (RU/mL)				
geometric mean (geometric coefficient of variation)				
Baseline, n=14	168.3 (± 138.9)			
Week 12, n=13	91 (± 200.4)			
Week 28, n=11	46.4 (± 319.6)			
Week 52, n=9	12.9 (± 358.4)			
Week 76, n=8	7.5 (± 140.4)			
Week 104, n=10	3.7 (± 72.7)			
Week 128, n=8	4.4 (± 112)			

Notes:

[7] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in anti-PLA2R autoantibody titers at the indicated time points

End point title	Change from Baseline in anti-PLA2R autoantibody titers at the indicated time points

End point description:

Anti-PLA2R autoantibody titers in serum were analyzed by means of a validated anti- PLA2R enzyme linked immunosorbent assay (ELISA) from Euroimmun. Baseline is defined as the Day 0 value and change from Baseline was calculated as ratio of post-Baseline value divided by the Baseline value. Only those participants available at the specified time points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Baseline and Weeks 12, 28, 52, 76, 104 and 128.

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[8]			
Units: Ratio				
geometric mean (geometric coefficient of variation)				
Week 12; n= 13	0.5362 (± 58.1)			
Week 28; n= 11	0.2666 (± 171)			
Week 52; n= 9	0.0737 (± 130.3)			
Week 76; n= 8	0.0436 (± 102.8)			
Week 104; n= 10	0.0212 (± 169.1)			
Week 128; n= 8	0.0284 (± 243.7)			

Notes:

[8] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with complete or partial remission

End point title	Number of participants with complete or partial remission

End point description:

Complete remission is defined as PCR <30 mg/mmol (proteinuria <0.3grams [g]/24 h) with no worsening in renal function (estimated glomerular filtration rate [eGFR] reduction from Baseline <15 percent). Partial remission is defined as PCR <350 mg/mmol (proteinuria <3.5 g/24 h) but >= 30 mg/mmol (proteinuria >= 0.3g/24h) and decrease of >50 percent from Day 0 Baseline, together with no consistent worsening in renal function (eGFR reduction from Baseline <15percent). Only those participants available at the specified time points were analyzed (represented by n=X in category titles).

End point type	Secondary

End point timeframe:

Baseline and Weeks 12, 28, 52, 76, 104 and 128

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[9]			
Units: Participants				
Week 12; Partial remission; n= 13	0			
Week 12; Complete remission; n= 13	0			
Week 28; Partial remission; n= 11	1			
Week 28; Complete remission; n= 11	0			
Week 52; Partial remission; n= 9	2			
Week 52; Complete remission; n= 9	1			
Week 76; Partial remission; n= 8	3			
Week 76; Complete remission; n= 8	0			
Week 104; Partial remission; n= 10	6			

Week 104; Complete remission; n= 10	1			
Week 128; Partial remission; n= 9	6			
Week 128; Complete remission; n= 9	1			

Notes:

[9] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Time to complete or partial remission

End point title	Time to complete or partial remission

End point description:

Time to complete or partial remission was estimated using the Kaplan-Meier method. Complete remission is defined as PCR <30 mg/mmol (proteinuria <0.3g/24 h) with no worsening in renal function (eGFR reduction from Baseline <15 percent). Partial remission is defined as PCR <350 mg/mmol (proteinuria <3.5 g/24 h) but >= 30 mg/mmol (proteinuria >= 0.3g/24h) and decrease of >50 percent from Day 0 Baseline, together with no consistent worsening in renal function (eGFR reduction from Baseline <15 percent). Only 1 participant reached complete remission. Hence, statistical analysis for complete remission was not performed.

End point type	Secondary

End point timeframe:

Baseline and up to Week 128/6 month follow up

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[10]			
Units: Weeks				
median (confidence interval 95%)				
Weeks	68.2 (28 to 93.6)			

Notes:

[10] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of complete or partial remission

End point title	Duration of complete or partial remission

End point description:

Complete remission is defined as PCR <30 mg/mmol (proteinuria <0.3g/24 h) with no worsening in renal function (eGFR reduction from Baseline <15percent). Partial remission is defined as PCR <350 mg/mmol (proteinuria <3.5 g/24 h) but >= 30 mg/mmol (proteinuria >= 0.3g/24h) and decrease of >50% from Day 0 Baseline, together with no consistent worsening in renal function (eGFR reduction from Baseline <15percent). Only those participants available at the specified time points were analyzed (represented by n=X in category titles). NA indicates that data was not available as only 1 participant reached complete remission. Hence, standard deviation for complete remission was not calculated.

End point type	Secondary

End point timeframe:

Baseline and up to Week 128/6 month follow up

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[11]			
Units: Days				
arithmetic mean (standard deviation)				
Complete remission; n= 1 Partial remission; n= 9	365 (± 99999) 378.6 (± 186.15)			

Notes:

[11] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with PLA2R autoantibody remission

End point title	Number of participants with PLA2R autoantibody remission

End point description:

Incidence of anti-PLA2R autoantibody remission were evaluated by full response and partial response. Full response is defined as antibody undetectable, partial response is defined as reduction in titers by 50 percent. For anti PLA2R autoantibody data, log transformation was applied before the formal analyses. Anti-PLA2R autoantibody blood samples were evaluated at Week 12, 28, 52, 76, 104 and 128/6 week post last-dose. Only those participants available at the specified time points were analyzed (represented by n=X in category titles).

End point type	Secondary

End point timeframe:

Baseline and Weeks 12, 28, 52, 76, 104 and 128

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[12]			
Units: Participants				
Week 12; full response; n= 13	1			
Week 12; partial response; n= 13	3			
Week 28; full response; n= 11	3			
Week 28; partial response; n= 11	6			
Week 52; full response; n= 9	4			
Week 52; partial response; n= 9	5			
Week 76; full response; n= 8	4			
Week 76; partial response; n= 8	4			
Week 104; full response; n= 10	10			
Week 104; partial response; n= 10	0			
Week 128; Full response; n= 8	8			
Week 128; partial response; n= 8	0			

Notes:
[12] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Time to anti-PLA2R autoantibody remission

End point title	Time to anti-PLA2R autoantibody remission

End point description:

Time to anti-PLA2R autoantibody remission was estimated using Kaplan-Meier method for full response and partial response full response with antibody undetectable and partial response with reduction in titers by 50 percent.

End point type	Secondary

End point timeframe:

Baseline and up to Week 128/6 month follow up

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[13]			
Units: Weeks				
median (confidence interval 95%)				
Partial response	16.2 (8 to 24)			
Complete response	82 (16 to 92)			

Notes:
[13] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with anti-PLA2R autoantibody relapse

End point title	Number of participants with anti-PLA2R autoantibody relapse

End point description:

Incidence of anti-PLA2R autoantibody relapse defined as antibody detectable after previously undetectable. Anti-PLA2R autoantibody blood samples were evaluated at Week 12, 28, 52, 76, 104/4 week post last dose, Only those participants available at the specified time points were analyzed (represented by n=X in category titles).

End point type	Secondary

End point timeframe:

Baseline and up to Week 128/6 month follow up

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[14]			
Units: Participants				
Week 12; n= 13	0			
Week 28; n= 11	0			
Week 52; n= 9	0			
Week 76; n= 8	0			
Week 104; n= 10	0			
Week 128; n= 8	0			

Notes:

[14] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: eGFR levels at the indicated time points

End point title	eGFR levels at the indicated time points

End point description:

eGFR was assessed from levels of creatinine using the 4 variable version of the modification of diet in renal disease (MDRD) equation as recommended by National Kidney Foundation-Chronic Kidney Disease (NKF-CKD) guidelines. Baseline for eGFR is defined as the mean of the screening and Day 0 values. Only those participants available at the specified time points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Baseline and Weeks 12, 28, 52, 76, 104 and 128/6 month follow-up.

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[15]			
Units: milliliter/minute (mL/min/1.73meter^2)				
geometric mean (geometric coefficient of variation)				
Baseline; n= 14	69.817 (± 32.9)			
Week 12; n= 13	66.2639 (± 35.4)			
Week 28; n= 11	65.0866 (± 36.1)			
Week 52; n= 7	65.1308 (± 45)			
Week 76; n= 8	61.6732 (± 47.1)			
Week 104; n= 10	69.7692 (± 39.1)			
Week 128; n= 9	64.7984 (± 39.2)			

Notes:
[15] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in eGFR levels at the indicated time points

End point title	Change from Baseline in eGFR levels at the indicated time points

End point description:

eGFR was assessed from levels of creatinine using the 4 variable version of the modification of diet in renal disease (MDRD) equation as recommended by national kidney foundation-chronic kidney disease (NKF-CKD) guidelines. Baseline for eGFR is defined as the mean of the Screening and Day 0 values and change from Baseline was calculated as ratio of post-Baseline value divided by the Baseline value. Only those participants available at the specified time points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Baseline and up to Week 128/6 month follow up

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[16]			
Units: Ratio				
geometric mean (geometric coefficient of variation)				
Week 2, n=14	0.9954 (± 10.8)			
Week 4, n= 13	0.919 (± 16.4)			
Week 8, n= 13	0.9035 (± 16.2)			
Week 12, n= 13	0.9339 (± 17.1)			
Week 16, n= 12	0.9521 (± 12.5)			
Week 20, n= 8	0.9819 (± 11.8)			
Week 24, n= 11	0.9274 (± 17.1)			
Week 28, n= 11	0.9694 (± 21.1)			
Week 32, n= 9	1.0099 (± 19.5)			
Week 36, n= 11	0.9692 (± 17.4)			
Week 40, n= 11	0.9425 (± 20.8)			
Week 44, n= 10	0.9531 (± 22.6)			

Week 48, n= 8	0.9929 (± 23.8)			
Week 52, n= 7	0.929 (± 27.7)			
Week 56, n= 9	1.0181 (± 21.9)			
Week 60, n= 9	0.9805 (± 26.8)			
Week 64, n=9	1.0217 (± 23.5)			
Week 68, n=8	1.0233 (± 24.6)			
Week 72, n=8	1.0168 (± 28.3)			
Week 76, n=8	1.0055 (± 33.3)			
Week 80, n=8	1.0431 (± 21.6)			
Week 84, n=8	0.9959 (± 25.3)			
Week 88, n=8	1.0529 (± 16.3)			
Week 92, n=8	1.0052 (± 26.3)			
Week 96, n=8	1.1204 (± 22.1)			
Week 100, n=8	1.1122 (± 24.7)			
Week 104, n=10	1.048 (± 23.3)			
Week 116; n= 8	1.0373 (± 19.8)			
Week 128, n=9	0.9971 (± 35.2)			

Notes:

[16] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Serum creatinine levels at the indicated time points

End point title	Serum creatinine levels at the indicated time points

End point description:

Serum creatinine was assessed as a clinical chemistry laboratory parameter from Baseline up to Week 128/6 month follow-up visit. Baseline for serum creatinine is defined as the mean of the Screening and Day 0 values. Only those participants available at the specified time points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Baseline and Weeks 12, 28, 52, 76, 104 and 128/6 month follow-up

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[17]			
Units: micromoles/liter (µmol/L)				
geometric mean (geometric coefficient of variation)				
Baseline; n= 14	97.1658 (± 22.8)			
Week 12; n= 13	100.6421 (± 26.8)			
Week 28; n= 11	99.9535 (± 24.8)			
Week 52; n= 7	96.6583 (± 30.2)			
Week 76; n= 8	103.0265 (± 32.8)			
Week 104; n= 10	92.4547 (± 29.6)			
Week 128; n= 9	97.726 (± 29.7)			

Notes:

[17] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in serum creatinine levels at the indicated time points

End point title	Change from Baseline in serum creatinine levels at the indicated time points

End point description:

Serum creatinine was assessed as a clinical chemistry laboratory parameter from Baseline up to Week 128/6 month follow-up visit. Baseline for serum creatinine is defined as the mean of the Screening and Day 0 values and change from Baseline was calculated as ratio of post-Baseline value divided by the Baseline value. Only those participants available at the specified time points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Baseline and Weeks 12, 28, 52, 76, 104 and 128/6 month follow-up

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[18]			
Units: Ratio				
geometric mean (geometric coefficient of variation)				
Week 12; n= 13	1.053 (± 14.8)			
Week 28; n= 11	1.0202 (± 18.6)			
Week 52; n= 7	1.0581 (± 23.7)			

Week 76; n= 8	0.9818 (± 28.7)			
Week 104; n= 10	0.9467 (± 20.1)			
Week 128; n= 9	0.9874 (± 30.4)			

Notes:

[18] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Serum albumin levels at indicated time points

End point title	Serum albumin levels at indicated time points

End point description:

Serum albumin was assessed as a clinical chemistry laboratory parameter from Baseline up to Week 128/6 month follow-up visit. Baseline for serum albumin is defined as the mean of the Screening and Day 0 values. Only those participants available at the specified time points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Baseline and Weeks 12, 28, 52, 76, 104 and 128/6 month follow-up.

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[19]			
Units: grams per liter (g/L)				
geometric mean (geometric coefficient of variation)				
Baseline; n= 14	23.3306 (± 22.7)			
Week 12; n= 13	24.4204 (± 27.5)			
Week 28; n= 11	27.8397 (± 23.4)			
Week 52; n= 7	31.9927 (± 18.3)			
Week 76; n= 8	33.9484 (± 10.9)			
Week 104; n= 10	39.1015 (± 7.5)			
Week 128; n= 9	39.2009 (± 8.8)			

Notes:

[19] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in levels of serum albumin at the indicated time

points

End point title	Change from Baseline in levels of serum albumin at the indicated time points

End point description:

Serum albumin was assessed as a clinical chemistry laboratory parameter from Baseline up to Week 128/6 month follow-up visit. Baseline for serum albumin is defined as the mean of the Screening and Day 0 values and change from Baseline was calculated as ratio of post-Baseline value divided by the Baseline value. Only those participants available at the specified time points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Baseline and Weeks 12, 28, 52, 76, 104 and 128/6 month follow-up

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[20]			
Units: ratio				
geometric mean (geometric coefficient of variation)				
Week 12; n= 13	1.0324 (± 15)			
Week 28; n= 11	1.1211 (± 16.9)			
Week 52; n= 7	1.2828 (± 28.1)			
Week 76; n= 8	1.3695 (± 23.8)			
Week 104; n= 10	1.5879 (± 19.6)			
Week 128; n= 9	1.5799 (± 24.7)			

Notes:

[20] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Serum cholesterol levels at indicated time points

End point title	Serum cholesterol levels at indicated time points

End point description:

Serum cholesterol was assessed as a clinical chemistry laboratory parameter from Baseline up to Week 128/6 month follow-up visit. Baseline for serum cholesterol is defined as the mean of the Screening and Day 0 values. Only those participants available at the specified time points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Baseline and Weeks 12, 28, 52, 76, 104 and 128/6 month follow-up

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[21]			
Units: millimoles per liter (mmol/L)				
geometric mean (geometric coefficient of variation)				
Baseline; n= 14	7.6423 (± 36)			
Week 12; n= 13	7.2336 (± 31.5)			
Week 28; n= 11	6.274 (± 23.1)			
Week 52; n= 7	5.8724 (± 18.6)			
Week 76; n= 8	5.0211 (± 18.4)			
Week 104; n= 10	4.8001 (± 24.5)			
Week 128; n= 9	4.2407 (± 12.7)			

Notes:

[21] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in serum cholesterol at the indicated time points

End point title	Change from Baseline in serum cholesterol at the indicated time points

End point description:

Serum cholesterol was assessed as a clinical chemistry laboratory parameter from Baseline up to Week 128/6 month follow-up visit. Baseline for serum cholesterol is defined as the mean of the Screening and Day 0 values and change from Baseline was calculated as ratio of post-Baseline value divided by the Baseline value. Only those participants available at the specified time points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Baseline and Weeks 12, 28, 52, 76, 104 and 128/6 month follow-up

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[22]			
Units: mmol/L				
geometric mean (geometric coefficient of variation)				
Week 12; n= 13	0.9238 (± 16.8)			
Week 28; n= 11	0.8896 (± 14.3)			
Week 52; n= 7	0.8571 (± 16.7)			
Week 76; n= 8	0.7111 (± 15)			

Week 104; n= 10	0.6851 (± 17.3)			
Week 128; n= 9	0.614 (± 15.7)			

Notes:

[22] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Immunoglobulin G (IgG) levels at indicated time points

End point title	Serum Immunoglobulin G (IgG) levels at indicated time points

End point description:

Serum IgG was assessed as a clinical chemistry laboratory parameter from Baseline up to Week 128/6 month follow-up visit. Baseline for serum IgG is defined as the pre-dose Day 0 value. Only those participants available at the specified time points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Baseline and Weeks 12, 28, 52, 76, 104 and 128/6 month follow-up

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[23]			
Units: g/L				
arithmetic mean (standard deviation)				
Baseline; n= 14	4.026 (± 1.681)			
Week 12; n= 13	3.871 (± 1.5266)			
Week 28; n= 11	4.405 (± 1.7833)			
Week 52; n= 8	5.823 (± 2.2572)			
Week 76; n= 8	6.05 (± 2.1103)			
Week 104; n= 10	7.611 (± 2.8301)			
Week 128; n= 9	8.609 (± 2.2597)			

Notes:

[23] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in serum IgG at the indicated time points

End point title	Change from Baseline in serum IgG at the indicated time points

End point description:

Serum IgG was assessed as a clinical chemistry laboratory parameter from Baseline up to Week 128/6 month follow-up visit. Baseline for serum IgG is defined as the pre-dose Day 0 value and change from Baseline was calculated as ratio of post-Baseline value divided by the Baseline value. Only those participants available at the specified time points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Baseline and Weeks 12, 28, 52, 76, 104 and 128/6 month follow up

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[24]			
Units: Ratio				
arithmetic mean (standard deviation)				
Week 12; n= 13	0.055 (± 0.6625)			
Week 28; n= 11	0.469 (± 1.4287)			
Week 52; n= 8	1.525 (± 2.4411)			
Week 76; n= 8	1.619 (± 1.6681)			
Week 104; n= 10	3.613 (± 2.5488)			
Week 128; n= 9	4.334 (± 2.0289)			

Notes:

[24] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with edema and edema extending beyond calf

End point title	Number of participants with edema and edema extending beyond calf

End point description:

Reduction of proteinuria lessens the risk of thromboembolic and cardiovascular effects and reduces the edema in participants. Investigators physically reviewed participants for clinical manifestations of idiopathic membranous glomerulonephropathy (IMGN) (e.g. edema extending beyond calf) during study and analysis was performed at Week 12, 28, 52, 76 Week 104. Only those participants available at the specified time points were analyzed (represented by n=X in category titles).

End point type	Secondary

End point timeframe:

Baseline and Weeks 12, 28, 52, 76, and 104

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[25]			
Units: Participants				
Week 0; oedema; n= 14	13			
Week 0; oedema extending beyond calf; n= 14	5			
Week 12; oedema; n= 12	9			
Week 12; Oedema extending beyond calf; n= 12	1			
Week 28;Oedema; n= 11	7			
Week 28; Oedema extending beyond calf; n= 11	1			
Week 52; oedema; n= 9	4			
Week 52;Oedema extending beyond calf; n= 9	1			
Week 76;Oedema; n=8	4			
Week 76;Oedema extending beyond calf; n= 8	0			
4 Week post final dose (PFD); Oedema; n=10	6			
4 Week PFD; Oedema extending beyond calf; n= 10	1			
Week 104 withdrawn (WD); Oedema; n= 1	0			
Week 104 WD;Oedema extending beyond calf; n=1	0			

Notes:

[25] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Summary of maximum observed serum concentration (Cmax) of belimumab at the indicated time points

End point title	Summary of maximum observed serum concentration (Cmax) of belimumab at the indicated time points

End point description:

The first occurrence of Cmax was determined directly from the serum concentration-time data. The pharmacokinetic (PK) parameters were calculated by standard non-compartmental analysis and all calculations of non-compartmental parameters are being based on actual sampling times.

End point type	Secondary

End point timeframe:

Baseline and up to 4 week post last dose

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[26]			
Units: nanograms per milliliter (ng/mL)				
arithmetic mean (standard deviation)				
Day 0, 5 minutes; n= 13	267996 (± 70598.02)			
Week 28, 5 minutes; n= 11	312462.2 (± 95171.16)			

Notes:

[26] - PK Population: all participants in the ITT Population for whom a PK sample was obtained and analyzed

Statistical analyses

No statistical analyses for this end point

Secondary: Summary of minimum observed concentration (Cmin) of belimumab at the indicated time points

End point title	Summary of minimum observed concentration (Cmin) of belimumab at the indicated time points

End point description:

Trough concentration (Cmin) samples collected on the specified days are being used to assess attainment whether there was sufficient belimumab despite it being lost in the urine from the proteinuria and to check if it improved as proteinuria resolved. Analysis was performed on pre-infusion samples at weeks 2,4,8,12,28,40,52,76 and the 4 week post last-dose.

End point type	Secondary

End point timeframe:

Baseline and up to 4 week post last dose

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[27]			
Units: ng/mL				
arithmetic mean (standard deviation)				
Pre-infusion; Week 2; n= 14	29940.8 (± 20918.28)			
Pre-infusion; Week 4; n= 12	41220.9 (± 35720.14)			
Pre-infusion; Week 8; n= 13	30350.9 (± 25505.7)			
Pre-infusion; Week 12; n= 11	30913.7 (± 30681.42)			
Pre-infusion; Week 28; n= 11	34904.7 (± 26388.6)			
Pre-infusion; Week 40; n= 10	40800.6 (± 28847.86)			
Pre-infusion; Week 52; n= 9	38375.9 (± 14136.23)			
Pre-infusion; Week 76; n= 8	65655.8 (± 32873.33)			
4 Weeks post last-dose; n= 9	60497.3 (± 28074.37)			

Notes:

[27] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Summary of area under the serum concentration-time curve to the last quantifiable concentration (AUC[0-2])

End point title	Summary of area under the serum concentration-time curve to the last quantifiable concentration (AUC[0-2])

End point description:

The AUC(0-2) was determined using the linear trapezoidal rule for increasing concentrations and the logarithmic trapezoidal rule for decreasing concentrations. Blood samples for PK analysis were collected at the following time points: pre-dose (on dosing days): Days 0, 1, 4, 7, 14 and Week 4, 8, 12, 28, 40, 52, 76 and 4 week post last dose. Post-dose (5 minutes after dosing complete): Days 0 and 28. The results will be posted at later date following post hoc analysis.

End point type	Secondary

End point timeframe:

Baseline and up to 4 week post last dose

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	0[28]			
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
ng/mL	()			

Notes:

[28] - PK Population. The results will be posted at later date following post hoc analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: Summary of total amount of urine excreted Ae(0-24)

End point title	Summary of total amount of urine excreted Ae(0-24)

End point description:

PK parameters from the urine concentration data: urine Ae(0-24) were assessed. 24 h urine collections for PK analysis were collected after the Day 0 and Weeks 12, 28, 52, 76 doses and at the 4 week post last dose visit. A population approach was undertaken to characterize the population PK parameters and associated variability of belimumab in nephrotic participants. The population approach could have provided derived clearance of belimumab for each participant after the first dose. The population PK analysis was conducted using nonlinear mixed-effect modeling (NONMEM) or appropriate nonlinear mixed-effect analysis software. Several samples were taken pre-dose at Day 0 and some at week 12 incorrectly which affects interpretation.

End point type	Secondary

End point timeframe:

Baseline and Up to 4 week post last dose

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[29]			
Units: ng/hour				
arithmetic mean (standard deviation)				
Day 0; n= 14	105826.23 (± 178943.857)			
Week 12; n= 12	95188.14 (± 130217.976)			
Week 28; n= 11	92997.94 (± 110142.599)			
Week 52; n= 9	219367.96 (± 391752.377)			
Week 76; n= 8	145645.34 (± 267292.225)			
4 Week post last dose; n= 6	7909.34 (± 16771.559)			

Notes:

[29] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in short form (SF)-36 v2 Quality of Life (QoL) questionnaire score

End point title	Change from Baseline in short form (SF)-36 v2 Quality of Life (QoL) questionnaire score

End point description:

Health-related quality of life was assessed through participant self-completion of the short form health survey (SF-36 version [v2]), a general health related quality of life metrics. Norm-based Scores (NBS) for physical functioning, role emotional, role physical were assessed. The remaining SF-36 component scores require re-scaling and therefore will be added at a later date. SF-36 was administered prior to any procedures at Weeks 12, 28, 52, 76 and 104/4 week post last dose. Item score were recorded and higher score represented better health status. Baseline is defined as Day 0 pre dose value and change from Baseline was calculated by subtracting the Baseline values from the individual post-randomization values. Only those participants available at the specified time points were analyzed (represented by n=X in category titles).

End point type	Secondary

End point timeframe:

Baseline and up to Week 104/4 week post last dose

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[30]			
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Physical functioning, Week 12; n= 12	-4.034 (± 5.1907)			
Physical functioning, Week 28; n= 11	-0.765 (± 3.678)			
Physical functioning, Week 52; n= 9	0.468 (± 7.3489)			
Physical functioning, Week 76; n= 7	0.601 (± 7.9409)			
Physical functioning 4 Week post final dose;n=11	0.765 (± 11.7275)			
Role emotional, Week 12; n= 12	0 (± 10.4831)			
Role emotional, Week 28; n= 11	1.413 (± 15.1824)			
Role emotional, Week 52; n= 9	3.023 (± 11.4621)			
Role emotional, Week 76; n= 7	3.332 (± 7.2475)			
Role emotional, 4 Week post final dose; n= 11	6.007 (± 10.0413)			
Role physical, Week 12; n= 12	0.816 (± 11.0681)			
Role physical, Week 28; n= 11	3.34 (± 8.4324)			
Role physical, Week 52; n= 9	3.537 (± 9.1726)			
Role physical, Week 76; n= 7	7.697 (± 12.2803)			
Role physical 4 Week post final dose; n= 11	5.789 (± 11.4489)			

Notes:

[30] - ITT Population

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

An AE is any untoward medical occurrence in a clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. The analysis was performed on Safety Population which comprised of all participants who were randomized into the study. SAE is any untoward medical occurrence that at any dose results in death, is life-threatening, Requires hospitalization or prolongation of existing hospitalization, Results in disability/incapacity, is a congenital anomaly/birth defect, may require medical or surgical intervention, is associated with liver injury and impaired liver function.

End point type	Secondary

End point timeframe:

Baseline and up to Week 128/6 month follow up

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[31]			
Units: Participants				
AE	14			
SAE	3			

Notes:

[31] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with abnormal clinical chemistry and hematology values

End point title	Number of participants with abnormal clinical chemistry and hematology values

End point description:

Blood samples were collected from participants for evaluation of clinical chemistry and hematology parameters. The clinical chemistry parameters included albumin, alkaline phosphatase (alk.phosph.), alanine amino transferase (ALT), aspartate amino transferase (AST), total and direct bilirubin, calcium, cholesterol, chloride, carbon dioxide, creatinine, gamma glutamyl transferase (GGT), glucose, potassium, lactate dehydrogenase (LD), magnesium, sodium, phosphorus, total protein, blood urea nitrogen (BUN) and uric acid. The hematology parameters included basophils, eosinophil, hemoglobin, hematocrit, lymphocytes, monocytes, total neutrophils, platelets, red blood cells (RBC) count and white blood cells (WBC) count. Participants were counted in the category that their value changes to (low or high) for the specific time points. Only those participants with data available at the specified data points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Baseline and up to Week 116/16 week follow-up visit

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[32]			
Units: Participants				
Albumin; Week 12; to high; n= 13	0			
Albumin; Week 12; to low; n= 13	0			
Albumin; Week 28; to high; n= 11	0			
Albumin; Week 28; to low; n= 11	0			
Albumin; Week 52; to high; n= 7	0			
Albumin; Week 52; to low; n= 7	0			
Albumin; Week 76; to high; n= 8	0			
Albumin; Week 76; to low; n= 8	0			
Albumin; Week 104; to high; n= 10	0			
Albumin; Week 104; to low; n= 10	0			

Albumin; 16 Week follow up; to high; n= 8	0			
Albumin; 16 Week follow up; to low; n= 8	0			
Alk.phosph.; Week 12; to high; n= 13	0			
Alk.phosph.; Week 12; to low; n= 13	0			
Alk.phosph.; Week 28; to high; n= 11	0			
Alk.phosph.; Week 28; to low; n= 11	0			
Alk.phosph.; Week 52; to high; n= 7	0			
Alk.phosph.; Week 52; to low; n= 7	0			
Alk.phosph.; Week 76; to high; n= 8	0			
Alk.phosph.; Week 76; to low; n= 8	0			
Alk.phosph.; Week 104; to high; n= 10	0			
Alk.phosph.; Week 104; to low; n= 10	0			
Alk.phosph.; 16 Week follow up; to high; n= 8	0			
Alk.phosph.; 16 Week follow up; to low; n= 8	0			
ALT; Week 12; to high; n= 13	0			
ALT; Week 12; to low; n= 13	0			
ALT; Week 28; to high; n= 11	0			
ALT; Week 28; to low; n= 11	0			
ALT; Week 52; to high; n= 7	0			
ALT; Week 52; to low; n= 7	0			
ALT; Week 76; to high; n= 8	0			
ALT; Week 76; to low; n= 8	0			
ALT; Week 104; to high; n= 10	0			
ALT; Week 104; to low; n= 10	0			
ALT; 16 Week follow up; to high; n= 8	0			
ALT; 16 Week follow up; to low; n= 8	0			
AST; Week 12; to high; n= 13	0			
AST; Week 12; to low; n= 13	0			
AST; Week 28; to high; n= 11	1			
AST; Week 28; to low; n= 11	0			
AST; Week 52; to high; n= 7	0			
AST; Week 52; to low; n= 7	0			
AST; Week 76; to high; n= 8	0			
AST; Week 76; to low; n= 8	0			
AST; Week 104; to high; n= 10	0			
AST; Week 104; to low; n= 10	0			
AST; 16 Week follow up; to high; n= 8	0			
AST; 16 Week follow up; to low; n= 8	0			
Direct bilirubin; Week 12; to high; n= 13	0			
Direct bilirubin; Week 12; to low; n= 13	0			
Direct bilirubin; Week 28; to high; n= 11	0			
Direct bilirubin; Week 28; to low; n= 11	0			
Direct bilirubin; Week 52; to high; n= 7	0			
Direct bilirubin; Week 52; to low; n= 7	0			
Direct bilirubin; Week 76; to high; n= 8	0			
Direct bilirubin; Week 76; to low; n= 8	0			
Direct bilirubin; Week 104; to high; n= 10	0			

Direct bilirubin; Week 104; to low; n= 10	0			
Direct bilirubin; 16 Week follow up; to high; n=8	0			
Direct bilirubin; 16 Week follow up; to low; n= 8	0			
Total bilirubin; Week 12; to high; n= 12	0			
Total bilirubin; Week 12; to low; n= 12	0			
Total bilirubin; Week 28; to high; n= 11	0			
Total bilirubin; Week 28; to low; n= 11	0			
Total bilirubin; Week 52; to high; n= 7	0			
Total bilirubin; Week 52; to low; n= 7	0			
Total bilirubin; Week 76; to high; n= 8	0			
Total bilirubin; Week 76; to low; n= 8	0			
Total bilirubin; Week 104; to high; n= 10	0			
Total bilirubin; Week 104; to low; n= 10	0			
Total bilirubin; 16 Week follow up; to high; n= 8	0			
Total bilirubin; 16 Week follow up; to low; n= 8	0			
Calcium; Week 12; to high; n= 12	0			
Calcium; Week 12; to low; n= 12	0			
Calcium; Week 28; to high; n= 11	0			
Calcium; Week 28; to low; n= 11	0			
Calcium; Week 52; to high; n= 7	0			
Calcium; Week 52; to low; n= 7	0			
Calcium; Week 76; to high; n= 8	0			
Calcium; Week 76; to low; n= 8	0			
Calcium; Week 104; to high; n= 10	1			
Calcium; Week 104; to low; n= 10	1			
Calcium; 16 Week follow up; to high; n= 8	0			
Calcium; 16 Week follow up; to low; n= 8	0			
Cholesterol; Week 12; to high; n= 13	0			
Cholesterol; Week 12; to low; n= 13	0			
Cholesterol; Week 28; to high; n= 11	0			
Cholesterol; Week 28; to low; n= 11	0			
Cholesterol; Week 52; to high; n= 7	0			
Cholesterol; Week 52; to low; n= 7	0			
Cholesterol; Week 76; to high; n= 8	0			
Cholesterol; Week 76; to low; n= 8	0			
Cholesterol; Week 104; to high; n= 10	0			
Cholesterol; Week 104; to low; n= 10	0			
Cholesterol; 16 Week follow up; to high; n= 8	0			
Cholesterol; 16 Week follow up; to low; n= 8	0			
Chloride; Week 12; to high; n= 13	1			
Chloride; Week 12; to low; n= 13	0			
Chloride; Week 28; to high; n= 11	2			
Chloride; Week 28; to low; n= 11	0			
Chloride; Week 52; to high; n= 7	0			
Chloride; Week 52; to low; n= 7	0			

Chloride; Week 76; to high; n= 8	0			
Chloride; Week 76; to low; n= 8	0			
Chloride; Week 104; to high; n= 10	0			
Chloride; Week 104; to low; n= 10	0			
Chloride; 16 Week follow up; to high; n= 8	0			
Chloride; 16 Week follow up; to low; n= 8	0			
Carbon dioxide; Week 12; to high; n= 13	0			
Carbon dioxide; Week 12; to low; n= 13	1			
Carbon dioxide; Week 28; to high; n= 11	0			
Carbon dioxide; Week 28; to low; n= 11	3			
Carbon dioxide; Week 52; to high; n= 7	0			
Carbon dioxide; Week 52; to low; n= 7	0			
Carbon dioxide; Week 76; to high; n= 8	0			
Carbon dioxide; Week 76; to low; n= 8	0			
Carbon dioxide; Week 104; to high; n= 10	0			
Carbon dioxide; Week 104; to low; n= 10	1			
Carbon dioxide; 16 Week follow up; to high; n= 8	0			
Carbon dioxide; 16 Week follow up; to low; n= 8	0			
Creatinine; Week 12; to high; n= 13	2			
Creatinine; Week 12; to low; n= 13	0			
Creatinine; Week 28; to high; n= 11	0			
Creatinine; Week 28; to low; n= 11	0			
Creatinine; Week 52; to high; n= 7	0			
Creatinine; Week 52; to low; n= 7	0			
Creatinine; Week 76; to high; n= 8	2			
Creatinine; Week 76; to low; n= 8	1			
Creatinine; Week 104; to high; n= 10	0			
Creatinine; Week 104; to low; n= 10	0			
Creatinine; 16 Week follow up; to high; n= 8	0			
Creatinine; 16 Week follow up; to low; n= 8	0			
GGT; Week 12; to high; n= 13	0			
GGT; Week 12; to low; n= 13	0			
GGT; Week 28; to high; n= 11	0			
GGT; Week 28; to low; n= 11	0			
GGT; Week 52; to high; n= 7	0			
GGT; Week 52; to low; n= 7	0			
GGT; Week 76; to high; n= 8	0			
GGT; Week 76; to low; n= 8	0			
GGT; Week 104; to high; n= 10	0			
GGT; Week 104; to low; n= 10	0			
GGT; 16 Week follow up; to high; n=8	0			
GGT; 16 Week follow up; to low; n= 8	0			
Glucose; Week 12; to high; n= 13	3			
Glucose; Week 12; to low; n= 13	0			
Glucose; Week 28; to high; n= 11	4			

Glucose; Week 28; to low; n= 11	0			
Glucose; Week 52; to high; n= 7	2			
Glucose; Week 52; to low; n= 7	0			
Glucose; Week 76; to high; n= 8	3			
Glucose; Week 76; to low; n= 8	0			
Glucose; Week 104; to high; n= 10	1			
Glucose; Week 104; to low; n= 10	0			
Glucose; 16 Week follow up; to high; n= 8	1			
Glucose; 16 Week follow up; to low; n= 8	1			
Potassium; Week 12; to high; n= 13	0			
Potassium; Week 12; to low; n= 13	0			
Potassium; Week 28; to high; n= 11	1			
Potassium; Week 28; to low; n= 11	1			
Potassium; Week 52; to high; n= 7	0			
Potassium; Week 52; to low; n= 7	0			
Potassium; Week 76; to high; n= 8	0			
Potassium; Week 76; to low; n= 8	0			
Potassium; Week 104; to high; n= 10	0			
Potassium; Week 104; to low; n= 10	0			
Potassium; 16 Week follow up; to high; n= 8	0			
Potassium; 16 Week follow up; to low; n= 8	0			
LD; Week 12; to high; n= 13	3			
LD; Week 12; to low; n= 13	0			
LD; Week 28; to high; n= 11	2			
LD; Week 28; to low; n= 11	0			
LD; Week 52; to high; n= 7	1			
LD; Week 52; to low; n= 7	0			
LD; Week 76; to high; n= 8	1			
LD; Week 76; to low; n= 8	0			
LD;Week 104; to high; n= 10	0			
LD;Week 104; to low; n= 10	0			
LD; 16 week follow-up; to high; n= 8	0			
LD; 16 week follow up; to low; n= 8	0			
Magnesium; Week 12; to high; n= 13	1			
Magnesium; Week 12; to low; n= 13	0			
Magnesium; Week 28; to high; n= 11	0			
Magnesium; Week 28; to low; n= 11	0			
Magnesium; Week 52; to high; n= 7	0			
Magnesium; Week 52; to low; n= 7	0			
Magnesium; Week 76; to high; n= 8	0			
Magnesium; Week 76; to low; n= 8	0			
Magnesium; Week 104; to high; n= 10	0			
Magnesium; Week 104; to low; n= 10	0			
Magnesium; 16 week follow up; to high; n= 8	0			
Magnesium; 16 week follow up; to low; n= 8	0			
Sodium; Week 12; to high; n= 12	0			
Sodium; Week 12; to low; n= 12	0			
Sodium; Week 28; to high; n= 11	0			

Sodium; Week 28; to low; n= 11	1			
Sodium; Week 52; to high; n= 7	0			
Sodium; Week 52; to low; n= 7	1			
Sodium; Week 76; to high; n= 8	0			
Sodium; Week 76; to low; n= 8	1			
Sodium; Week 104; to high; n= 10	0			
Sodium; Week 104; to low; n= 10	0			
Sodium; 16 week follow p; to high; n= 8	0			
Sodium; 16 week follow up; to low; n= 8	1			
Phosphorus; Week 12; to high; n= 13	1			
Phosphorus; Week 12; to low; n= 13	0			
Phosphorus; Week 28; to high; n= 11	2			
Phosphorus; Week 28; to low; n= 11	0			
Phosphorus; Week 52; to high; n= 7	0			
Phosphorus; Week 52; to low; n= 7	0			
Phosphorus; Week 76; to high; n= 8	0			
Phosphorus; Week 76; to low; n= 8	0			
Phosphorus;Week 104; to high; n= 10	1			
Phosphorus;Week 104; to low; n= 10	1			
Phosphorus; 16 week follow up; to high; n= 8	0			
Phosphorus; 16 week follow up; to low; n= 8	0			
Total protein; Week 12; to high; n= 12	0			
Total protein; Week 12; to low; n= 12	0			
Total protein; Week 28; to high; n= 11	0			
Total protein; Week 28; to low; n= 11	0			
Total protein; Week 52; to high; n= 7	0			
Total protein; Week 52; to low; n= 7	1			
Total protein; Week 76; to high; n= 8	0			
Total protein; Week 76; to low; n= 8	0			
Total protein; Week 104; to high; n= 10	0			
Total protein; Week 104; to low; n= 10	0			
Total protein; 16 Week follow up; to high; n= 8	0			
Total protein; 16 Week follow up; to low; n= 8	0			
BUN; Week 12; to high; n= 13	2			
BUN; Week 12; to low; n= 13	0			
BUN; Week 28; to high; n= 11	0			
BUN; Week 28; to low; n= 11	0			
BUN; Week 52; to high; n= 7	2			
BUN; Week 52; to low; n= 7	0			
BUN; Week 76; to high; n= 8	2			
BUN; Week 76; to low; n= 8	0			
BUN; Week 104; to high; n= 10	0			
BUN; Week 104; to low; n= 10	0			
BUN; 16 week follow up; to high; n= 8	0			
BUN; 16 week follow up; to low; n= 8	0			
Uric acid; Week 12; to high; n= 13	2			
Uric acid; Week 12; to low; n= 13	2			
Uric acid; Week 28; to high; n= 11	1			

Uric acid; Week 28; to low; n= 11	0			
Uric acid; Week 52; to high; n= 7	1			
Uric acid; Week 52; to low; n= 7	0			
Uric acid; Week 76; to high; n= 8	2			
Uric acid; Week 76; to low; n= 8	0			
Uric acid; Week 104; to high; n= 10	2			
Uric acid; Week 104; to low; n= 10	0			
Uric acid; 16 week follow up; to high; n= 8	2			
Uric acid; 16 week follow up; to low; n= 8	0			
Basophils; Week 12; to high; n= 12	0			
Basophils; Week 12; to low; n= 12	0			
Basophils; Week 28; to high; n= 11	0			
Basophils; Week 28; to low; n= 11	0			
Basophils; Week 52; to high; n= 9	0			
Basophils; Week 52; to low; n= 9	0			
Basophils; Week 76; to high; n= 8	0			
Basophils; Week 76; to low; n= 8	0			
Basophils; Week 104; to high; n= 9	0			
Basophils; Week 104; to low; n= 9	0			
Basophils; 16 week follow up; to high; n= 9	0			
Basophils; 16 week follow up; to low; n= 9	0			
Eosinophils; Week 12; to high; n= 12	1			
Eosinophils; Week 12; to low; n= 12	0			
Eosinophils; Week 28; to high; n= 11	1			
Eosinophils; Week 28; to low; n= 11	0			
Eosinophils; Week 52; to high; n= 9	0			
Eosinophils; Week 52; to low; n= 9	0			
Eosinophils; Week 76; to high; n= 8	1			
Eosinophils; Week 76; to low; n= 8	0			
Eosinophils; Week 104; to high; n= 9	0			
Eosinophils; Week 104; to low; n= 9	0			
Eosinophils; 16 week follow up; to high; n= 9	0			
Eosinophils; 16 week follow up; to low; n= 9	0			
Hemoglobin; Week 12; to high; n= 12	0			
Hemoglobin; Week 12; to low; n= 12	0			
Hemoglobin; Week 28; to high; n= 11	0			
Hemoglobin; Week 28; to low; n= 11	0			
Hemoglobin; Week 52; to high; n= 9	0			
Hemoglobin; Week 52; to low; n= 9	2			
Hemoglobin; Week 76; to high; n= 8	0			
Hemoglobin; Week 76; to low; n= 8	1			
Hemoglobin; Week 104; to high; n= 9	0			
Hemoglobin; Week 104; to low; n= 9	1			
Hemoglobin; 16 week follow up; to high; n= 9	0			
Hemoglobin; 16 week follow up; to low; n= 9	1			
Hematocrit; Week 12; to high; n= 12	0			

Hematocrit; Week 12; to low; n= 12	0			
Hematocrit; Week 28; to high; n= 11	1			
Hematocrit; Week 28; to low; n= 11	0			
Hematocrit; Week 52; to high; n= 9	0			
Hematocrit; Week 52; to low; n= 9	1			
Hematocrit; Week 76; to high; n= 8	0			
Hematocrit; Week 76; to low; n= 8	0			
Hematocrit; Week 104; to high; n= 9	0			
Hematocrit; Week 104; to low; n= 9	1			
Hematocrit; 16 week follow up; to high; n= 9	0			
Hematocrit; 16 week follow up; to low; n= 9	1			
Lymphocytes; Week 12; to high; n= 12	0			
Lymphocytes; Week 12; to low; n= 12	0			
Lymphocytes; Week 28; to high; n= 11	0			
Lymphocytes; Week 28; to low; n= 11	0			
Lymphocytes; Week 52; to high; n= 9	0			
Lymphocytes; Week 52; to low; n= 9	0			
Lymphocytes; Week 76; to high; n= 8	0			
Lymphocytes; Week 76; to low; n= 8	0			
Lymphocytes; Week 104; to high; n= 9	0			
Lymphocytes; Week 104; to low; n= 9	0			
Lymphocytes; 16 week follow up; to high; n= 9	0			
Lymphocytes; 16 week follow up; to low; n= 9	0			
Monocytes; Week 12; to high; n= 12	0			
Monocytes; Week 12; to low; n= 12	0			
Monocytes; Week 28; to high; n= 11	0			
Monocytes; Week 28; to low; n= 11	0			
Monocytes; Week 52; to high; n= 9	0			
Monocytes; Week 52; to low; n= 9	0			
Monocytes; Week 76; to high; n= 8	0			
Monocytes; Week 76; to low; n= 8	0			
Monocytes; Week 104; to high; n= 9	0			
Monocytes; Week 104; to low; n= 9	0			
Monocytes; 16 week follow up; to high; n= 9	0			
Monocytes; 16 week follow up; to low; n= 9	0			
Neutrophils; Week 12; to high; n= 12	1			
Neutrophils; Week 12; to low; n= 12	0			
Neutrophils; Week 28; to high; n= 11	0			
Neutrophils; Week 28; to low; n= 11	0			
Neutrophils; Week 52; to high; n= 9	0			
Neutrophils; Week 52; to low; n= 9	0			
Neutrophils; Week 76; to high; n= 8	0			
Neutrophils; Week 76; to low; n= 8	0			
Neutrophils; Week 104; to high; n= 9	2			
Neutrophils; Week 104; to low; n= 9	0			
Neutrophils; 16 week follow up; to high; n=9	1			

Neutrophils; 16 week follow up; to low; n= 9	0			
Platelet count; Week 12; to high; n= 12	3			
Platelet count; Week 12; to low; n= 12	0			
Platelet count; Week 28; to high; n= 11	2			
Platelet count; Week 28; to low; n= 11	0			
Platelet count; Week 52; to high; n= 9	0			
Platelet count; Week 52; to low; n= 9	0			
Platelet count; Week 76; to high; n= 8	0			
Platelet count; Week 76; to low; n= 8	0			
Platelet count; Week 104; to high; n= 9	1			
Platelet count; Week 104; to low; n= 9	0			
Platelet count; 16 week follow up; to high; n= 9	0			
Platelet count; 16 week follow up; to low; n= 9	0			
RBC; Week 12; to high; n= 12	0			
RBC; Week 12; to low; n= 12	3			
RBC; Week 28; to high; n= 11	0			
RBC; Week 28; to low; n= 11	1			
RBC; Week 52; to high; n= 9	0			
RBC; Week 52; to low; n= 9	1			
RBC; Week 76; to high; n= 8	0			
RBC; Week 76; to low; n= 8	0			
RBC; Week 104; to high; n= 9	0			
RBC; Week 104; to low; n= 9	0			
RBC; 16 week follow up; to high; n= 9	0			
RBC; 16 week follow up; to low; n= 9	1			
WBC; Week 12; to high; n= 12	1			
WBC; Week 12; to low; n= 12	0			
WBC; Week 28; to high; n= 11	0			
WBC; Week 28; to low; n= 11	0			
WBC; Week 52; to high; n= 9	0			
WBC; Week 52; to low; n= 9	0			
WBC; Week 76; to high; n= 8	0			
WBC; Week 76; to low; n= 8	0			
WBC; Week 104; to high; n= 9	2			
WBC; Week 104; to low; n= 9	0			
WBC; 16 week follow up; to high; n= 9	1			
WBC; 16 week follow up; to low; n= 9	0			

Notes:

[32] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with urinalysis dipstick findings

End point title	Number of participants with urinalysis dipstick findings

End point description:

Urine samples were collected for urinalysis by dipstick method from Baseline up to Week 116/16 months follow up and number of participants with findings were presented for Baseline, Week 12, 28, 52, 76, 104/4 weeks post last-dose and Week 116/16 week follow up (WF). The urinalysis parameters included

occult blood, glucose, ketones, protein. The findings were presented as trace or 1/10 g/100 milliliter (dL), trace, negative, 4+, 3+, 3+ or 1 g/dL, 2+ or 1/2 g/dL, 2+, 1+ or 1/4 g/dL and 1+. Only participants present at the specific time points were presented (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Baseline and up to Week 116/16 Week follow up

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[33]			
Units: Participants				
Week 12; occult blood; Trace or 1/10 g/DL; n= 12	0			
Week 12;Occult Blood; Trace; n= 12	1			
Week 12; Occult Blood; negative; n= 12	2			
Week 12; Occult Blood; 4+; n= 12	0			
Week 12; Occult Blood; 3+ OR 1 G/DL; n= 12	0			
Week 12; Occult Blood; 3+; n= 12	2			
Week 12; Occult Blood; 2+ OR 1/2 G/DL; n= 12	0			
Week 12; Occult Blood; 2+ ; n= 12	6			
Week 12; Occult Blood;1+ OR 1/4 G/DL; n= 12	0			
Week 12; Occult Blood; 1+; n= 12	1			
Week 12; glucose; Trace or 1/10 g/DL; n= 12	3			
Week 12;glucose; Trace; n= 12	0			
Week 12; glucose; negative; n= 12	8			
Week 12; glucose; 4+; n= 12	0			
Week 12; glucose; 3+ OR 1 G/DL; n= 12	0			
Week 12; glucose; 3+; n= 12	0			
Week 12; glucose; 2+ OR 1/2 G/DL; n= 12	0			
Week 12; glucose; 2+ ; n= 12	0			
Week 12; glucose;1+ OR 1/4 G/DL; n= 12	1			
Week 12; glucose; 1+; n= 12	0			
Week 12; ketones; Trace or 1/10 g/DL; n= 12	0			
Week 12; ketones; Trace; n= 12	0			
Week 12; ketones; negative; n= 12	12			
Week 12; ketones; 4+; n= 12	0			
Week 12; ketones; 3+ OR 1 G/DL; n= 12	0			
Week 12; ketones; 3+; n= 12	0			
Week 12; ketones; 2+ OR 1/2 G/DL; n= 12	0			
Week 12; ketones; 2+ ; n= 12	0			
Week 12; ketones;1+ OR 1/4 G/DL; n= 12	0			

Week 12; ketones; 1+; n= 12	0			
Week 12; protein; Trace or 1/10 g/DL; n= 12	0			
Week 12; Protein; Trace; n= 12	0			
Week 12; Protein; negative; n= 12	0			
Week 12; Protein; 4+; n= 12	0			
Week 12; Protein; 3+ OR 1 G/DL; n= 12	0			
Week 12; Protein; 3+; n= 12	8			
Week 12; Protein; 2+ OR 1/2 G/DL; n= 12	0			
Week 12; Protein; 2+ ; n= 12	3			
Week 12; Protein;1+ OR 1/4 G/DL; n= 12	0			
Week 12; Protein; 1+; n= 12	1			
Week 28; occult blood; Trace or 1/10 g/DL; n= 11	0			
Week 28;Occult Blood; Trace; n= 11	2			
Week 28; Occult Blood; negative; n= 11	1			
Week 28; Occult Blood; 4+; n= 11	0			
Week 28; Occult Blood; 3+ OR 1 G/DL; n= 11	0			
Week 28; Occult Blood; 3+; n= 11	0			
Week 28; Occult Blood; 2+ OR 1/2 G/DL; n= 11	0			
Week 28; Occult Blood; 2+ ; n= 11	4			
Week 28; Occult Blood;1+ OR 1/4 G/DL; n= 11	0			
Week 28; Occult Blood; 1+; n= 11	4			
Week 28; glucose; Trace or 1/10 g/DL; n= 11	1			
Week 28;glucose; Trace; n= 11	0			
Week 28; glucose; negative; n= 11	9			
Week 28; glucose; 4+; n= 11	0			
Week 28; glucose; 3+ OR 1 G/DL; n= 11	0			
Week 28; glucose; 3+; n= 11	0			
Week 28; glucose; 2+ OR 1/2 G/DL; n= 11	0			
Week 28; glucose; 2+ ; n= 11	0			
Week 28; glucose;1+ OR 1/4 G/DL; n= 11	1			
Week 28; glucose; 1+; n= 11	0			
Week 28; ketones; Trace or 1/10 g/DL; n= 11	0			
Week 28; ketones; Trace; n= 11	0			
Week 28; ketones; negative; n= 11	11			
Week 28; ketones; 4+; n= 11	0			
Week 28; ketones; 3+ OR 1 G/DL; n= 11	0			
Week 28; ketones; 3+; n= 11	0			
Week 28; ketones; 2+ OR 1/2 G/DL; n= 11	0			
Week 28; ketones; 2+ ; n= 11	0			
Week 28; ketones;1+ OR 1/4 G/DL; n= 11	0			
Week 28; ketones; 1+; n= 11	0			

Week 28; protein; Trace or 1/10 g/DL; n= 11	0			
Week 28; Protein; Trace; n= 11	0			
Week 28; Protein; negative; n= 11	0			
Week 28; protein; 4+; n= 11	0			
Week 28; Protein; 3+ OR 1 G/DL; n= 11	0			
Week 28; Protein; 3+; n= 11	10			
Week 28; Protein; 2+ OR 1/2 G/DL; n= 11	0			
Week 28; Protein; 2+ ; n= 11	1			
Week 28; Protein;1+ OR 1/4 G/DL; n= 11	0			
Week 28; Protein; 1+; n= 11	0			
Week 52; occult blood; Trace or 1/10 g/DL; n= 9	0			
Week 52;Occult Blood; Trace; n= 9	2			
Week 52; Occult Blood; negative; n= 9	3			
Week 52; Occult Blood; 4+; n= 9	0			
Week 52; Occult Blood; 3+ OR 1 G/DL; n= 9	0			
Week 52; Occult Blood; 3+; n= 9	0			
Week 52; Occult Blood; 2+ OR 1/2 G/DL; n= 9	0			
Week 52; Occult Blood; 2+ ; n= 9	4			
Week 52; Occult Blood;1+ OR 1/4 G/DL; n= 9	0			
Week 52; Occult Blood; 1+; n= 9	0			
Week 52; glucose; Trace or 1/10 g/DL; n= 9	2			
Week 52;glucose; Trace; n= 9	0			
Week 52; glucose; negative; n= 9	7			
Week 52; glucose; 4+; n= 9	0			
Week 52; glucose; 3+ OR 1 G/DL; n= 9	0			
Week 52; glucose; 3+; n= 9	0			
Week 52; glucose; 2+ OR 1/2 G/DL; n= 9	0			
Week 52; glucose; 2+ ; n= 9	0			
Week 52; glucose;1+ OR 1/4 G/DL; n= 9	0			
Week 52; glucose; 1+; n= 9	0			
Week 52; ketones; Trace or 1/10 g/DL; n= 9	0			
Week 52; ketones; Trace; n= 9	0			
Week 52; ketones; negative; n= 9	9			
Week 52; ketones; 4+; n= 9	0			
Week 52; ketones; 3+ OR 1 G/DL; n= 9	0			
Week 52; ketones; 3+; n= 9	0			
Week 52; ketones; 2+ OR 1/2 G/DL; n= 9	0			
Week 52; ketones; 2+ ; n= 9	0			
Week 52; ketones;1+ OR 1/4 G/DL; n= 9	0			
Week 52; ketones; 1+; n= 9	0			
Week 52; protein; Trace or 1/10 g/DL; n= 9	0			
Week 52; Protein; Trace; n= 9	0			

Week 52; Protein; negative; n= 9	0			
Week 52; protein; 4+; n= 9	0			
Week 52; Protein; 3+ OR 1 G/DL; n= 9	0			
Week 52; Protein; 3+; n= 9	4			
Week 52; Protein; 2+ OR 1/2 G/DL; n= 9	0			
Week 52; Protein; 2+ ; n= 9	3			
Week 52; Protein;1+ OR 1/4 G/DL; n= 9	0			
Week 52; Protein; 1+; n= 9	2			
Week 76; occult blood; Trace or 1/10 g/DL;n=7	0			
Week 76;Occult Blood; Trace; n= 7	3			
Week 76; Occult Blood; negative; n= 7	3			
Week 76; Occult Blood; 4+; n= 7	0			
Week 76; Occult Blood; 3+ OR 1 G/DL; n= 7	0			
Week 76; Occult Blood; 3+; n= 7	0			
Week 76; Occult Blood; 2+ OR 1/2 G/DL; n= 7	0			
Week 76; Occult Blood; 2+ ; n= 7	0			
Week 76; Occult Blood;1+ OR 1/4 G/DL; n= 7	0			
Week 76; Occult Blood; 1+; n= 7	1			
Week 76; glucose; Trace or 1/10 g/DL; n= 7	2			
Week 76;glucose; Trace; n= 7	0			
Week 76; glucose; negative; n= 7	5			
Week 76; glucose; 4+; n= 7	0			
Week 76; glucose; 3+ OR 1 G/DL; n= 7	0			
Week 76; glucose; 3+; n= 7	0			
Week 76; glucose; 2+ OR 1/2 G/DL; n= 7	0			
Week 76; glucose; 2+ ; n= 7	0			
Week 76; glucose;1+ OR 1/4 G/DL; n= 7	0			
Week 76; glucose; 1+; n= 7	0			
Week 76; ketones; Trace or 1/10 g/DL; n= 7	0			
Week 76; ketones; Trace; n= 7	0			
Week 76; ketones; negative; n= 7	7			
Week 76; ketones; 4+; n= 7	0			
Week 76; ketones; 3+ OR 1 G/DL; n= 7	0			
Week 76; ketones; 3+; n= 7	0			
Week 76; ketones; 2+ OR 1/2 G/DL; n= 7	0			
Week 76; ketones; 2+ ; n= 7	0			
Week 76; ketones;1+ OR 1/4 G/DL; n= 7	0			
Week 76; ketones; 1+; n= 7	0			
Week 76; protein; Trace or 1/10 g/DL; n= 7	0			
Week 76; Protein; Trace; n= 7	0			
Week 76; Protein; negative; n= 7	1			
Week 76; protein; 4+; n= 7	0			
Week 76; Protein; 3+ OR 1 G/DL; n= 7	0			

Week 76; Protein; 3+; n= 7	1			
Week 76; Protein; 2+ OR 1/2 G/DL; n= 7	0			
Week 76; Protein; 2+ ; n= 7	4			
Week 76; Protein;1+ OR 1/4 G/DL; n= 7	0			
Week 76; Protein; 1+; n= 7	1			
Week 104; occult blood; Trace or 1/10 g/DL;n=10	0			
Week 104;Occult Blood; Trace; n= 10	0			
Week 104; Occult Blood; negative; n= 10	8			
Week 104; Occult Blood; 4+; n= 10	0			
Week 104; Occult Blood; 3+ OR 1 G/DL; n= 10	0			
Week 104; Occult Blood; 3+; n= 10	0			
Week 104; Occult Blood; 2+ OR 1/2 G/DL; n= 10	0			
Week 104; Occult Blood; 2+ ; n=10	1			
Week 104; Occult Blood;1+ OR 1/4 G/DL; n= 10	0			
Week 104; Occult Blood; 1+; n= 10	1			
Week 104; glucose; Trace or 1/10 g/DL; n= 10	2			
Week 104 ;glucose; Trace; n= 10	0			
Week 104; glucose; negative; n= 10	7			
Week 104; glucose; 4+; n= 10	0			
Week 104; glucose; 3+ OR 1 G/DL; n= 10	0			
Week 104; glucose; 3+; n= 10	0			
Week 104; glucose; 2+ OR 1/2 G/DL; n= 10	0			
Week 104; glucose; 2+ ; n= 10	0			
Week 104; glucose;1+ OR 1/4 G/DL; n= 10	1			
Week 104; glucose; 1+; n= 10	0			
Week 104; ketones; Trace or 1/10 g/DL; n= 10	0			
Week 104; ketones; Trace; n= 10	0			
Week 104; ketones; negative; n= 10	10			
Week 104; ketones; 4+; n= 10	0			
Week 104; ketones; 3+ OR 1 G/DL; n= 10	0			
Week 104; ketones; 3+; n= 10	0			
Week 104; ketones; 2+ OR 1/2 G/DL; n= 10	0			
Week 104; ketones; 2+ ; n= 10	0			
Week 104; ketones;1+ OR 1/4 G/DL; n= 10	0			
Week 104; ketones; 1+; n= 10	0			
Week 104; protein; Trace or 1/10 g/DL; n= 10	0			
Week 104; Protein; Trace; n= 10	0			
Week 104; Protein; negative; n= 10	1			
Week 104; protein; 4+; n= 10	0			
Week 104; Protein; 3+ OR 1 G/DL; n= 10	0			

Week 104; Protein; 3+; n= 10	3			
Week 104; Protein; 2+ OR 1/2 G/DL; n= 10	0			
Week 104; Protein; 2+ ; n= 10	6			
Week 104; Protein;1+ OR 1/4 G/DL; n= 10	0			
Week 104; Protein; 1+; n= 10	0			
16 WF; Occult blood; TRACE OR 1/10 G/DL; n= 9	0			
16 WF; Occult blood; TRACE; n= 9	2			
16 WF; Occult blood; NEGATIVE; n= 9	6			
16 WF; Occult blood; 4+; n= 9	0			
16 WF; Occult blood; 3+ OR 1 G/DL; n= 9	0			
16 WF; Occult blood; 3+; n= 9	0			
16 WF; Occult blood; 2+ OR 1/2 G/DL; n= 9	0			
16 WF; Occult blood; 2+; n= 9	1			
16 WF; Occult blood; 1+ OR 1/4 G/DL; n= 9	0			
16 WF; Occult blood; 1+; n= 9	0			
16 WF; Glucose; TRACE OR 1/10 G/DL; n= 9	1			
16 WF; Glucose; TRACE; n= 9	0			
16 WF; Glucose; negative; n= 9	7			
16 WF; Glucose; 4+; n= 9	0			
16 WF; Glucose; 3+ OR 1 G/DL; n= 9	0			
16 WF; Glucose; 3+; n= 9	0			
16 WF; Glucose; 2+ OR 1/2 G/DL; n= 9	1			
16 WF; Glucose; 2+; n= 9	0			
16 WF; Glucose; 1+ OR 1/4 G/DL; n=9	0			
16 WF; Glucose; 1+; n=9	0			
16 WF; Ketones; TRACE OR 1/10 G/DL; n= 9	0			
16 WF; Ketones; TRACE; n= 9	0			
16 WF; Ketones; negative; n= 9	9			
16 WF; Ketones; 4+; n= 9	0			
16 WF; Ketones; 3+ OR 1 G/DL; n= 9	0			
16 WF; Ketones; 3+; n= 9	0			
16 WF; Ketones; 2+ OR 1/2 G/DL; n= 9	0			
16 WF; Ketones; 2+; n= 9	0			
16 WF; Ketones; 1+ OR 1/4 G/DL; n= 9	0			
16 WF; Ketones; 1+; n= 9	0			
16 WF; Protein; TRACE OR 1/10 G/DL; n= 9	0			
16 WF; Protein; TRACE; n= 9	1			
16 WF; Protein; negative; n= 9	0			
16 WF; Protein; 4+; n= 9	0			
16 WF; Protein; 3+ OR 1 G/DL; n= 9	0			
16 WF; Protein; 3+; n= 9	3			
16 WF; Protein; 2+ OR 1/2 G/DL; n= 9	0			
16 WF; Protein; 2+; n= 9	4			
16 WF; Protein; 1+ OR 1/4 G/DL; n= 9	0			
16 WF; Protein; 1+; n= 9	1			

Notes:

[33] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in systolic blood pressure (SBP) and diastolic blood pressure (DBP)

End point title	Change from Baseline in systolic blood pressure (SBP) and diastolic blood pressure (DBP)

End point description:

SBP and DBP were measured from Baseline throughout the treatment period up to Week 116/ 16 week follow-up visit. The Baseline value was taken at Day 0 pre dose and change from Baseline was defined as post dose visit value minus Baseline value. Mean and standard deviation (SD) were measured and presented for Week 12, 28, 52, 76, 104 withdrawn visit, 4 Week post last dose and 16 Week follow-up visit. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline and up to week 116/16 week follow-up visit

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[34]			
Units: millimeter of mercury (mmHg)				
arithmetic mean (standard deviation)				
Week 12; SBP; n= 12	-4.2 (± 17.23)			
Week 28; SBP; n= 11	-5.8 (± 18.14)			
Week 52; SBP; n= 9	-1.9 (± 18.66)			
Week 76; SBP; n= 8	-1.3 (± 11.3)			
4 Week post last dose; SBP; n= 10	-12.2 (± 11.78)			
16 Week follow up; SBP; n= 9	-7.4 (± 15.72)			
Week 104 withdrawn visit; SBP; n= 2	-1 (± 5.66)			
Week 12; DBP; n= 12	3.8 (± 12.94)			
Week 28; DBP; n= 11	0.8 (± 10.75)			
Week 52; DBP; n= 9	1.2 (± 11.87)			
Week 76; DBP; n= 8	2.8 (± 9.68)			
4 Week post last dose; DBP; n= 10	-3.3 (± 9.87)			
16 Week follow up; DBP; n= 9	2.4 (± 14.98)			
Week 104 withdrawn visit; DBP; n= 2	5.5 (± 2.12)			

Notes:

[34] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in pulse rate

End point title	Change from Baseline in pulse rate

End point description:

Pulse rate was measured from Baseline throughout the treatment period up to Week 116/ 16 week follow-up visit. The Baseline value was taken at Day 0 pre dose and change from Baseline was defined as post dose visit value minus Baseline value. Mean and standard deviation (SD) were measured and presented for Week 12, 28, 52, 76, 104 withdrawn visit, 4 Week post last dose and 16 Week post last dose visits. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline and up to Week 116/16 week follow-up visit

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[35]			
Units: Beats per minute				
arithmetic mean (standard deviation)				
Week 12; n= 12	-0.7 (± 11.4)			
Week 28; n= 11	1 (± 7.9)			
Week 52; n= 9	-1.7 (± 13.11)			
Week 76; n= 8	-2.3 (± 15.77)			
4 Week post last dose; n= 10	-2.8 (± 15.33)			
16 Week follow up; n= 9	-0.9 (± 16.72)			
Week 104 withdrawn visit; n= 2	5 (± 7.07)			

Notes:

[35] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in temperature

End point title	Change from Baseline in temperature

End point description:

Temperature was measured from Baseline throughout the treatment period up to Week 116/ 16 week follow-up visit. The Baseline value was taken at Day 0 pre dose and change from Baseline was defined as post dose visit value minus Baseline value. Mean and standard deviation (SD) were measured and presented for Week 12, 28, 52, 76, 104 withdrawn visit, 4 Week post last dose and 16 week post last dose visits. Only those participants with data available at the specified data points were analyzed (represented by n= X in the category titles).

End point type	Secondary

End point timeframe:

Baseline and up to Week 116/16 week follow-up visit

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[36]			
Units: Celsius				
arithmetic mean (standard deviation)				
Week 12; n= 12	-0.09 (± 0.591)			
Week 28; n= 11	0 (± 0.453)			
Week 52; n= 9	-0.11 (± 0.639)			
Week 76; n= 8	-0.17 (± 0.486)			
4 Week post last dose; n= 8	-0.06 (± 0.604)			
16 Week follow up; n= 6	0.3 (± 0.424)			
Week 104 withdrawn visit; n= 2	0.15 (± 0.353)			

Notes:

[36] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with positive immunogenicity findings

End point title	Number of participants with positive immunogenicity findings

End point description:

Blood samples of participants were collected pre-dose on Weeks 0, 12, 28, 40, 52, 76, 4 week post last dose and 16 week post last dose visit for belimumab immunogenicity assay. No participants showed positive immunogenicity findings.

End point type	Secondary

End point timeframe:

Baseline and up to Week 116/16 week follow-up visit

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[37]			
Units: Participants				
Participants	0			

Notes:

[37] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Urine membrane attack complex (MAC) levels

End point title	Urine membrane attack complex (MAC) levels

End point description:

Urine membrane attack complex was assayed quantitatively by ELISA method. Urine MAC samples were collected at Day 0 and Weeks 8, 28, 52, 76 and 4 week post last dose. Results were normalized using urine creatinine concentration to adjust for urine dilution. Endpoint was moved to 'Exploratory' in Protocol amendment 5 as risk of availability of functioning assay for urine membrane attack complex was noted. No assay was subsequently found and samples were not analyzed.

End point type	Secondary

End point timeframe:

Baseline and up to 4 week post last dose

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	0[38]			
Units: Micrograms/micromoles (ug/umol)				
geometric mean (geometric coefficient of variation)				
Micrograms/micromoles (ug/umol)	()			

Notes:

[38] - ITT Population. No assay was subsequently found and samples were not analyzed

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in urine membrane attack complex (MAC)

End point title	Change from Baseline in urine membrane attack complex (MAC)

End point description:

Urine membrane attack complex will be assayed quantitatively by ELISA method. Urine MAC samples are being collected at Day 0 and Weeks 8, 28, 52, 76 and 4 week post last dose. Results will be normalized using urine creatinine concentration to adjust for urine dilution, before calculation of the ratio as value at time point divided by value at Baseline (Day 0). Endpoint was changed to 'exploratory' as risk of availability of functioning assay for urine membrane attack complex was noted. No assay was subsequently found and samples were not analyzed.

End point type	Secondary

End point timeframe:

Baseline and up to 4 week post last dose

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	0[39]			
Units: Ratio				
geometric mean (geometric coefficient of variation)				
Ratio	()			

Notes:

[39] - ITT Population. No assay was subsequently found and samples were not analyzed

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in B Cell and T Cell markers concentration

End point title	Change from Baseline in B Cell and T Cell markers concentration

End point description:

B cell Facs panels were used to measure changes over the course of therapy in B cell subsets such as transitional, naïve, memory and plasma B cell compartments by percent of the B cell compartments and absolute numbers. T cell Facs panel were used to measure changes in T cell subsets, such as T regs and CD4+ and CD8+ T cells, in terms of numbers and expression of activation markers to establish if B cell targeting with belimumab affects the T cell compartment perhaps through limiting B cell antigen presentation or cytokine release. Baseline is defined as Day 0 value and change from Baseline was calculated as ratio of post-Baseline value divided by the Baseline value. Only those participants available at the specified time points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Baseline and up to Week 128/6 month post last dose

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[40]			
Units: Ratio				
geometric mean (geometric coefficient of variation)				
CD19+; Week 8; n= 12	0.7221 (± 82.1)			
CD19+; Week 16; n= 11	0.9209 (± 63.6)			
CD19+; Week 28; n= 10	1.0049 (± 71.6)			
CD19+; Week 104; n= 10	0.5193 (± 156.2)			
CD19+; 6 month follow up; n= 7	0.3828 (± 185.7)			
CD19+ CD24b+ CD38b+ CD27-; Week 8; n= 12	0.2352 (± 340)			
CD19+ CD24b+ CD38b+ CD27-; Week 16; n= 11	0.6228 (± 316.7)			
CD19+ CD24b+ CD38b+ CD27-; Week 28; n= 10	0.6119 (± 656)			
CD19+ CD24b+ CD38b+ CD27-; Week 104; n= 10	0.3582 (± 405.1)			
CD19+ CD24b+ CD38b+ CD27-; 6 month follow up; n= 7	1.6471 (± 534)			
CD19+ CD27- IgD+; Week 8; n= 12	0.349 (± 131.6)			

CD19+ CD27- IgD+; Week 16; n= 11	0.4486 (± 94.7)			
CD19+ CD27- IgD+; Week 28; n= 10	0.4561 (± 82.5)			
CD19+ CD27- IgD+; Week 104; n= 10	0.1808 (± 298.6)			
CD19+ CD27- IgD+; 6 month follow up; n= 7	0.3278 (± 189.2)			
CD19+ CD27-; Week 8; n= 12	0.4074 (± 109.2)			
CD19+ CD27-; Week 16; n= 11	0.5079 (± 88.1)			
CD19+ CD27-; Week 28; n= 10	0.5165 (± 76.5)			
CD19+ CD27-; Week 104; n= 10	0.2602 (± 236.9)			
CD19+ CD27-; 6 month follow up; n= 7	0.3756 (± 186)			
CD19lo CD38hi CD27hi; Week 8; n= 12	0.5982 (± 555.4)			
CD19lo CD38hi CD27hi; Week 16; n= 11	0.4128 (± 1085.7)			
CD19lo CD38hi CD27hi; Week 28; n= 10	0.4481 (± 651.6)			
CD19lo CD38hi CD27hi; Week 104; n= 10	0.2615 (± 238.8)			
CD19lo CD38hi CD27hi; 6 month follow up; n= 7	0.0647 (± 1269.7)			
CD19+ CD24+ CD27+ ; Week 8; n= 12	2.0747 (± 65.3)			
CD19+ CD24+ CD27+ ; Week 16; n= 11	2.4161 (± 61.2)			
CD19+ CD24+ CD27+ ; Week 28; n= 10	3.1294 (± 64.2)			
CD19+ CD24+ CD27+ ; Week 104; n= 10	0.6089 (± 104014.8)			
CD19+ CD24+ CD27+ ; 6 month follow up; n= 7	0.7952 (± 328.6)			
CD19+CD27+; Week 8; n= 12	1.9195 (± 69.9)			
CD19+CD27+; Week 16; n= 11	2.3132 (± 62.7)			
CD19+CD27+; Week 28; n= 10	3.1352 (± 65.6)			
CD19+CD27+; Week 104; n= 10	1.3273 (± 127.7)			
CD19+CD27+; 6 month follow up; n= 7	0.3338 (± 158.2)			
CD19+CD27+IgD; Week 8; n= 12	1.9365 (± 69.6)			
CD19+CD27+IgD; Week 16; n= 11	2.3147 (± 75.1)			
CD19+CD27+IgD; Week 28; n= 10	3.2313 (± 51.1)			
CD19+CD27+IgD; Week 104; n= 10	1.2814 (± 102.3)			
CD19+CD27+IgD; 6 month follow up; n= 7	0.2413 (± 163.9)			
CD19+CD27+IgD-; Week 8; n= 12	1.8846 (± 67.7)			
CD19+CD27+IgD-; Week 16; n= 11	2.2113 (± 70.4)			

CD19+CD27+IgD-; Week 28; n= 10	3.0478 (± 73.2)			
CD19+CD27+IgD-; Week 104; n= 10	1.3051 (± 147.1)			
CD19+CD27+IgD-; 6 month follow up; n= 7	0.344 (± 163.8)			
CD4+ CD25hi CD45RA- IL7Rhi; Week 8; n= 12	0.701 (± 86.7)			
CD4+ CD25hi CD45RA- IL7Rhi; Week 16; n= 10	0.534 (± 221.3)			
CD4+ CD25hi CD45RA- IL7Rhi; Week 28; n= 9	0.5718 (± 669.2)			
CD4+ CD25hi CD45RA- IL7Rhi; Week 104; n= 10	4.1865 (± 509.4)			
CD4+ CD25hi CD45RA- IL7Rh; 6 month follow up; n= 7	1.8067 (± 1456.7)			
CD4+ CD45RA- IL-7Rhi; Week 8; n= 12	1.4174 (± 19513.4)			
CD4+ CD45RA- IL-7Rhi; Week 16; n= 10	1.8613 (± 99527.6)			
CD4+ CD45RA- IL-7Rhi; Week 28; n=9	2.8378 (± 49940.7)			
CD4+ CD45RA- IL-7Rhi; Week 104; n= 10	0.1517 (± 33534.3)			
CD4+ CD45RA- IL-7Rhi; 6 month follow-up; n= 7	0.3532 (± 966.4)			
CD4+ CD25hi xIL-7Rlo; Week 8; n= 12	0.7285 (± 85.7)			
CD4+ CD25hi xIL-7Rlo; Week 16; n= 11	0.6232 (± 317.6)			
CD4+ CD25hi xIL-7Rlo; Week 28; n= 10	0.701 (± 961.5)			
CD4+ CD25hi xIL-7Rlo; Week 104; n= 10	3.1025 (± 932.7)			
CD4+ CD25hi xIL-7Rlo; 6 month follow-up; n= 7	2.0827 (± 832.7)			
CD4+ CD25hi IL-7Rlo; Week 8; 12	2.3001 (± 29702.5)			
CD4+ CD25hi IL-7Rlo; Week 16; n= 10	2.9023 (± 136702.6)			
CD4+ CD25hi IL-7Rlo; Week 28; n= 9	3.3453 (± 35372.4)			
CD4+ CD25hi IL-7Rlo; Week 104; n= 10	0.341 (± 72506.2)			
CD4+ CD25hi IL-7Rlo; 6 month follow up; n= 7	0.9978 (± 32.7)			
CD4+ CD45RA-; Week 8; n= 12	0.7532 (± 44.5)			
CD4+ CD45RA-; Week 16; n= 11	0.7638 (± 55.4)			
CD4+ CD45RA-; Week 28; n= 10	0.9032 (± 71.1)			
CD4+ CD45RA-; 104; n= 10	0.975 (± 95.8)			
CD4+ CD45RA-; 6 month follow up; n= 7	1.0792 (± 90)			

Notes:

[40] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in cytokines/chemokine

End point title	Change from Baseline in cytokines/chemokine

End point description:

Cytokine/chemokine associated with T helper skewing or autoimmune pathology will be analyzed using Luminex, ELISA. Serum analyte quantification were used to confirm altered protein levels of any gene expression increases or decreases identified by transcriptomic analysis. Endpoint was moved to 'Exploratory' in Protocol amendment 5 as benefits of assessing cytokines was deemed low. Samples were not analyzed.

End point type	Secondary

End point timeframe:

Baseline and up to Week 104/4 week post last dose

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	0[41]			
Units: Ratio				
geometric mean (geometric coefficient of variation)				
Ratio	()			

Notes:

[41] - ITT Population. Samples were not analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Serum BLys levels

End point title	Serum BLys levels

End point description:

Free BLyS protein were analyzed using an ELISA. Serum samples were collected before treatment and after belimumab washout at Week 0 and Week 116/16 week follow-up visit.

End point type	Secondary

End point timeframe:

Baseline and Week 116/16 week follow-up visit

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	14[42]			
Units: pg/mL				
geometric mean (geometric coefficient of variation)				
Day 0; n= 14	969.9595 (± 16.8)			

16 week follow up; n= 8	12357.5558 (± 123.3)			

Notes:

[42] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Urine BLys levels as a ratio to creatinine

End point title	Urine BLys levels as a ratio to creatinine

End point description:

B lymphocyte stimulator (BLyS) normalized by creatinine as a ratio of BLyS: creatinine. Free BLyS protein is being analyzed using an ELISA. Urine samples are being collected before treatment and after belimumab washout at Week 0 and Week 116/16 week follow-up visit. Only raw BLyS values available and unable to be assessed due to lack of comparison to a creatinine as a urine concentration marker.

End point type	Secondary

End point timeframe:

Baseline and Week 116/16 week follow-up visit

End point values	Belimumab 10 mg/kg IV			
Subject group type	Reporting group			
Number of subjects analysed	0[43]			
Units: pg/mmol				
geometric mean (geometric coefficient of variation)				
pg/mmol	()			

Notes:

[43] - ITT Population. Only raw BLyS values available and unable to be assessed due to lack of comparison

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

On-therapy serious adverse events (SAEs) and non-serious adverse events (AEs) are presented from the start of study treatment up to end of study.

Adverse event reporting additional description:

On-therapy SAEs and non-serious AEs are reported for members of the ITT Population, comprised of all participants who received at least one dose of investigational drug.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups

Reporting group title	Belimumab 10 mg/kg IV

Reporting group description:

Participants received 10 milligrams per kilogram (mg/kg) belimumab intravenous (IV) infusion at Week 0 Week 2 and Week 4, then every 4 weeks over 24 weeks. Participants then entered the long-term phase of the study and received belimumab 10 mg/kg every 4 weeks up to Week 100 or until complete remission had been achieved.

Serious adverse events	Belimumab 10 mg/kg IV		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 14 (21.43%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Investigations			
Weight decreased			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Embolism			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Cellulitis			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Belimumab 10 mg/kg IV		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 14 (100.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Skin papilloma			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
General disorders and administration site conditions			
Malaise			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Chest pain			
subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	2		
Pyrexia			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Chest discomfort			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Immune system disorders			
Seasonal allergy			

subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	2		
Oropharyngeal pain			
subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	3		
Epistaxis			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Productive cough			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Insomnia			
subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	2		
Investigations			
Eosinophil count increased			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Blood parathyroid hormone increased			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Injury, poisoning and procedural complications			
Limb injury			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Cardiac disorders			

Angina pectoris subjects affected / exposed occurrences (all) Palpitations subjects affected / exposed occurrences (all)	 1 / 14 (7.14%) 1 1 / 14 (7.14%) 2		
Nervous system disorders Headache subjects affected / exposed occurrences (all) Dizziness subjects affected / exposed occurrences (all) Migraine subjects affected / exposed occurrences (all) Presyncope subjects affected / exposed occurrences (all) Hypoaesthesia subjects affected / exposed occurrences (all) Peripheral sensory neuropathy subjects affected / exposed occurrences (all) Sciatica subjects affected / exposed occurrences (all)	 2 / 14 (14.29%) 7 2 / 14 (14.29%) 3 1 / 14 (7.14%) 1 1 / 14 (7.14%) 1 1 / 14 (7.14%) 1 1 / 14 (7.14%) 1 1 / 14 (7.14%) 1		
Ear and labyrinth disorders Tinnitus subjects affected / exposed occurrences (all)	 1 / 14 (7.14%) 1		
Eye disorders Periorbital oedema subjects affected / exposed occurrences (all)	 1 / 14 (7.14%) 1		
Gastrointestinal disorders			

Diarrhoea				
subjects affected / exposed	2 / 14 (14.29%)			
occurrences (all)	3			
Abdominal pain				
subjects affected / exposed	1 / 14 (7.14%)			
occurrences (all)	1			
Abdominal pain upper				
subjects affected / exposed	1 / 14 (7.14%)			
occurrences (all)	1			
Ascites				
subjects affected / exposed	1 / 14 (7.14%)			
occurrences (all)	1			
Dyspepsia				
subjects affected / exposed	2 / 14 (14.29%)			
occurrences (all)	3			
Irritable bowel syndrome				
subjects affected / exposed	1 / 14 (7.14%)			
occurrences (all)	1			
Nausea				
subjects affected / exposed	1 / 14 (7.14%)			
occurrences (all)	1			
Rectal haemorrhage				
subjects affected / exposed	2 / 14 (14.29%)			
occurrences (all)	2			
Vomiting				
subjects affected / exposed	2 / 14 (14.29%)			
occurrences (all)	2			
Gingival bleeding				
subjects affected / exposed	1 / 14 (7.14%)			
occurrences (all)	1			
Haemorrhoids				
subjects affected / exposed	1 / 14 (7.14%)			
occurrences (all)	1			
Melaena				
subjects affected / exposed	1 / 14 (7.14%)			
occurrences (all)	1			

Toothache			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	2		
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	2		
Rash pruritic			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Skin lesion			
subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	2		
Swelling face			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	3		
Angioedema			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Renal and urinary disorders			
Tubulointerstitial nephritis			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Costovertebral angle tenderness			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Muscle spasms			
subjects affected / exposed	4 / 14 (28.57%)		
occurrences (all)	12		
Arthralgia			
subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	2		
Flank pain			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		

Joint swelling			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Myalgia			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Pain in extremity			
subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	2		
Back pain			
subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	4		
Musculoskeletal discomfort			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Neck pain			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Tendonitis			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	6 / 14 (42.86%)		
occurrences (all)	10		
Cellulitis			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Lower respiratory tract infection			
subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	2		
Oral candidiasis			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Respiratory tract infection			

subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	4		
Rhinitis			
subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	2		
Urinary tract infection			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	2		
Viral upper respiratory tract infection			
subjects affected / exposed	5 / 14 (35.71%)		
occurrences (all)	5		
Viral infection			
subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	2		
Influenza			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Labyrinthitis			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Lower respiratory tract infection viral			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 May 2012	Clarification of stopping criteria; additional rationale for hypogammaglobulinaemia including stopping criteria and monitoring; removal of Disease-Related Events provision; clarification of SRT.
21 December 2012	Addition of Benlysta program generic suicidality monitoring text; extension of biopsy inclusion to 7 years (3 years non-active); extension of time before stopping study treatment when hypogammaglobulinaemia without improvement; removal of requirement for 6 month post dose immunogenicity; addition of aliskiren, ACTH to prohibited medications; minor clarifications and consistency corrections.
10 January 2014	Addition of 6 month post treatment follow-up; PML text revision; alternative use of 24h protein excretion instead of uPCR in eligibility and for increased dosing frequency threshold; reduction in rituximab washout; removal NSAID prohibition; removal of change in urine belimumab endpoint; minor clarifications and consistency corrections
06 March 2014	Strengthening of discouragement against use of NSAIDs.
22 June 2016	Modification and clarification of secondary and exploratory endpoints, due to change in protocol template; clarification of Week 104 withdrawn visit; addition of serum IgG as an efficacy marker; clarification of text defining populations and confirmatory samples.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported