



Clinical trial results:

BEL114424: A Phase 2 Pilot, Multicentered, Randomised, Double Blind, Placebo-Controlled Study to Evaluate the Potential for Efficacy and the Safety of Belimumab plus Standard of Care versus Placebo plus Standard of Care in the Prevention of Allograft Rejection in Adult Subjects After Renal Transplantation.

Summary

EudraCT number	2011-006215-56
Trial protocol	GB
Global end of trial date	08 February 2016

Results information

Result version number	v2 (current)
This version publication date	10 May 2017
First version publication date	21 October 2016
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	114424
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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	09 June 2016
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	08 February 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Efficacy: To estimate the change in naïve B cells following belimumab 10 mg/kg (or placebo) in addition to standard of care immunosuppressants in renal transplant patients from the time of transplantation up to 24 weeks.

Safety: To assess the safety and tolerability of belimumab 10 mg/kg (or placebo) in renal transplant patients in addition to standard of care immunosuppressants.

Protection of trial subjects:

Not applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	13 September 2013
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: 25
Worldwide total number of subjects	25
EEA total number of subjects	25

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)	22
From 65 to 84 years	3
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 30 renal transplant recipients were enrolled, of which 28 were randomized and 25 were transplanted.

Pre-assignment

Screening details:

Participants were randomized to 1 of the 2 treatments groups in a 1:1 ratio and received standard of care in addition to investigational products (IPs). Participants received IP infusion on Day 0, Day 14, Day 28 and every 4 weeks thereafter for a total of 7 infusions.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Participants received normal saline (0.9% sodium chloride) via intravenous infusion over 1 hour, every 4 weeks for 24 weeks (with an additional dose at week 2) in addition to standard of care assessments, treatment and other interventions according to institutional protocols from the time of transplantation throughout the study.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received normal saline (0.9% sodium chloride) via intravenous infusion over 1 hour, every 4 weeks for 24 weeks (with an additional dose at week 2)

Arm title	Belimumab 10mg/kg
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Arm description:

Participants received 10 milligram (mg) /kilogram (kg) belimumab in 250 milliliter (mL) normal saline via intravenous infusion over 1 hour, every 4 weeks for 24 weeks (with an additional dose at week 2) standard of care assessments, treatment and other interventions according to institutional protocols from the time of transplantation throughout the study.

Arm type	Experimental
Investigational medicinal product name	Belimumab 10mg/kg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received 10 milligram (mg) /kilogram (kg) belimumab in 250 milliliter (mL) normal saline via intravenous infusion over 1 hour, every 4 weeks for 24 weeks (with an additional dose at week 2)

Number of subjects in period 1	Placebo	Belimumab 10mg/kg
Started	13	12
Completed	11	9
Not completed	2	3
Adverse event, serious fatal	1	-
Consent withdrawn by subject	1	1
Adverse event, non-fatal	-	2

Baseline characteristics

Reporting groups

Reporting group title	Placebo
Reporting group description:	
Participants received normal saline (0.9% sodium chloride) via intravenous infusion over 1 hour, every 4 weeks for 24 weeks (with an additional dose at week 2) in addition to standard of care assessments, treatment and other interventions according to institutional protocols from the time of transplantation throughout the study.	
Reporting group title	Belimumab 10mg/kg
Reporting group description:	
Participants received 10 milligram (mg) /kilogram (kg) belimumab in 250 milliliter (mL) normal saline via intravenous infusion over 1 hour, every 4 weeks for 24 weeks (with an additional dose at week 2) standard of care assessments, treatment and other interventions according to institutional protocols from the time of transplantation throughout the study.	

Reporting group values	Placebo	Belimumab 10mg/kg	Total
Number of subjects	13	12	25
Age categorical Units: Subjects			
Age continuous			
Age continuous description			
Units: years			
arithmetic mean	51	54.3	
standard deviation	± 14.02	± 11.02	-
Gender categorical			
Gender categorical description			
Units: Subjects			
Female	4	7	11
Male	9	5	14
Race/Ethnicity, Customized			
Units: Subjects			
White/Caucasian	12	11	23
Asian	1	1	2

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: Participants received normal saline (0.9% sodium chloride) via intravenous infusion over 1 hour, every 4 weeks for 24 weeks (with an additional dose at week 2) in addition to standard of care assessments, treatment and other interventions according to institutional protocols from the time of transplantation throughout the study.	
Reporting group title	Belimumab 10mg/kg
Reporting group description: Participants received 10 milligram (mg) /kilogram (kg) belimumab in 250 milliliter (mL) normal saline via intravenous infusion over 1 hour, every 4 weeks for 24 weeks (with an additional dose at week 2) standard of care assessments, treatment and other interventions according to institutional protocols from the time of transplantation throughout the study.	

Primary: Change from Baseline in naïve B cells from Baseline to Week 24

End point title	Change from Baseline in naïve B cells from Baseline to Week 24
End point description: Naïve B cell is cell that is not exposed to antigen. Naïve B cell count is CD20+CD27 concentration of cells (conc-cell)/cubic millimeter (cumm). Change from Baseline in naïve B cells was calculated as the value at Week 24 minus the value at Baseline. MITT Population consisted of all participants randomized to treatment, who have had taken at least one dose of study. Participants analyzed included those who had data at Week 24 for naïve B cells count (MITT Population). Baseline value used in the analysis was of Day 0 (Day of transplant). Adjusted mean differences (treatment-placebo) and 95% confidence intervals for differences were obtained from mixed-models repeated-measures (MMRM) model, with fixed categorical effects of treatment, visit, donor type and treatment-by-visit interaction and fixed continuous covariates of Baseline and Baseline-by-visit interaction. A compound symmetry variance structure was used to model the within-participant errors, shared across treatments.	
End point type	Primary
End point timeframe: Baseline and Week 24	

End point values	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9 ^[1]	7		
Units: cells/mm ³				
least squares mean (standard error)	4 (± 25.55)	-30.4 (± 27.5)		

Notes:

[1] - Modified Intent to treat (MITT) Population

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Belimumab 10mg/kg v Placebo

Number of subjects included in analysis	16
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-34.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-109.5
upper limit	40.7
Variability estimate	Standard error of the mean
Dispersion value	37.24

Primary: Number of participants with Adverse events (AEs), Serious adverse events (SAEs) and Adverse Events of Special Interest (AESI)

End point title	Number of participants with Adverse events (AEs), Serious adverse events (SAEs) and Adverse Events of Special Interest (AESI) ^[2]
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End point description:

Number of participants with AEs, SAEs and AESI are summarized. The On-treatment (OT) phase started on the day and time of receiving the start of the first infusion and ended on the last dose date plus 28 days. The Post-treatment (PT) phase started 29 days after day of last dose up to 1 year. An AE is any untoward medical occurrence, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. SAE is defined as 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 or event that but may jeopardize the subject or may require medical or surgical intervention to prevent one of the other outcomes listed. AESI included malignant neoplasms, infusion/anaphylaxis/hypersensitivity reactions, all infections, depression/suicide/self-injury, deaths.

End point type	Primary
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End point timeframe:

Up to 1 year

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: There are no statistical data to report.

End point values	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[3]	12		
Units: Participants				
OT AEs	10	11		
PT AEs	9	10		
OT SAEs	7	5		
PT SAEs	2	2		
Malignant neoplasms	0	0		
Post-Infusion Systemic Reactions	0	1		
All Infections	6	7		
Depression/suicide/self-injury	0	0		
Deaths	1	0		

Notes:

[3] - mITT Population

Statistical analyses

No statistical analyses for this end point

Primary: Number of incidence of all infections and serious infections

End point title	Number of incidence of all infections and serious infections ^[4]
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End point description:

All infections included: 1. Opportunistic infections per-clinical assessment, 2. Herpes Zoster, a. Recurrent, b. Disseminated, 3. Sepsis. Opportunistic infections were identified using list of preferred terms as per Medical Dictionary for Regulatory Activities (MedDRA) version 18.1. Any events falling under these preferred terms were adjudicated to determine if criteria was met for an opportunistic infection.

End point type	Primary
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End point timeframe:

Up to 1 year

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: There are no statistical data to report.

End point values	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[5]	12		
Units: Infections				
All Infections	8	7		
Serious Infections	2	1		
All Opportunistic Infections	7	5		
Serious Opportunistic Infections	1	0		
All Herpes Zoster	0	1		
Serious Herpes Zoster	0	0		
Sepsis	3	2		
Serious Sepsis	2	1		

Notes:

[5] - mITT Population

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in systolic blood pressure (SBP) and diastolic blood pressure (DBP) at Week 24 and Week 52

End point title	Change from Baseline in systolic blood pressure (SBP) and diastolic blood pressure (DBP) at Week 24 and Week 52 ^[6]
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End point description:

Change from Baseline in SBP and DBP were assessed at Week 24 (at the end of therapy) and at Week 52 (at study end). Change from Baseline was calculated as the value at Week 24 and Week 52 minus

the value at Baseline. Baseline value used in the analysis was of Day 0 (Day of transplant). Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

End point type	Primary
End point timeframe:	
Baseline, Week 24 and Week 52	

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: There are no statistical data to report.

End point values	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[7]	12		
Units: millimeter of mercury (mmHg)				
arithmetic mean (standard deviation)				
DBP Week 24; n=9, 7	-4.444 (± 14.3275)	7.286 (± 13.8289)		
DBP Week 52; n=11, 10	-6.545 (± 13.9668)	4.2 (± 8.5479)		
SBP Week 24; n=9, 7	2 (± 26.096)	10 (± 35.9444)		
SBP Week 52; n=11, 10	-2.909 (± 27.2046)	3.3 (± 27.9008)		

Notes:

[7] - mITT Population

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in heart rate from Baseline at Week 24 and Week 52

End point title	Change from Baseline in heart rate from Baseline at Week 24 and Week 52 ^[8]
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End point description:

Change from Baseline in heart rate was assessed at Week 24 (at the end of therapy) and at Week 52 (at study end). Change from Baseline was calculated as the value at Week 24 and Week 52 minus the value at Baseline. Baseline value used in the analysis was of Day 0 (Day of transplant). Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

End point type	Primary
End point timeframe:	
Baseline, Week 24 and Week 52	

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: There are no statistical data to report.

End point values	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[9]	12		
Units: Beats per minute (BPM)				
arithmetic mean (standard deviation)				
Week 24; n=8, 6	5.125 (± 16.8983)	1.5 (± 13.6345)		

Week 52; n=11, 9	2 ($\pm$ 11.5065)	-2.444 ($\pm$ 15.42)		
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Notes:

[9] - mITT Population

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in body temperature from Baseline at Week 24 and Week 52

End point title	Change from Baseline in body temperature from Baseline at Week 24 and Week 52 ^[10]
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End point description:

Change from Baseline in body temperature was assessed at Week 24 (at the end of therapy) and at Week 52 (at study end). Change from Baseline was calculated as the value at Week 24 and Week 52 minus the value at Baseline. Baseline value used in the analysis was of Day 0 (Day of transplant). Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

End point type	Primary
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End point timeframe:

Baseline, Week 24 and Week 52

Notes:

[10] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: There are no statistical data to report.

End point values	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[11]	12		
Units: Degree Centigrade				
arithmetic mean (standard deviation)				
Week 24; n=8, 6	0.025 ($\pm$ 0.7025)	-0.233 ($\pm$ 0.5007)		
Week 52; n=11, 10	-0.045 ($\pm$ 0.4803)	0.03 ($\pm$ 0.5417)		

Notes:

[11] - mITT Population

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants outside the normal range (NR) for SBP and DBP at Week 24 and Week 52

End point title	Number of participants outside the normal range (NR) for SBP and DBP at Week 24 and Week 52 ^[12]
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End point description:

Number of participants outside the normal range (NR) for SBP and DBP was assessed at Week 24 (at the end of therapy) and at Week 52 (at study end). Number of participants outside the normal range are summarized by less than (<) normal range and greater than (>) normal range categories at Week 24 and Week 52. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

End point type	Primary
End point timeframe:	
Week 24 and Week 52	
Notes:	
[12] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.	
Justification: There are no statistical data to report.	

End point values	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[13]	12		
Units: Participants				
DBP, > NR, Week 24; n=9, 7	1	1		
DBP, < NR, Week 24; n=9, 7	1	2		
DBP, > NR, Week 52; n=11, 10	3	0		
DBP, < NR, Week 52; n=11, 10	2	1		
SBP, > NR, Week 24; n=9, 7	5	3		
SBP, < NR, Week 24; n=9, 7	0	0		
SBP, > NR, Week 52; n=11, 10	5	4		
SBP, < NR, Week 52; n=11, 10	0	1		

Notes:

[13] - mITT Population

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants outside the normal range (NR) for heart rate at Week 24 and Week 52

End point title	Number of participants outside the normal range (NR) for heart rate at Week 24 and Week 52 ^[14]
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End point description:

Number of participants outside the normal range (NR) for heart rate was assessed at Week 24 (at the end of therapy) and at Week 52 (at study end). Number of participants outside the normal range are summarized by less than (<) normal range and greater than (>) normal range categories at Week 24 and Week 52. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

End point type	Primary
End point timeframe:	
Week 24 and Week 52	

Notes:

[14] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: There are no statistical data to report.

End point values	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[15]	12		
Units: Participants				
> NR Week 24; n=8, 6	1	0		
< NR Week 24; n=8, 6	2	0		
> NR Week 52; n=11, 9	0	0		

< NR Week 52; n=11, 9	1	1		
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Notes:

[15] - mITT Population

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants outside the normal range (NR) for body temperature at Week 24 and Week 52

End point title	Number of participants outside the normal range (NR) for body temperature at Week 24 and Week 52 ^[16]
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End point description:

Number of participants outside the normal range (NR) for body temperature was assessed at Week 24 (at the end of therapy) and at Week 52 (at study end). Number of participants outside the normal range are summarized by less than (<) normal range and greater than (>) normal range categories at Week 24 and Week 52. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

End point type	Primary
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End point timeframe:

Week 24 and Week 52

Notes:

[16] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: There are no statistical data to report.

End point values	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[17]	12		
Units: Participants				
> NR Week 24; n=8, 6	0	0		
< NR Week 24; n=8, 6	3	4		
> NR Week 52; n=11, 10	0	0		
< NR Week 52; n=11, 10	5	2		

Notes:

[17] - mITT Population

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in the indicated hematology parameters at Week 24 and Week 52

End point title	Change from Baseline in the indicated hematology parameters at Week 24 and Week 52 ^[18]
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End point description:

Hematology parameters included: basophils (B), eosinophils (E), lymphocytes (L), monocytes (M), total neutrophils (N), platelet count (PC) and white blood cells (WBC). Change from Baseline in haematology parameter was assessed at Week 24 (at the end of therapy) and at Week 52 (at study end). Change from Baseline was calculated as the value on Week 24 and Week 52 minus the value at Baseline. Baseline value used in the analysis was of Day 0 (Day of transplant). Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

End point type	Primary
End point timeframe:	
Baseline, Week 24 and Week 52	

Notes:

[18] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: There are no statistical data to report.

End point values	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[19]	12		
Units: Gills/Liter (GI/L)				
arithmetic mean (standard deviation)				
B Week 24; n=9, 6	-0.001 (± 0.0215)	-0.015 (± 0.0207)		
B Week 52; n=10, 10	0.033 (± 0.1024)	-0.005 (± 0.0357)		
E Week 24; n=9, 6	-0.531 (± 1.025)	-0.14 (± 0.1274)		
E Week 52; n=10, 10	-0.392 (± 0.8048)	-0.127 (± 0.1489)		
L Week 24; n=9, 6	-0.218 (± 0.6457)	-0.347 (± 0.3467)		
L Week 52; n=10, 10	0.085 (± 0.5841)	-0.245 (± 0.3357)		
M Week 24; n=9, 6	-0.097 (± 0.2231)	-0.365 (± 0.3509)		
M Week 52; n=10, 10	0.001 (± 0.1799)	-0.111 (± 0.3892)		
TN Week 24; n=9, 6	0.946 (± 2.6602)	-0.083 (± 2.4752)		
TN Week 52; n=10, 10	1.657 (± 3.5533)	-0.606 (± 3.3406)		
PC Week 24; n=9, 6	15.9 (± 59.64)	7.3 (± 40.35)		
PC Week 52; n=11, 10	18.1 (± 55.81)	-10 (± 54.14)		
WBC Week 24; n=9, 6	0.1 (± 3.483)	-0.95 (± 2.868)		
WBC Week 52; n=11, 10	1.47 (± 3.572)	-1.11 (± 3.557)		

Notes:

[19] - mITT Population

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in the haematology parameter- hemoglobin at Week 24 and Week 52

End point title	Change from Baseline in the haematology parameter- hemoglobin at Week 24 and Week 52 ^[20]
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End point description:

Change from Baseline in hemoglobin was assessed at Week 24 (at the end of therapy) and at Week 52 (at study end). Change from Baseline was calculated as the value on Week 24 and Week 52 minus the value at Baseline. Baseline value used in the analysis was of Day 0 (Day of transplant). Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

End point type	Primary
End point timeframe:	
Baseline, Week 24 and Week 52	
Notes:	
[20] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.	
Justification: There are no statistical data to report.	

End point values	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[21]	12		
Units: Grams per Liter (G/L)				
arithmetic mean (standard deviation)				
Week 24; n=9, 6	5.4 (± 24.84)	13.2 (± 28.9)		
Week 52; n=11, 10	12.6 (± 22.69)	6.3 (± 23.48)		

Notes:

[21] - mITT Population

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in the hematology parameter- hematocrit at Week 24 and Week 52

End point title	Change from Baseline in the hematology parameter- hematocrit at Week 24 and Week 52 ^[22]
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End point description:

Endpoint was assessed at Week 24 (at the end of therapy) and at Week 52 (at study end). Change from Baseline was calculated as the value on Week 24 and Week 52 minus the value at Baseline. Baseline value used in the analysis was of Day 0 (Day of transplant). Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

End point type	Primary
End point timeframe:	
Baseline, Week 24 and Week 52	
Notes:	
[22] - 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	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[23]	12		
Units: Percentage of blood				
arithmetic mean (standard deviation)				
Week 24; n=9, 6	0.0216 (± 0.06625)	0.0477 (± 0.0954)		
Week 52; n=11, 10	0.0434 (± 0.06813)	0.0238 (± 0.07045)		

Notes:

[23] - mITT Population

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in haematology parameter- Mean Corpuscular Hemoglobin (MCH) at Week 24 and Week 52

End point title	Change from Baseline in haematology parameter- Mean Corpuscular Hemoglobin (MCH) at Week 24 and Week 52 ^[24]
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End point description:

Change from Baseline in MCH was assessed at Week 24 (at the end of therapy) and at Week 52 (at study end). Change from Baseline was calculated as the value on Week 24 and Week 52 minus the value at Baseline. Baseline value used in the analysis was of Day 0 (Day of transplant). Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

End point type	Primary
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End point timeframe:

Baseline, Week 24 and Week 52

Notes:

[24] - 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	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[25]	12		
Units: Picogram (pg)				
arithmetic mean (standard deviation)				
Week 24; n=8, 6	-0.79 (± 2.173)	-1.37 (± 2.683)		
Week 52; n=10, 10	-1.59 (± 1.516)	-1.93 (± 2.743)		

Notes:

[25] - mITT Population

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in haematology parameter- mean corpuscular volume (MCV) at Week 24 and Week 52

End point title	Change from Baseline in haematology parameter- mean corpuscular volume (MCV) at Week 24 and Week 52 ^[26]
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End point description:

Change from Baseline in MCV was assessed at Week 24 (at the end of therapy) and at Week 52 (at study end). Change from Baseline was calculated as the value on Week 24 and Week 52 minus the value at Baseline. Baseline value used in the analysis was of Day 0 (Day of transplant). Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

End point type	Primary
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End point timeframe:

Baseline, Week 24 and Week 52

Notes:

[26] - 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	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[27]	12		
Units: Femtoliter (FL)				
arithmetic mean (standard deviation)				
Week 24; n=9, 6	-1.73 (± 6.43)	-2.55 (± 8.198)		
Week 52; n=11, 10	-3.58 (± 4.34)	-4.61 (± 7.041)		

Notes:

[27] - mITT Population

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in haematology parameter- red blood cell (RBC) at Week 24 and Week 52

End point title	Change from Baseline in haematology parameter- red blood cell (RBC) at Week 24 and Week 52 ^[28]
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End point description:

Change from Baseline in RBC was assessed at Week 24 (at the end of therapy) and at Week 52 (at study end). Change from Baseline was calculated as the value on Week 24 and Week 52 minus the value at Baseline. Baseline value used in the analysis was of Day 0 (Day of transplant). Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

End point type	Primary
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End point timeframe:

Baseline, Week 24 and Week 52

Notes:

[28] - 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	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[29]	12		
Units: Tera (TI)/L				
arithmetic mean (standard deviation)				
Week 24; n=9, 6	0.298 (± 0.6716)	0.645 (± 0.8097)		
Week 52; n=11, 10	0.635 (± 0.7064)	0.468 (± 0.5884)		

Notes:

[29] - mITT Population

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in clinical chemistry parameter- albumin at Week 24 and Week 52

End point title	Change from Baseline in clinical chemistry parameter- albumin
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End point description:

Change from Baseline in albumin was assessed at Week 24 (at the end of therapy) and at Week 52 (at study end). Change from Baseline was calculated as the value on Week 24 and Week 52 minus the value at Baseline. Baseline value used in the analysis was of Day 0 (Day of transplant). Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

End point type	Primary
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End point timeframe:

Baseline, Week 24 and Week 52

Notes:

[30] - 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	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[31]	12		
Units: G/L				
arithmetic mean (standard deviation)				
Week 24; n=9, 7	4.1 (± 2.62)	2.9 (± 4.91)		
Week 52; n=10, 10	2.9 (± 3)	1.8 (± 4.98)		

Notes:

[31] - mITT Population

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in clinical chemistry parameter- ALP, ALT, AST at Week 24 and Week 52

End point title	Change from Baseline in clinical chemistry parameter- ALP, ALT, AST at Week 24 and Week 52 ^[32]
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End point description:

Clinical chemistry parameter included alkaline phosphatase (ALP), alanine amino Transferase (ALT) and aspartate amino transferase (AST). Endpoint was assessed at Week 24 (at the end of therapy) and at Week 52 (at study end). Change from Baseline was calculated as the value on Week 24 and Week 52 minus the value at Baseline. Baseline value used in the analysis was of Day 0 (Day of transplant). Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

End point type	Primary
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End point timeframe:

Baseline, Week 24 and Week 52

Notes:

[32] - 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	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[33]	12		
Units: International Unit (IU)/L				
arithmetic mean (standard deviation)				
ALP Week 24; n=9, 7	-16 (± 26.14)	-5 (± 60.03)		
ALP Week 52; n=10, 10	-17.5 (± 35.25)	19.9 (± 80.63)		
ALT Week 24; n=9, 7	1 (± 15.86)	5.1 (± 7.56)		
ALT Week 52; n=10, 10	-2.5 (± 11.16)	2.1 (± 5.8)		
AST Week 24; n=6, 3	3.2 (± 7.91)	7.3 (± 4.04)		
AST Week 52; n=7, 4	3.3 (± 5.68)	9.3 (± 3.86)		

Notes:

[33] - mITT Population

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in clinical chemistry parameter- direct bilirubin, total bilirubin and creatinine at Week 24 and Week 52

End point title	Change from Baseline in clinical chemistry parameter- direct bilirubin, total bilirubin and creatinine at Week 24 and Week 52 ^[34]
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End point description:

Clinical chemistry parameters included direct bilirubin (DB), total bilirubin (TB) and creatinine (C). Endpoint was assessed at Week 24 (at the end of therapy) and at Week 52 (at study end). Change from Baseline was calculated as the value on Week 24 and Week 52 minus the value at Baseline. Baseline value used in the analysis was of Day 0 (Day of transplant). Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

End point type	Primary
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End point timeframe:

Baseline, Week 24 and Week 52

Notes:

[34] - 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	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[35]	12		
Units: Micromole per Liter (umol/L)				
arithmetic mean (standard deviation)				
DB Week 24; n=8, 3	0.6 (± 1.51)	-0.7 (± 3.06)		
DB Week 52; n=9, 5	0.9 (± 1.54)	0.2 (± 1.3)		
TB Week 24; n=9, 7	3 (± 6.5)	2.7 (± 5.22)		
TB Week 52; n=10, 10	2.9 (± 5.26)	2.9 (± 3.38)		
C Week 24; n=9, 7	-471.1 (± 317.54)	-571.3 (± 183.53)		
C Week 52; n=10, 10	-468.4 (± 310.54)	-609.8 (± 271.89)		

Notes:

[35] - mITT Population

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in clinical chemistry parameter- Ca, CO2/Bicar, Gl, K, Na, PhI, U/BUN at Week 24 and Week 52

End point title	Change from Baseline in clinical chemistry parameter- Ca, CO2/Bicar, Gl, K, Na, PhI, U/BUN at Week 24 and Week 52 ^[36]
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End point description:

Clinical chemistry parameters included calcium (Ca), carbon dioxide content/bicarbonate (CO2/Bicar), glucose (Gl), potassium (K), sodium (Na), phosphorus inorganic (PhI), urea/blood urine nitrogen (U/BUN). Endpoint was assessed at Week 24 (at the end of therapy) and at Week 52 (at study end). Change from Baseline was calculated as the value on Week 24 and Week 52 minus the value at Baseline. Baseline value used in the analysis was of Day 0 (Day of transplant). Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

End point type	Primary
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End point timeframe:

Baseline, Week 24 and Week 52

Notes:

[36] - 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	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[37]	12		
Units: Millimole (MMOL)/L				
arithmetic mean (standard deviation)				
Ca Week 24; n=9, 7	0.116 (± 0.1344)	0.167 (± 0.1942)		
Ca Week 52; n=10, 9	0.116 (± 0.1013)	0.128 (± 0.1386)		
CO2/Bicar Week 24; n=7, 6	-3.73 (± 5.951)	1.7 (± 3.449)		
CO2/Bicar Week 52; n=8, 9	-2.68 (± 5.142)	0.77 (± 3.588)		
Gl Week 24; n=5, 5	0.2 (± 3.093)	-0.04 (± 2.003)		
Gl Week 52; n=5, 8	-0.32 (± 2.483)	1.79 (± 4.107)		
K Week 24; n=9, 7	0.06 (± 0.723)	-0.63 (± 0.923)		
K Week 52; n=10, 10	-0.02 (± 0.535)	-0.44 (± 0.877)		
Na Week 24; n=9, 7	-0.6 (± 4.03)	5.9 (± 5.01)		
Na Week 52; n=10, 10	-0.7 (± 3.71)	2.2 (± 4.71)		
PhI Week 24; n=8, 7	-0.225 (± 0.3843)	-0.913 (± 0.5862)		
PhI Week 52; n=9, 9	-0.227 (± 0.4234)	-0.726 (± 0.5453)		

U/BUN Week 24; n=9, 6	-5.91 (± 12.164)	-9.47 (± 9.128)		
U/BUN Week 52; n=10, 9	-8.13 (± 14.967)	-9.01 (± 7.323)		

Notes:

[37] - mITT Population

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in clinical chemistry parameter- glomerular filtration rate (GFR) at Week 24 and Week 52

End point title	Change from Baseline in clinical chemistry parameter- glomerular filtration rate (GFR) at Week 24 and Week 52 ^[38]
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End point description:

Change from Baseline in GFR was assessed at Week 24 (at the end of therapy) and at Week 52 (at study end). Change from Baseline was calculated as the value on Week 24 and Week 52 minus the value at Baseline. Baseline value used in the analysis was of Day 0 (Day of transplant). Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

End point type	Primary
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End point timeframe:

Baseline, Week 24 and Week 52

Notes:

[38] - 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	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[39]	12		
Units: milliliter (mL)/Minute (min)				
arithmetic mean (standard deviation)				
Week 24; n=9, 7	42.8 (± 23.604)	44.36 (± 10.731)		
Week 52; n=10, 10	42.33 (± 29.14)	53.75 (± 15.176)		

Notes:

[39] - mITT Population

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in immunoglobulin A (IgA), immunoglobulin G (IgG) and immunoglobulin M (IgM) at Week 24 and Week 52

End point title	Change from Baseline in immunoglobulin A (IgA), immunoglobulin G (IgG) and immunoglobulin M (IgM) at Week 24 and Week 52 ^[40]
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End point description:

Change from Baseline in immunoglobulins IgA, IgG and IgM was assessed at Week 24 (at the end of therapy) and at Week 52 (at study end). Change from Baseline was calculated as the value on Week 24 and Week 52 minus the value at Baseline. Baseline value used in the analysis was of Day 0 (Day of transplant). Only those participants available at the specified time points were analyzed (represented by

n=X, X in the category titles).

End point type	Primary
End point timeframe:	
Baseline, Week 24 and Week 52	

Notes:

[40] - 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	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[41]	12		
Units: G/L				
arithmetic mean (standard deviation)				
IgA Week 24; n=2, 3	-0.5 (± 0.2828)	-0.433 (± 0.6429)		
IgA Week 52; n=2, 3	-0.3 (± 0)	-0.5 (± 0.5292)		
IgG Week 24; n=6, 6	-1.02 (± 1.184)	-2.4 (± 1.731)		
IgG Week 52; n=10, 9	0.78 (± 3.595)	-2.13 (± 1.702)		
IgM Week 24; n=2, 3	-0.1 (± 0)	-0.133 (± 0.3512)		
IgM Week 52; n=2, 3	0 (± 0)	-0.333 (± 0.4933)		

Notes:

[41] - mITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Median Percent change from Baseline in memory B cell count at Week 24 and Week 52

End point title	Median Percent change from Baseline in memory B cell count at Week 24 and Week 52
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End point description:

Memory B cells are B cell sub-type that are formed within germinal centres following primary infection and are important in generating an accelerated and more robust antibody-mediated immune response in the case of re-infection. Memory B cell count included CD20+CD27+ cells/mm³. Baseline value used in the analysis was of Day 0 (Day of transplant). Endpoint was assessed at Week 24 (at the end of therapy) and at Week 52 (at study end). Percent change from Baseline in Memory B cell count was calculated as the value at Week 24 and Week 52 minus the value at Baseline multiplied by 100. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles). Median Difference and 95% confidence interval of difference obtained using the Hodges-Lehmann method.

End point type	Secondary
End point timeframe:	
Baseline, Week 24 and Week 52	

End point values	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[42]	12		
Units: Percent change				
median (full range (min-max))				
Week 24; n=9, 7	-12.5 (-88 to 320)	177.8 (40 to 800)		
Week 52; n=10, 7	2.4 (-67 to 340)	-33.3 (-80 to 44)		

Notes:

[42] - mITT Population

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description:	
Week 24 comparison	
Comparison groups	Placebo v Belimumab 10mg/kg
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Median difference (final values)
Point estimate	204.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	90
upper limit	550

Statistical analysis title	Statistical analysis 2
Statistical analysis description:	
Week 52 comparison	
Comparison groups	Placebo v Belimumab 10mg/kg
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Median difference (final values)
Point estimate	-33.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-169.84
upper limit	25

Secondary: Activated memory B cells count at Week 24 and Week 52

End point title	Activated memory B cells count at Week 24 and Week 52
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End point description:

Activated memory B cell-CD95% count is CD19+CD27+CD95 cells/mL. Adjusted mean difference (treatment-placebo) and 95% confidence intervals for differences were obtained from MMRM model, with fixed categorical effects of treatment, visit, donor type and treatment-by-visit interaction and fixed continuous covariates of Baseline and Baseline-by-visit interaction. A compound symmetry variance structure was used to model the within-participant errors, shared across treatments. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

End point type	Secondary
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End point timeframe:

Week 24 and Week 52

End point values	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[43]	12		
Units: cells/mL				
least squares mean (standard error)				
Week 24; n=9, 7	37157.2 (± 16664.42)	38389.6 (± 18682.83)		
Week 52; n=10, 8	24220.8 (± 15744.17)	11092.5 (± 17711.36)		

Notes:

[43] - mITT Population

Statistical analyses

Statistical analysis title	Statistical analysis 1
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Statistical analysis description:

Week 24 comparison

Comparison groups	Placebo v Belimumab 10mg/kg
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	1232.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-50457
upper limit	52921.8
Variability estimate	Standard error of the mean
Dispersion value	25735.56

Statistical analysis title	Statistical analysis 2
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Statistical analysis description:

Week 52 comparison

Comparison groups	Placebo v Belimumab 10mg/kg
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Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-13128.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	-61868.9
upper limit	35612.2
Variability estimate	Standard error of the mean
Dispersion value	24165.18

Secondary: Activated memory B cells percentage at Week 24 and Week 52

End point title	Activated memory B cells percentage at Week 24 and Week 52
End point description:	Activated memory B cell-CD95% percentage is CD19+CD27+CD95+ (%CD19/CD27). Adjusted mean difference (treatment-placebo) and 95% confidence intervals for differences were obtained from MMRM model, with fixed categorical effects of treatment, visit, donor type and treatment-by-visit interaction and fixed continuous covariates of Baseline and Baseline-by-visit interaction. A compound symmetry variance structure was used to model the within-participant errors, shared across treatments. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).
End point type	Secondary
End point timeframe:	
Week 24 and Week 52	

End point values	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[44]	12		
Units: Percentage of activated memory B cells				
least squares mean (standard error)				
Week 24; n=9, 7	32.8 (± 5.94)	19 (± 6.06)		
Week 52; n=11, 10	32 (± 5.07)	38.8 (± 5.48)		

Notes:

[44] - mITT Population

Statistical analyses

Statistical analysis title	Statistical analysis 2
Comparison groups	Placebo v Belimumab 10mg/kg

Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	6.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.6
upper limit	22.2
Variability estimate	Standard error of the mean
Dispersion value	7.68

Statistical analysis title	Statistical analysis 1
Statistical analysis description:	
Week 24 comparison	
Comparison groups	Placebo v Belimumab 10mg/kg
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-13.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-31.3
upper limit	3.7
Variability estimate	Standard error of the mean
Dispersion value	8.78

Secondary: Transitional B cells count at Week 24 and Week 52	
End point title	Transitional B cells count at Week 24 and Week 52
End point description:	
Transitional B cell count (Newell) is CD19+CD24b+CD38b+IgD+ (cells/mL). Adjusted mean difference (treatment-placebo) and 95% confidence intervals for differences were obtained from MMRM model, with fixed categorical effects of treatment, visit, donor type and treatment-by-visit interaction and fixed continuous covariates of Baseline and Baseline-by-visit interaction. A compound symmetry variance structure was used to model the within-participant errors, shared across treatments. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).	
End point type	Secondary
End point timeframe:	
Week 24 and Week 52	

End point values	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[45]	12		
Units: cells/mL				
least squares mean (standard error)				
Week 24; n=9, 7	5470 (± 2910.9)	2679 (± 3518.4)		
Week 52; n=10, 8	7110 (± 2836.7)	6652 (± 3291.5)		

Notes:

[45] - mITT Population

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description:	
Week 24 comparison	
Comparison groups	Placebo v Belimumab 10mg/kg
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2791
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12105
upper limit	6524
Variability estimate	Standard error of the mean
Dispersion value	4651.1

Statistical analysis title	Statistical analysis 2
Statistical analysis description:	
Week 52 comparison	
Comparison groups	Placebo v Belimumab 10mg/kg
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-458
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9487
upper limit	8572
Variability estimate	Standard error of the mean
Dispersion value	4501.8

Secondary: Transitional B cells percentage at Week 24 and Week 52

End point title	Transitional B cells percentage at Week 24 and Week 52
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End point description:

Transitional B cell percentage (Newell) is CD19+CD24b+CD38b+IgD+ (%CD19+). Adjusted mean difference (treatment-placebo) and 95% confidence intervals for differences were obtained from MMRM model, with fixed categorical effects of treatment, visit, donor type and treatment-by-visit interaction and fixed continuous covariates of Baseline and Baseline-by-visit interaction. A compound symmetry variance structure was used to model the within-participant errors, shared across treatments. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

End point type	Secondary
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End point timeframe:

Week 24 and Week 52

End point values	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[46]	12		
Units: Percentage of transitional B cells				
least squares mean (standard error)				
Week 24; n=9, 7	2.43 (± 0.776)	1.14 (± 0.869)		
Week 52; n=11, 10	2.61 (± 0.713)	3.41 (± 0.731)		

Notes:

[46] - mITT Population

Statistical analyses

Statistical analysis title	Statistical analysis 1
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Statistical analysis description:

Week 24 comparison

Comparison groups	Placebo v Belimumab 10mg/kg
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.59
upper limit	1.01
Variability estimate	Standard error of the mean
Dispersion value	1.156

Statistical analysis title	Statistical analysis 2
Statistical analysis description:	
Week 52 comparison	
Comparison groups	Placebo v Belimumab 10mg/kg
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.24
upper limit	2.82
Variability estimate	Standard error of the mean
Dispersion value	1.017

Secondary: Activated T cell count at Week 24 and Week 52

End point title	Activated T cell count at Week 24 and Week 52
End point description:	
A T cell is a type of lymphocyte that plays a central role in cell-mediated immunity. Activated T cell count Codarri is CD4+ CD25hi CD45RA- IL 7Rhi (cells/mL). Adjusted mean difference (treatment-placebo) and 95% confidence intervals for differences were obtained from MMRM model, with fixed categorical effects of treatment, visit, donor type and treatment-by-visit interaction and fixed continuous covariates of Baseline and Baseline-by-visit interaction. A compound symmetry variance structure was used to model the within-participant errors, shared across treatments. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).	
End point type	Secondary
End point timeframe:	
Week 24 and Week 52	

End point values	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[47]	12		
Units: cells/mL				
least squares mean (standard error)				
Week 24; n=9, 6	109279.5 (± 22998.02)	78952.7 (± 26155.19)		
Week 52; n=10, 7	122304.7 (± 21898.24)	75349.4 (± 24313.62)		

Notes:

[47] - mITT Population

Statistical analyses

Statistical analysis title	Statistical analysis 1
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Statistical analysis description:**Week 24 comparison**

Comparison groups	Placebo v Belimumab 10mg/kg
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-30326.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-100559.1
upper limit	39905.3
Variability estimate	Standard error of the mean
Dispersion value	34677.86

Statistical analysis title

Statistical analysis 2

Statistical analysis description:**Week 52 comparison**

Comparison groups	Placebo v Belimumab 10mg/kg
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-46955.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-113218.9
upper limit	19308.3
Variability estimate	Standard error of the mean
Dispersion value	32594.81

Secondary: Activated T cell percentage at Week 24 and Week 52

End point title	Activated T cell percentage at Week 24 and Week 52
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End point description:

Activated T cell percentage (Codarri)= CD4+ CD25hi CD45RA- IL 7Rhi (% of CD4+). Adjusted mean difference (treatment-placebo) and 95% confidence intervals for differences were obtained from MMRM model, with fixed categorical effects of treatment, visit, donor type and treatment-by-visit interaction and fixed continuous covariates of Baseline and Baseline-by-visit interaction. A compound symmetry variance structure was used to model the within-participant errors, shared across treatments. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

End point type	Secondary
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End point timeframe:Week 24 and Week 52

End point values	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[48]	12		
Units: Percentage of activated T cell				
least squares mean (standard error)				
Week 24; n=9, 6	17 ($\pm$ 2.29)	14 ($\pm$ 2.58)		
Week 52; n=10, 7	15.2 ($\pm$ 2.15)	14.7 ($\pm$ 2.33)		

Notes:

[48] - mITT Population

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description:	
Week 24 comparison	
Comparison groups	Placebo v Belimumab 10mg/kg
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.1
upper limit	4.2
Variability estimate	Standard error of the mean
Dispersion value	3.54

Statistical analysis title	Statistical analysis 2
Statistical analysis description:	
Week 52 comparison	
Comparison groups	Placebo v Belimumab 10mg/kg
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.2
upper limit	6.3

Variability estimate	Standard error of the mean
Dispersion value	3.35

Secondary: Regulatory T cell count at Week 24 and Week 52

End point title	Regulatory T cell count at Week 24 and Week 52
End point description: Regulatory T cell count is CD4+ CD25hi IL-7Rlo (cells/mL). Adjusted mean difference (treatment-placebo) and 95% confidence intervals for differences were obtained from MMRM model, with fixed categorical effects of treatment, visit, donor type and treatment-by-visit interaction and fixed continuous covariates of Baseline and Baseline-by-visit interaction. A compound symmetry variance structure was used to model the within-participant errors, shared across treatments. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).	
End point type	Secondary
End point timeframe: Week 24 and Week 52	

End point values	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[49]	12		
Units: cells/mL				
least squares mean (standard error)				
Week 24; n= 9, 7	23586.2 (± 8427.77)	24234.5 (± 9238.41)		
Week 52; n= 10, 8	33038.7 (± 7676.99)	27419.8 (± 9093.84)		

Notes:

[49] - mITT Population

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description: Week 24 comparison	
Comparison groups	Placebo v Belimumab 10mg/kg
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	648.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24661.1
upper limit	25957.7
Variability estimate	Standard error of the mean
Dispersion value	12618.44

Statistical analysis title	Statistical analysis 2
Statistical analysis description: Week 52 comparison	
Comparison groups	Placebo v Belimumab 10mg/kg
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-5618.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-29994.8
upper limit	18757
Variability estimate	Standard error of the mean
Dispersion value	12153.03

Secondary: Regulatory T cell (%CD4) at Week 24 and Week 52

End point title	Regulatory T cell (%CD4) at Week 24 and Week 52
End point description: Regulatory T cell (%CD4) = CD4+ CD25hi IL-7Rlo (% of CD4+). Adjusted mean difference (treatment-placebo) and 95% confidence intervals for differences were obtained from MMRM model, with fixed categorical effects of treatment, visit, donor type and treatment-by-visit interaction and fixed continuous covariates of Baseline and Baseline-by-visit interaction. A compound symmetry variance structure was used to model the within-participant errors, shared across treatments. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).	
End point type	Secondary
End point timeframe: Week 24 and Week 52	

End point values	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[50]	12		
Units: Percentage of Regulatory T cell				
least squares mean (standard error)				
Week 24; n= 9, 7	4.4 (± 1.12)	4.6 (± 1.25)		
Week 52; n= 11, 10	5 (± 1.01)	4.4 (± 1.04)		

Notes:

[50] - mITT Population

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description:	
Week 24 comparison	
Comparison groups	Placebo v Belimumab 10mg/kg
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.2
upper limit	3.5
Variability estimate	Standard error of the mean
Dispersion value	1.67

Statistical analysis title	Statistical analysis 2
Statistical analysis description:	
Week 52 comparison	
Comparison groups	Placebo v Belimumab 10mg/kg
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.5
upper limit	2.3
Variability estimate	Standard error of the mean
Dispersion value	1.45

Secondary: Mean Activated: regulatory T cell ratio at Week 24 and Week 52	
End point title	Mean Activated: regulatory T cell ratio at Week 24 and Week 52
End point description:	
Activated: regulatory T cell ratio is Activated T cell CD4+CD25hi CD45RA IL 7Rhi (absolute number)/Regulatory T cell CD4+CD25hi CD45RA IL 7Rlo (absolute number). Adjusted mean difference (treatment-placebo) and 95% confidence intervals for differences were obtained from MMRM model, with fixed categorical effects of treatment, visit, donor type and treatment-by-visit interaction and fixed continuous covariates of Baseline and Baseline-by-visit interaction. A compound symmetry variance structure was used to model the within-participant errors, shared across treatments. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).	
End point type	Secondary

End point timeframe:
Week 24 and Week 52

End point values	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[51]	12		
Units: Ratio				
least squares mean (standard error)				
Week 24; n= 9, 6	4.88 (± 0.832)	3.33 (± 0.915)		
Week 52; n= 10, 7	4.62 (± 0.779)	3.61 (± 0.942)		

Notes:

[51] - mITT Population

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description: Week 24 comparison	
Comparison groups	Belimumab 10mg/kg v Placebo
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.07
upper limit	0.98
Variability estimate	Standard error of the mean
Dispersion value	1.255

Statistical analysis title	Statistical analysis 2
Statistical analysis description: Week 52 comparison	
Comparison groups	Belimumab 10mg/kg v Placebo
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-1.01

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.68
upper limit	1.67
Variability estimate	Standard error of the mean
Dispersion value	1.329

Secondary: Proportion of participants with episodes of acute rejection at Week 24 and Week 52

End point title	Proportion of participants with episodes of acute rejection at Week 24 and Week 52
End point description: The endpoint diagnosis was made by a proven biopsy result. Number of rejections only counted once per participant. The proportion of participants with episodes of acute rejection was assessed at Week 24 (at the end of therapy) and at Week 52 (at study end). Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).	
End point type	Secondary
End point timeframe: Week 24 and Week 52	

End point values	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[52]	12		
Units: Proportion of participants				
Week 24; n=5, 6	2	2		
Week 52; n=5, 6	3	2		

Notes:

[52] - mITT Population. Participants analyzed had at least one biopsy.

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description: Week 24 comparison	
Comparison groups	Placebo v Belimumab 10mg/kg
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Proportion
Point estimate	-0.067
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.638
upper limit	0.505

Statistical analysis title	Statistical analysis 2
Statistical analysis description: Week 52 comparison	
Comparison groups	Placebo v Belimumab 10mg/kg
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Proportion
Point estimate	-0.267
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.838
upper limit	0.305

Secondary: Mean Serum Creatinine at Week 24 and Week 52

End point title	Mean Serum Creatinine at Week 24 and Week 52
End point description: Adjusted mean difference for serum creatinine values (treatment-placebo) and 95% confidence intervals for differences were obtained from MMRM model, with fixed categorical effects of treatment, visit, donor type and treatment-by-visit interaction and fixed continuous covariates of Baseline and Baseline-by-visit interaction, at Week 24 and Week 52. A compound symmetry variance structure was used to model the within-participant errors, shared across treatments. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).	
End point type	Secondary
End point timeframe: Week 24 and Week 52	

End point values	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[53]	12		
Units: micromole/L				
least squares mean (standard error)				
Week 24; n=9, 7	115.1 (± 35.24)	112.3 (± 38.2)		
Week 52; n= 10, 10	135.4 (± 33.5)	122.6 (± 33.37)		

Notes:

[53] - mITT Population

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description:	
Week 24 comparison	
Comparison groups	Belimumab 10mg/kg v Placebo
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-105.9
upper limit	100.3
Variability estimate	Standard error of the mean
Dispersion value	52.06

Statistical analysis title	Statistical analysis 2
Statistical analysis description:	
Week 52 comparison	
Comparison groups	Belimumab 10mg/kg v Placebo
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-12.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-107.1
upper limit	81.4
Variability estimate	Standard error of the mean
Dispersion value	47.52

Secondary: Mean eGFR at Week 24 and Week 52

End point title	Mean eGFR at Week 24 and Week 52
End point description:	
The estimated glomerular filtration rate (eGFR) were calculated by the abbreviated Modification of Diet in Renal Disease (MDRD) equation. Adjusted mean difference(treatment-placebo) and 95% confidence intervals for differences were obtained from MMRM model, with fixed categorical effects of treatment, visit, donor type and treatment-by-visit interaction and fixed continuous covariates of Baseline and Baseline-by-visit interaction at Week 24 and Week 52. A compound symmetry variance structure was used to model the within-participant errors, shared across treatments. Only those participants available at the indicated time points were analyzed (represented by n= X, X in the category titles).	
End point type	Secondary
End point timeframe:	
Week 24 and Week 52	

End point values	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13 ^[54]	12		
Units: mL/minute/1.73 square meter (m ²)				
least squares mean (standard error)				
Week 24; n=9, 7	62.25 (± 6.119)	49.33 (± 6.897)		
Week 52; n= 10, 10	58.99 (± 5.732)	56.29 (± 5.765)		

Notes:

[54] - mITT Population

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description:	
Week 24 comparison	
Comparison groups	Belimumab 10mg/kg v Placebo
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-12.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	-31.56
upper limit	5.71
Variability estimate	Standard error of the mean
Dispersion value	9.44

Statistical analysis title	Statistical analysis 2
Statistical analysis description:	
Week 52 comparison	
Comparison groups	Belimumab 10mg/kg v Placebo
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-2.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.11
upper limit	13.72
Variability estimate	Standard error of the mean
Dispersion value	8.315

Secondary: Mean Prednisolone use at Week 24

End point title	Mean Prednisolone use at Week 24
End point description:	
Adjusted mean difference (treatment-placebo) for Prednisolone use and 95% confidence intervals for differences were obtained from MMRM model, with fixed categorical effects of treatment, visit, donor type and treatment-by-visit interaction and fixed continuous covariates of Baseline and Baseline-by-visit interaction at Week 24. A compound symmetry variance structure was used to model the within-participant errors, shared across treatments. Only those participants available at indicated timepoints were analyzed (represented by n=X, X in the category titles).	
End point type	Secondary
End point timeframe:	
Week 24	

End point values	Placebo	Belimumab 10mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10 ^[55]	7		
Units: mg/day				
least squares mean (standard error)	5.71 (± 1.438)	5.27 (± 1.713)		

Notes:

[55] - mITT Population

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo v Belimumab 10mg/kg
Number of subjects included in analysis	17
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.84
upper limit	3.96
Variability estimate	Standard error of the mean
Dispersion value	2.225

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Serious adverse events (SAEs) and non-serious adverse events (AEs) were collected from the start of study medication until follow-up (up to 52 weeks).

Adverse event reporting additional description:

On-treatment SAEs and non-serious AEs are reported for MITT Population.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	18.1
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Reporting groups

Reporting group title	Placebo
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Reporting group description:

Participants received normal saline (0.9% sodium chloride) via intravenous infusion over 1 hour, every 4 weeks for 24 weeks (with an additional dose at week 2) in addition to standard of care assessments, treatment and other interventions according to institutional protocols from the time of transplantation throughout the study.

Reporting group title	Belimumab 10mg/kg
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Reporting group description:

Participants received 10 mg /kg belimumab in 250 mL normal saline via intravenous infusion over 1 hour, every 4 weeks for 24 weeks (with an additional dose at week 2) standard of care assessments, treatment and other interventions according to institutional protocols from the time of transplantation throughout the study.

Serious adverse events	Placebo	Belimumab 10mg/kg	
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 13 (53.85%)	5 / 12 (41.67%)	
number of deaths (all causes)	2	0	
number of deaths resulting from adverse events			
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatinine increased			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Hip fracture			

subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Lymphocele			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiac failure acute			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Transplant rejection			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			

subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pulmonary oedema			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Delirium			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Focal segmental glomerulosclerosis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glomerulonephritis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Cellulitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile colitis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia urinary tract infection			

subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cyst infection			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo	Belimumab 10mg/kg	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 13 (69.23%)	9 / 12 (75.00%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Respiratory disorder			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 13 (7.69%)	2 / 12 (16.67%)	
occurrences (all)	1	2	
Polyomavirus test positive			
subjects affected / exposed	2 / 13 (15.38%)	1 / 12 (8.33%)	
occurrences (all)	2	1	
Cytomegalovirus test positive			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Epstein-Barr virus test positive			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Injury, poisoning and procedural complications			
Hip fracture			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Infusion related reaction			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	

Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	2	
Tachycardia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 13 (0.00%)	2 / 12 (16.67%)	
occurrences (all)	0	2	
Headache			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Migraine			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Paraesthesia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Tremor			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	4 / 13 (30.77%)	4 / 12 (33.33%)	
occurrences (all)	4	4	
Anaemia			
subjects affected / exposed	3 / 13 (23.08%)	2 / 12 (16.67%)	
occurrences (all)	3	2	
Anaemia vitamin B12 deficiency			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Iron deficiency anaemia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Polycythaemia			

subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Thrombocytopenia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	3 / 13 (23.08%)	5 / 12 (41.67%)	
occurrences (all)	3	6	
Dyspepsia			
subjects affected / exposed	2 / 13 (15.38%)	2 / 12 (16.67%)	
occurrences (all)	2	2	
Oesophagitis			
subjects affected / exposed	1 / 13 (7.69%)	1 / 12 (8.33%)	
occurrences (all)	1	1	
Vomiting			
subjects affected / exposed	0 / 13 (0.00%)	2 / 12 (16.67%)	
occurrences (all)	0	2	
Duodenal ulcer			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Duodenitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Mouth ulceration			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Ulcerative gastritis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			

Cold sweat subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 12 (0.00%) 0	
Hyperhidrosis subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 12 (8.33%) 1	
Vasculitic rash subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 12 (0.00%) 0	
Renal and urinary disorders Renal artery stenosis subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 12 (0.00%) 0	
Musculoskeletal and connective tissue disorders Myalgia subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 12 (0.00%) 0	
Infections and infestations Urinary tract infection subjects affected / exposed occurrences (all)	2 / 13 (15.38%) 3	4 / 12 (33.33%) 4	
Lower respiratory tract infection subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	2 / 12 (16.67%) 2	
Nasopharyngitis subjects affected / exposed occurrences (all)	2 / 13 (15.38%) 2	1 / 12 (8.33%) 1	
Tonsillitis subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	1 / 12 (8.33%) 1	
Wound infection subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	1 / 12 (8.33%) 1	
Onychomycosis subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 12 (0.00%) 0	

Oral candidiasis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Pneumonia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Polyomavirus-associated nephropathy			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Renal cyst infection			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Upper respiratory tract infection			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	1 / 13 (7.69%)	1 / 12 (8.33%)	
occurrences (all)	1	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
23 April 2013	The protocol has been amended to provide clarification that this study is not powered to detect clinical efficacy endpoints, and that there is a strong focus on biomarker endpoints to help determine the potential for efficacy. The study objectives have been reworded to reflect a greater emphasis on defining pharmacodynamic responses with belimumab and understanding the impact of belimumab on biomarkers in order to provide a clear assessment of potential for clinical efficacy with belimumab. Endpoints and analysis sections and the Time and Events table have been updated accordingly.
01 July 2013	The protocol has been amended to provide clarification of the randomisation strategy and to update sponsor team contact details.
04 September 2013	The protocol has been amended to provide clarification of timings of study events, correction of safety statement, addition of information from IB update and typographic errors have been addressed.
16 October 2013	The protocol has been amended to change the eligibility criteria of the donor kidney.
19 May 2014	The protocol has been amended to update safety information and to include additional sites. Changes have been made to the endpoints, infusion times on Day 0 and the randomization procedure. Clarity is provided surrounding the number enrolled and randomized to achieve 20 completed subjects. Reference to a supplement has been added which has been issued for the current IB. Changes have been made to the statistical analysis section to ensure consistency with the endpoint section and the primary analysis has been clarified.
21 July 2015	The protocol has been amended to remove the planned interim data analysis (programming and statistical analysis) of the data up to and including week 24. Analysis of all data will now be undertaken following the week 52 time point (end of study).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported