ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: January 6, 2015

ClinicalTrials.gov ID: NCT00282347

Study Identification

Unique Protocol ID:	U2970g
Brief Title:	A Study to Evaluate the Efficacy and Safety of Rituximab in Subjects With International Society of Nephrology/Renal Pathology Society (ISN/RPS) 2003 Class III or IV Lupus Nephritis (LUNAR)
Official Title:	A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Rituximab in Subjects With ISN/RPS Class III or IV Lupus Nephritis
Secondary IDs:	

Study Status

Record Verification:	January 2015
Overall Status:	Completed
Study Start:	January 2006 []
Primary Completion:	January 2009 [Actual]
Study Completion:	January 2013 [Actual]

Sponsor/Collaborators

Sponsor:	Genentech, Inc.
Responsible Party:	Sponsor
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	

U.S. FDA-regulated Device:	
Unapproved/Uncleared Device:	No
U.S. FDA IND/IDE:	Yes
IND/IDE Information:	FDA Center: CDER IND/IDE Number: 12159 Serial Number: 032 Has Expanded Access No
Human Subjects Review:	Board Status:
Data Monitoring:	No
FDA Regulated Intervention:	Yes
Section 801 Clinical Trial:	Yes

Study Description

Brief Summary:	This was a Phase III, randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy and safety of rituximab in combination with mycophenolate mofetil (MMF) compared with placebo in combination with MMF in subjects diagnosed with International Society of Nephrology/Renal Pathology Society (ISN/RPS) 2003 Class III or IV lupus nephritis.
Detailed Description:	In addition to receiving study drug (rituximab or placebo), participants in each treatment group received mycophenolate mofetil at a starting dose of 1500 mg/day IV in 3 divided doses and were titrated up by 500 mg/week to 3000 mg/day by Week 4, as tolerated. Participants in each treatment group also received methylprednisolone 1000 mg IV prior to and 3 days following the first study drug infusion and methylprednisolone 100 mg IV prior to the other study drug infusions. Participants in each treatment group also received diphenhydramine 50 mg orally and acetaminophen 1000 mg orally 30-60 minutes prior to each study drug infusion. From Days 2 to 16, participants in each treatment group received prednisone 0.75 mg/kg/day orally (maximum dose of 60 mg) except on the day of the second methylprednisolone dose. On Day 16, a taper was initiated to achieve a dose of 10 mg/day by Week 16.

Conditions

Conditions:	Lupus Nephritis
Keywords:	Class IV LN Lupus LUNAR LN

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Interventional Study Model:	Parallel Assignment
Number of Arms:	2
Masking:	Double (Participant, Investigator)
Allocation:	Randomized
Enrollment:	144 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Rituximab Participants received rituximab 1000 mg intravenously (IV) on Days 1, 15, 168, and 182. They also received mycophenolate mofetil, methylprednisolone, diphenhydramine, acetaminophen, and prednisone; see the Detailed Description for details.	Drug: Rituximab Rituximab was provided as a sterile solution for injection. Other Names: • Rituxan • MabThera • Zytux Drug: Mycophenolate mofetil Other Names: • CellCept Drug: Methylprednisolone Drug: Diphenhydramine Drug: Acetaminophen Drug: Prednisone
Placebo Comparator: Placebo Participants received placebo intravenously (IV) on Days 1, 15, 168, and 182. They also received mycophenolate mofetil, methylprednisolone, diphenhydramine, acetaminophen, and prednisone; see the Detailed Description for details.	Drug: Placebo Placebo was provided as a sterile solution for injection. Drug: Mycophenolate mofetil Other Names: • CellCept Drug: Methylprednisolone Drug: Diphenhydramine Drug: Acetaminophen Drug: Prednisone

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 16 Years

Maximum Age: 75 Years

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Diagnosis of systemic lupus erythematosus (SLE) according to current American College of Rheumatology (ACR) criteria.
- Diagnosis of International Society of Nephrology/Renal Pathology Society (ISN/RPS) 2003 Class III or IV lupus nephritis (LN), with either active or active/chronic disease.
- Proteinuria.
- 16-75 years of age.

Exclusion Criteria:

- Retinitis, poorly controlled seizure disorder, acute confusional state, myelitis, stroke or stroke syndrome, cerebellar ataxia, or dementia that is currently active and resulting from SLE.
- Unstable subjects with thrombocytopenia experiencing or at high risk for developing clinically significant bleeding or organ dysfunction requiring therapies such as plasmapheresis or acute blood or platelet transfusions.
- Lack of peripheral venous access.
- Pregnancy or lactation.
- History of severe allergic or anaphylactic reactions to monoclonal antibodies.
- Significant or uncontrolled medical disease in any organ system not related to SLE or LN, which, in the investigator's opinion, would preclude subject participation.
- Concomitant chronic conditions, excluding SLE (eg, asthma, Crohn's disease) that require oral or systemic corticosteroid use in the 52 weeks prior to screening.
- History of renal transplant.
- Known human immunodeficiency virus (HIV) infection.
- Known active infection of any kind (but excluding fungal infection of nail beds) or any major episode of infection requiring hospitalization or treatment with intravenous anti-infectives within 4 weeks of randomization or oral anti-infectives within 2 weeks of randomization.
- History of deep space infection within 1 year of screening.
- History of serious recurrent or chronic infection.
- History of cancer, including solid tumors, hematological malignancies, and carcinoma in situ (except basal cell carcinomas of the skin that have been treated or excised and have resolved).
- Currently active alcohol or drug abuse or history of alcohol or drug abuse within 52 weeks prior to screening.

- Major surgery requiring hospitalization within 4 weeks of screening (excluding diagnostic surgery).
- Treatment with cyclophosphamide or calcineurin inhibitors within the 90 days prior to screening.
- Use of mycophenolate mofetil (MMF) at a dose of > 2 grams daily for longer than the 90 days prior to screening.
- Intolerance or history of allergic reaction to MMF.
- Intolerance or history of allergic reaction to both angiotensin-converting enzyme (ACE) inhibitors and angiotensin-receptor blockers.
- Use of oral prednisone (or corticosteroid equivalent) at a dose of > 20 mg/day for longer than the 14 days prior to screening.
- Previous treatment with CAMPATH-1H (alemtuzumab).
- Previous treatment with a B-cell targeted therapy.
- Treatment with any investigational agent (including biologic agents approved for other indications) within 28 days of the start of the screening period or 5 half-lives of the investigational drug (whichever is longer).
- Receipt of a live vaccine within the 28 days prior to screening.
- Intolerance or contraindication to oral or IV corticosteroids.
- Current therapy with a nonsteroidal anti-inflammatory agent.
- Positive hepatitis B sAg or hepatitis C serology.

Contacts/Locations

Central Contact Person: Genentech Trial Information Support Line
Telephone: 888-662-6728

Central Contact Backup:

Study Officials: Paul Brunetta, MD
Study Director
Genentech, Inc.

Locations:

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Participant Flow

Reporting Groups

	Description
Rituximab	Participants received rituximab 1000 mg intravenously (IV) on Days 1, 15, 168, and 182. They also received mycophenolate mofetil, methylprednisolone, diphenhydramine, acetaminophen, and prednisone; see the Detailed Description for details.
Placebo	Participants received placebo intravenously (IV) on Days 1, 15, 168, and 182. They also received mycophenolate mofetil, methylprednisolone, diphenhydramine, acetaminophen, and prednisone; see the Detailed Description for details.

Treatment Period

	Rituximab	Placebo
Started	72	72
Completed	67	63
Not Completed	5	9
Death	2	0
Lost to Follow-up	2	5
Withdrawal by Subject	1	3
Physician Decision	0	1

Safety Follow-up Period

	Rituximab	Placebo
Started	67	63
Completed	64	57
Not Completed	3	6
Lost to Follow-up	0	2
Withdrawal by Subject	2	1

	Rituximab	Placebo
Physician Decision	1	1
Protocol Deviation	0	2

B Cell Follow-up Period

	Rituximab	Placebo
Started	20	4
Completed	15	4
Not Completed	5	0
Withdrawal by Subject	2	0
Physician Decision	1	0
Reason Not Specified	2	0

Baseline Characteristics

Reporting Groups

	Description
Rituximab	Participants received rituximab 1000 mg intravenously (IV) on Days 1, 15, 168, and 182. They also received mycophenolate mofetil, methylprednisolone, diphenhydramine, acetaminophen, and prednisone; see the Detailed Description for details.
Placebo	Participants received placebo intravenously (IV) on Days 1, 15, 168, and 182. They also received mycophenolate mofetil, methylprednisolone, diphenhydramine, acetaminophen, and prednisone; see the Detailed Description for details.

Baseline Measures

	Rituximab	Placebo	Total
Overall Number of Participants	72	72	144

		Rituximab	Placebo	Total
Age, Customized Measure Type: Number Unit of measure: participants	Number Analyzed	72 participants	72 participants	144 participants
< 18 years		2	1	3
18 to < 35 years		48	48	96
35 to < 50 years		18	19	37
≥ 50 years		4	4	8
Age, Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	72 participants	72 participants	144 participants
		31.8 (9.6)	29.4 (9.3)	30.6 (9.5)
Sex: Female, Male Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	72 participants	72 participants	144 participants
	Female	63 87.5%	67 93.06%	130 90.28%
	Male	9 12.5%	5 6.94%	14 9.72%

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants Who Achieved a Complete Renal Response (CRR), a Partial Renal Response (PRR), or no Renal Response (NRR) at Week 52
Measure Description	A participant had a CRR if they met the following 3 criteria: (1) Normalization of serum creatinine (SC) as evidenced by a SC level ≤ the upper limit of the normal range of central laboratory values or a SC level ≤ 15% greater than Baseline, if Baseline SC was within the normal range of the central laboratory values; (2) Inactive urinary sediment (as evidenced by < 5 red blood cells/high-power field (RBCs/HPF) and absence of red cell casts; (3) Urinary protein (UP) to creatinine ratio (CR) < 0.5. A participant had a PRR if they met the following 3 criteria: (1) A SC level ≤ 15% above Baseline; (2) RBCs/HPF ≤ 50% above Baseline and no RBC casts; (3) 50% improvement in the UP to CR, with 1 of the following conditions met: If the Baseline UP to CR was ≤ 3.0, then a UP to CR of < 1.0 or if the Baseline UP to CR was > 3.0, then a UP to CR of ≤ 3.0. A participant had a NRR if they did not achieve either a CRR or PRR.
Time Frame	Week 52

Analysis Population Description

Intent-to-treat population: All randomized participants who received any amount of study drug (rituximab or placebo).

Reporting Groups

	Description
Rituximab	Participants received rituximab 1000 mg intravenously (IV) on Days 1, 15, 168, and 182. They also received mycophenolate mofetil, methylprednisolone, diphenhydramine, acetaminophen, and prednisone; see the Detailed Description for details.
Placebo	Participants received placebo intravenously (IV) on Days 1, 15, 168, and 182. They also received mycophenolate mofetil, methylprednisolone, diphenhydramine, acetaminophen, and prednisone; see the Detailed Description for details.

Measured Values

	Rituximab	Placebo
Overall Number of Participants Analyzed	72	72
Percentage of Participants Who Achieved a Complete Renal Response (CRR), a Partial Renal Response (PRR), or no Renal Response (NRR) at Week 52 Measure Type: Number Unit of measure: Percentage of participants		
CRR	26.4	30.6
PRR	30.6	15.3
NRR	43.1	54.2

Statistical Analysis 1 for Percentage of Participants Who Achieved a Complete Renal Response (CRR), a Partial Renal Response (PRR), or no Renal Response (NRR) at Week 52

Statistical Analysis Overview	Comparison Group Selection	Rituximab, Placebo
	Comments	[Not specified]
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.5538
	Comments	[Not specified]
	Method	Other [Stratified Wilcoxon-Rank Sum Test]

	Comments	[Not specified]

2. Secondary Outcome Measure:

Measure Title	Percentage of Participants Who Achieved a Complete Renal Response at Week 24 and Maintained it to Week 52
Measure Description	A participant had a complete renal response if they met the following 3 criteria: (1) Normalization of serum creatinine as evidenced by a serum creatinine level ≤ the upper limit of the normal range of central laboratory values or a serum creatinine level ≤ 15% greater than Baseline, if Baseline serum creatinine was within the normal range of the central laboratory values; (2) Inactive urinary sediment (as evidenced by < 5 red blood cells/high-power field and absence of red cell casts; (3) Urinary protein to creatinine ratio < 0.5.
Time Frame	Week 24 to Week 52

Analysis Population Description

Intent-to-treat population: All randomized participants who received any amount of study drug (rituximab or placebo).

Reporting Groups

	Description
Rituximab	Participants received rituximab 1000 mg intravenously (IV) on Days 1, 15, 168, and 182. They also received mycophenolate mofetil, methylprednisolone, diphenhydramine, acetaminophen, and prednisone; see the Detailed Description for details.
Placebo	Participants received placebo intravenously (IV) on Days 1, 15, 168, and 182. They also received mycophenolate mofetil, methylprednisolone, diphenhydramine, acetaminophen, and prednisone; see the Detailed Description for details.

Measured Values

	Rituximab	Placebo
Overall Number of Participants Analyzed	72	72
Percentage of Participants Who Achieved a Complete Renal Response at Week 24 and Maintained it to Week 52 Measure Type: Number Unit of measure: Percentage of participants	1.4	6.9

3. Secondary Outcome Measure:

Measure Title	Percentage of Participants Who Achieved a Complete Renal Response at Week 52

Measure Description	A participant had a complete renal response if they met the following 3 criteria: (1) Normalization of serum creatinine as evidenced by a serum creatinine level ≤ the upper limit of the normal range of central laboratory values or a serum creatinine level ≤ 15% greater than Baseline, if Baseline serum creatinine was within the normal range of the central laboratory values; (2) Inactive urinary sediment (as evidenced by < 5 red blood cells/high-power field and absence of red cell casts; (3) Urinary protein to creatinine ratio < 0.5.
Time Frame	Week 52

Analysis Population Description

Intent-to-treat population: All randomized participants who received any amount of study drug (rituximab or placebo).

Reporting Groups

	Description
Rituximab	Participants received rituximab 1000 mg intravenously (IV) on Days 1, 15, 168, and 182. They also received mycophenolate mofetil, methylprednisolone, diphenhydramine, acetaminophen, and prednisone; see the Detailed Description for details.
Placebo	Participants received placebo intravenously (IV) on Days 1, 15, 168, and 182. They also received mycophenolate mofetil, methylprednisolone, diphenhydramine, acetaminophen, and prednisone; see the Detailed Description for details.

Measured Values

	Rituximab	Placebo
Overall Number of Participants Analyzed	72	72
Percentage of Participants Who Achieved a Complete Renal Response at Week 52 Measure Type: Number Unit of measure: Percentage of participants	26.4	30.6

4. Secondary Outcome Measure:

Measure Title	Percentage of Participants With a Baseline Urine Protein to Creatinine Ratio of > 3.0 Who Achieved a Urine Protein to Creatinine Ratio of < 1.0 at Week 52
Measure Description	
Time Frame	Baseline to Week 52

Analysis Population Description

Intent-to-treat population: All randomized participants who received any amount of study drug (rituximab or placebo). Only those participants with a Baseline urine protein to creatinine ratio of > 3.0 were included in the analysis.

Reporting Groups

	Description
Rituximab	Participants received rituximab 1000 mg intravenously (IV) on Days 1, 15, 168, and 182. They also received mycophenolate mofetil, methylprednisolone, diphenhydramine, acetaminophen, and prednisone; see the Detailed Description for details.
Placebo	Participants received placebo intravenously (IV) on Days 1, 15, 168, and 182. They also received mycophenolate mofetil, methylprednisolone, diphenhydramine, acetaminophen, and prednisone; see the Detailed Description for details.

Measured Values

	Rituximab	Placebo
Overall Number of Participants Analyzed	38	41
Percentage of Participants With a Baseline Urine Protein to Creatinine Ratio of > 3.0 Who Achieved a Urine Protein to Creatinine Ratio of < 1.0 at Week 52 Measure Type: Number Unit of measure: Percentage of participants	47.4	53.7

5. Secondary Outcome Measure:

Measure Title	British Isles Lupus Assessment Group (BILAG) Index Score Over 52 Weeks
Measure Description	The BILAG Index assesses 86 clinical signs and symptoms and laboratory measures of systemic lupus erythematosus in 8 organ system domains: General, mucocutaneous, neurological, musculoskeletal, cardiorespiratory, vasculitis, renal, and hematologic. Most of the 86 items are rated on the following scale: 0=Not present, 1=Improving, 2=Same, 3=Worse, 4=New. Some items are rated as either Yes or No. A single alphabetic score of A (very active) through E (not or never active) for each of the 8 domains is determined from the rating of the individual items in each domain. The total BILAG score is the sum of the scores of the 8 domains where A=9, B=3, C=1, D=0, and E=0. The total score ranges from 0 to 72 with a higher score indicating greater lupus activity. To calculate a BILAG score over the 52 week treatment period of the study, the area under the response-time curve of BILAG scores assessed every 4 weeks was divided by the number of days in the time curve minus the Baseline BILAG score.
Time Frame	Baseline to Week 52

Analysis Population Description

Intent-to-treat population: All randomized participants who received any amount of study drug (rituximab or placebo).

Reporting Groups

	Description
Rituximab	Participants received rituximab 1000 mg intravenously (IV) on Days 1, 15, 168, and 182. They also received mycophenolate mofetil, methylprednisolone, diphenhydramine, acetaminophen, and prednisone; see the Detailed Description for details.
Placebo	Participants received placebo intravenously (IV) on Days 1, 15, 168, and 182. They also received mycophenolate mofetil, methylprednisolone, diphenhydramine, acetaminophen, and prednisone; see the Detailed Description for details.

Measured Values

	Rituximab	Placebo
Overall Number of Participants Analyzed	72	72
British Isles Lupus Assessment Group (BILAG) Index Score Over 52 Weeks Mean (Standard Deviation) Unit of measure: Units on a scale	-8.49 (5.79)	-8.58 (5.14)

6. Secondary Outcome Measure:

Measure Title	Time to Achieve a Complete Renal Response
Measure Description	
Time Frame	Baseline to Week 52

Analysis Population Description

Intent-to-treat population: All randomized participants who received any amount of study drug (rituximab or placebo).

Reporting Groups

	Description
Rituximab	Participants received rituximab 1000 mg intravenously (IV) on Days 1, 15, 168, and 182. They also received mycophenolate mofetil, methylprednisolone, diphenhydramine, acetaminophen, and prednisone; see the Detailed Description for details.
Placebo	Participants received placebo intravenously (IV) on Days 1, 15, 168, and 182. They also received mycophenolate mofetil, methylprednisolone, diphenhydramine, acetaminophen, and prednisone; see the Detailed Description for details.

Measured Values

	Rituximab	Placebo
Overall Number of Participants Analyzed	72	72
Time to Achieve a Complete Renal Response Median (95% Confidence Interval) Unit of measure: Weeks	11.99 (8.31 to NA) [1]	12.12 (9.26 to 13.47)

[1] The upper limit of the confidence interval could not be estimated due to too few events.

7. Secondary Outcome Measure:

Measure Title	Change From Baseline in the Systemic Lupus Erythematosus Expanded Health Survey Physical Function Score at Week 52
Measure Description	The systemic lupus erythematosus Expanded Health Survey is based on the Short Form 36 Health survey with additional questions specific to lupus. The physical function component score of the survey can range from 0-100. A higher score indicates better health. A positive change score indicates improvement.
Time Frame	Baseline to Week 52

Analysis Population Description

Intent-to-treat population: All randomized participants who received any amount of study drug (rituximab or placebo).

Reporting Groups

	Description
Rituximab	Participants received rituximab 1000 mg intravenously (IV) on Days 1, 15, 168, and 182. They also received mycophenolate mofetil, methylprednisolone, diphenhydramine, acetaminophen, and prednisone; see the Detailed Description for details.
Placebo	Participants received placebo intravenously (IV) on Days 1, 15, 168, and 182. They also received mycophenolate mofetil, methylprednisolone, diphenhydramine, acetaminophen, and prednisone; see the Detailed Description for details.

Measured Values

	Rituximab	Placebo
Overall Number of Participants Analyzed	72	72

	Rituximab	Placebo
Change From Baseline in the Systemic Lupus Erythematosus Expanded Health Survey Physical Function Score at Week 52 Mean (Standard Deviation) Unit of measure: Units on a scale	4.8 (10.4)	5.7 (9.4)

8. Secondary Outcome Measure:

Measure Title	Change From Baseline in Anti-double-stranded DNA at Week 52
Measure Description	
Time Frame	Baseline to Week 52

Analysis Population Description

Intent-to-treat population: All randomized participants who received any amount of study drug (rituximab or placebo).

Reporting Groups

	Description
Rituximab	Participants received rituximab 1000 mg intravenously (IV) on Days 1, 15, 168, and 182. They also received mycophenolate mofetil, methylprednisolone, diphenhydramine, acetaminophen, and prednisone; see the Detailed Description for details.
Placebo	Participants received placebo intravenously (IV) on Days 1, 15, 168, and 182. They also received mycophenolate mofetil, methylprednisolone, diphenhydramine, acetaminophen, and prednisone; see the Detailed Description for details.

Measured Values

	Rituximab	Placebo
Overall Number of Participants Analyzed	72	72
Change From Baseline in Anti-double-stranded DNA at Week 52 Mean (Standard Deviation) Unit of measure: IU/mL	0.45 (0.35)	1.06 (2.19)

9. Secondary Outcome Measure:

Measure Title	Change From Baseline in C3 and C4 Complement Levels at Week 52
Measure Description	
Time Frame	Baseline to Week 52

Analysis Population Description

Intent-to-treat population: All randomized participants who received any amount of study drug (rituximab or placebo).

Reporting Groups

	Description
Rituximab	Participants received rituximab 1000 mg intravenously (IV) on Days 1, 15, 168, and 182. They also received mycophenolate mofetil, methylprednisolone, diphenhydramine, acetaminophen, and prednisone; see the Detailed Description for details.
Placebo	Participants received placebo intravenously (IV) on Days 1, 15, 168, and 182. They also received mycophenolate mofetil, methylprednisolone, diphenhydramine, acetaminophen, and prednisone; see the Detailed Description for details.

Measured Values

	Rituximab	Placebo
Overall Number of Participants Analyzed	72	72
Change From Baseline in C3 and C4 Complement Levels at Week 52 Mean (Standard Deviation) Unit of measure: mg/dL		
C3 Complement	37.5 (28.7)	25.9 (32.5)
C4 Complement	9.9 (7.5)	6.6 (8.9)

Reported Adverse Events

Time Frame	Baseline to the end of the study (up to 7 years)

Adverse Event Reporting Description	Safety analysis population: All randomized subjects who receive any amount of study drug (rituximab or placebo). Adverse events reported for the B cell follow-up period only include adverse events that occurred in participants who were followed after the last participant reached study Week 78.

Reporting Groups

	Description
Rituximab - Treatment and Safety Follow-up Periods	Participants received rituximab 1000 mg intravenously (IV) on Days 1, 15, 168, and 182. They also received mycophenolate mofetil, methylprednisolone, diphenhydramine, acetaminophen, and prednisone; see the Detailed Description for details.
Placebo - Treatment and Safety Follow-up Periods	Participants received placebo intravenously (IV) on Days 1, 15, 168, and 182. They also received mycophenolate mofetil, methylprednisolone, diphenhydramine, acetaminophen, and prednisone; see the Detailed Description for details.
Rituximab - B Cell Follow-up Period	Participants received rituximab 1000 mg intravenously (IV) on Days 1, 15, 168, and 182. They also received mycophenolate mofetil, methylprednisolone, diphenhydramine, acetaminophen, and prednisone; see the Detailed Description for details.
Placebo - B Cell Follow-up Period	Participants received placebo intravenously (IV) on Days 1, 15, 168, and 182. They also received mycophenolate mofetil, methylprednisolone, diphenhydramine, acetaminophen, and prednisone; see the Detailed Description for details.

All-Cause Mortality

	Rituximab - Treatment and Safety Follow-up Periods	Placebo - Treatment and Safety Follow-up Periods	Rituximab - B Cell Follow-up Period	Placebo - B Cell Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total All-Cause Mortality	/	/	/	/

Serious Adverse Events

	Rituximab - Treatment and Safety Follow-up Periods	Placebo - Treatment and Safety Follow-up Periods	Rituximab - B Cell Follow-up Period	Placebo - B Cell Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	24/73 (32.88%)	29/71 (40.85%)	3/20 (15%)	0/4 (0%)
Blood and lymphatic system disorders				
Anaemia [A] †	3/73 (4.11%)	3/71 (4.23%)	0/20 (0%)	0/4 (0%)

	Rituximab - Treatment and Safety Follow-up Periods	Placebo - Treatment and Safety Follow-up Periods	Rituximab - B Cell Follow-up Period	Placebo - B Cell Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Coagulopathy [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Disseminated Intravascular Coagulation [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Febrile Neutropenia [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Haemolytic Anaemia [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Leukopenia [A] †	2/73 (2.74%)	0/71 (0%)	0/20 (0%)	0/4 (0%)
Nephrogenic anemia [A] †	0/73 (0%)	0/71 (0%)	1/20 (5%)	0/4 (0%)
Neutropenia [A] †	2/73 (2.74%)	0/71 (0%)	0/20 (0%)	0/4 (0%)
Cardiac disorders				
Atrial Fibrillation [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Myocardial Infarction [A] †	1/73 (1.37%)	0/71 (0%)	0/20 (0%)	0/4 (0%)
Pericardial Effusion [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Pericarditis [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Endocrine disorders				
Thyroiditis [A] †	1/73 (1.37%)	0/71 (0%)	0/20 (0%)	0/4 (0%)
Gastrointestinal disorders				
Abdominal Pain [A] †	1/73 (1.37%)	0/71 (0%)	0/20 (0%)	0/4 (0%)
Ascites [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Diarrhoea [A] †	1/73 (1.37%)	0/71 (0%)	0/20 (0%)	0/4 (0%)
Gastrointestinal Haemorrhage [A] †	1/73 (1.37%)	0/71 (0%)	0/20 (0%)	0/4 (0%)
Haemorrhoids [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Lower Gastrointestinal Haemorrhage [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Nausea [A] †	1/73 (1.37%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)

	Rituximab - Treatment and Safety Follow-up Periods	Placebo - Treatment and Safety Follow-up Periods	Rituximab - B Cell Follow-up Period	Placebo - B Cell Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
General disorders				
Chest Pain [A] †	0/73 (0%)	2/71 (2.82%)	0/20 (0%)	0/4 (0%)
Drug Intolerance [A] †	1/73 (1.37%)	0/71 (0%)	0/20 (0%)	0/4 (0%)
Generalized Oedema [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Oedema [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Immune system disorders				
Antiphospholipid Syndrome [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Infections and infestations				
Bacteraemia [A] †	1/73 (1.37%)	0/71 (0%)	0/20 (0%)	0/4 (0%)
Bacterial Infection [A] †	1/73 (1.37%)	0/71 (0%)	0/20 (0%)	0/4 (0%)
Bronchitis [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Bronchopneumonia [A] †	1/73 (1.37%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Catheter Related Infection [A] †	1/73 (1.37%)	0/71 (0%)	0/20 (0%)	0/4 (0%)
Cellulitis [A] †	2/73 (2.74%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Cytomegalovirus Colitis [A] †	1/73 (1.37%)	0/71 (0%)	0/20 (0%)	0/4 (0%)
Fungal Sepsis [A] †	1/73 (1.37%)	0/71 (0%)	0/20 (0%)	0/4 (0%)
Gastroenteritis [A] †	0/73 (0%)	2/71 (2.82%)	0/20 (0%)	0/4 (0%)
Gastroenteritis Viral [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Genital Herpes [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Herpes Zoster [A] †	1/73 (1.37%)	2/71 (2.82%)	0/20 (0%)	0/4 (0%)
Histoplasmosis [A] †	1/73 (1.37%)	0/71 (0%)	0/20 (0%)	0/4 (0%)
Impetigo [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)

	Rituximab - Treatment and Safety Follow-up Periods	Placebo - Treatment and Safety Follow-up Periods	Rituximab - B Cell Follow-up Period	Placebo - B Cell Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Lobar Pneumonia [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Pneumonia [A] †	2/73 (2.74%)	3/71 (4.23%)	0/20 (0%)	0/4 (0%)
Pneumonia Cryptococcal [A] †	1/73 (1.37%)	0/71 (0%)	0/20 (0%)	0/4 (0%)
Pneumonia Cytomegaloviral [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Sepsis [A] †	1/73 (1.37%)	0/71 (0%)	0/20 (0%)	0/4 (0%)
Sinusitis [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Soft Tissue Infection [A] †	1/73 (1.37%)	0/71 (0%)	0/20 (0%)	0/4 (0%)
Subcutaneous Abscess [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Upper Respiratory Tract Infection [A] †	1/73 (1.37%)	0/71 (0%)	0/20 (0%)	0/4 (0%)
Urinary Tract Infection [A] †	1/73 (1.37%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Wound Infection [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Investigations				
International Normalized Ratio Decreased [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Metabolism and nutrition disorders				
Diabetes Mellitus [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Hypoalbuminaemia [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Musculoskeletal and connective tissue disorders				
Arthralgia [A] †	1/73 (1.37%)	0/71 (0%)	0/20 (0%)	0/4 (0%)
Pain in Extremity [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Systemic Lupus Erythematosus [A] †	0/73 (0%)	2/71 (2.82%)	0/20 (0%)	0/4 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				

	Rituximab - Treatment and Safety Follow-up Periods	Placebo - Treatment and Safety Follow-up Periods	Rituximab - B Cell Follow-up Period	Placebo - B Cell Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Basal Cell Carcinoma [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Breast cancer [A] †	0/73 (0%)	0/71 (0%)	1/20 (5%)	0/4 (0%)
Nervous system disorders				
Cerebral Ischaemia [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Convulsion [A] †	0/73 (0%)	2/71 (2.82%)	0/20 (0%)	0/4 (0%)
Hypersensitive Encephalopathy [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Ruptured Cerebral Aneurysm [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Syncope [A] †	1/73 (1.37%)	0/71 (0%)	0/20 (0%)	0/4 (0%)
Vasculitis Cerebral [A] †	1/73 (1.37%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Pregnancy, puerperium and perinatal conditions				
Abortion [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Abortion Spontaneous [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Psychiatric disorders				
Depression [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Psychotic Disorder [A] †	1/73 (1.37%)	0/71 (0%)	0/20 (0%)	0/4 (0%)
Renal and urinary disorders				
Azotaemia [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Pyelonephritis [A] †	0/73 (0%)	0/71 (0%)	1/20 (5%)	0/4 (0%)
Renal Failure [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Renal Failure Acute [A] †	1/73 (1.37%)	3/71 (4.23%)	0/20 (0%)	0/4 (0%)
Respiratory, thoracic and mediastinal disorders				
Pleural Effusion [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)

	Rituximab - Treatment and Safety Follow-up Periods	Placebo - Treatment and Safety Follow-up Periods	Rituximab - B Cell Follow-up Period	Placebo - B Cell Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Pleurisy [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Pneumonitis [A] †	2/73 (2.74%)	0/71 (0%)	0/20 (0%)	0/4 (0%)
Pulmonary Embolism [A] †	1/73 (1.37%)	0/71 (0%)	0/20 (0%)	0/4 (0%)
Respiratory Failure [A] †	1/73 (1.37%)	0/71 (0%)	0/20 (0%)	0/4 (0%)
Skin and subcutaneous tissue disorders				
Rash Vesicular [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Urticaria [A] †	1/73 (1.37%)	0/71 (0%)	0/20 (0%)	0/4 (0%)
Surgical and medical procedures				
Renal transplant [A] †	0/73 (0%)	0/71 (0%)	1/20 (5%)	0/4 (0%)
Vascular disorders				
Deep Vein Thrombosis [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Hypertension [A] †	0/73 (0%)	2/71 (2.82%)	0/20 (0%)	0/4 (0%)
Hypotension [A] †	1/73 (1.37%)	0/71 (0%)	0/20 (0%)	0/4 (0%)
Malignant Hypertension [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Thrombosis [A] †	1/73 (1.37%)	0/71 (0%)	0/20 (0%)	0/4 (0%)
Vasculitis [A] †	0/73 (0%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Vena Cava Thrombosis [A] †	1/73 (1.37%)	0/71 (0%)	0/20 (0%)	0/4 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (Unspecified)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Rituximab - Treatment and Safety Follow-up Periods	Placebo - Treatment and Safety Follow-up Periods	Rituximab - B Cell Follow-up Period	Placebo - B Cell Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	69/73 (94.52%)	66/71 (92.96%)	8/20 (40%)	0/4 (0%)
Blood and lymphatic system disorders				
Anaemia [A] †	10/73 (13.7%)	9/71 (12.68%)	0/20 (0%)	0/4 (0%)
Leukopenia [A] †	7/73 (9.59%)	2/71 (2.82%)	0/20 (0%)	0/4 (0%)
Cardiac disorders				
Palpitations [A] †	2/73 (2.74%)	4/71 (5.63%)	0/20 (0%)	0/4 (0%)
Tachycardia [A] †	6/73 (8.22%)	5/71 (7.04%)	0/20 (0%)	0/4 (0%)
Ear and labyrinth disorders				
Ear infection [A] †	0/73 (0%)	0/71 (0%)	1/20 (5%)	0/4 (0%)
Endocrine disorders				
Amenorrhoea [A] †	0/73 (0%)	0/71 (0%)	1/20 (5%)	0/4 (0%)
Cushingoid [A] †	4/73 (5.48%)	2/71 (2.82%)	0/20 (0%)	0/4 (0%)
Eye disorders				
Conjunctivitis [A] †	3/73 (4.11%)	4/71 (5.63%)	0/20 (0%)	0/4 (0%)
Vision Blurred [A] †	3/73 (4.11%)	4/71 (5.63%)	0/20 (0%)	0/4 (0%)
Gastrointestinal disorders				
Abdominal Discomfort [A] †	4/73 (5.48%)	2/71 (2.82%)	0/20 (0%)	0/4 (0%)
Abdominal Distension [A] †	4/73 (5.48%)	4/71 (5.63%)	0/20 (0%)	0/4 (0%)
Abdominal Pain [A] †	3/73 (4.11%)	4/71 (5.63%)	0/20 (0%)	0/4 (0%)
Abdominal Pain Upper [A] †	4/73 (5.48%)	4/71 (5.63%)	0/20 (0%)	0/4 (0%)
Dental Caries [A] †	4/73 (5.48%)	2/71 (2.82%)	0/20 (0%)	0/4 (0%)

	Rituximab - Treatment and Safety Follow-up Periods	Placebo - Treatment and Safety Follow-up Periods	Rituximab - B Cell Follow-up Period	Placebo - B Cell Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Diarrhoea [A] †	28/73 (38.36%)	28/71 (39.44%)	0/20 (0%)	0/4 (0%)
Dyspepsia [A] †	5/73 (6.85%)	9/71 (12.68%)	0/20 (0%)	0/4 (0%)
Gastroesophageal Reflux Disease [A] †	2/73 (2.74%)	7/71 (9.86%)	0/20 (0%)	0/4 (0%)
Haemorrhoids [A] †	4/73 (5.48%)	2/71 (2.82%)	0/20 (0%)	0/4 (0%)
Nausea [A] †	20/73 (27.4%)	21/71 (29.58%)	0/20 (0%)	0/4 (0%)
Vomiting [A] †	19/73 (26.03%)	14/71 (19.72%)	0/20 (0%)	0/4 (0%)
General disorders				
Chest Pain [A] †	4/73 (5.48%)	10/71 (14.08%)	0/20 (0%)	0/4 (0%)
Chills [A] †	2/73 (2.74%)	4/71 (5.63%)	0/20 (0%)	0/4 (0%)
Fatigue [A] †	12/73 (16.44%)	9/71 (12.68%)	0/20 (0%)	0/4 (0%)
Oedema [A] †	8/73 (10.96%)	7/71 (9.86%)	0/20 (0%)	0/4 (0%)
Oedema Peripheral [A] †	6/73 (8.22%)	11/71 (15.49%)	0/20 (0%)	0/4 (0%)
Pain [A] †	2/73 (2.74%)	4/71 (5.63%)	0/20 (0%)	0/4 (0%)
Pyrexia [A] †	9/73 (12.33%)	4/71 (5.63%)	0/20 (0%)	0/4 (0%)
Immune system disorders				
Seasonal Allergy [A] †	5/73 (6.85%)	0/71 (0%)	0/20 (0%)	0/4 (0%)
Infections and infestations				
Bronchitis [A] †	6/73 (8.22%)	4/71 (5.63%)	0/20 (0%)	0/4 (0%)
Candidiasis [A] †	4/73 (5.48%)	3/71 (4.23%)	0/20 (0%)	0/4 (0%)
Cellulitis [A] †	3/73 (4.11%)	4/71 (5.63%)	0/20 (0%)	0/4 (0%)
Fungal skin infection [A] †	0/73 (0%)	0/71 (0%)	1/20 (5%)	0/4 (0%)
Gastroenteritis [A] †	8/73 (10.96%)	7/71 (9.86%)	0/20 (0%)	0/4 (0%)

	Rituximab - Treatment and Safety Follow-up Periods	Placebo - Treatment and Safety Follow-up Periods	Rituximab - B Cell Follow-up Period	Placebo - B Cell Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Gastroenteritis Viral [A] †	1/73 (1.37%)	4/71 (5.63%)	0/20 (0%)	0/4 (0%)
Herpes Zoster [A] †	11/73 (15.07%)	8/71 (11.27%)	0/20 (0%)	0/4 (0%)
Influenza [A] †	3/73 (4.11%)	4/71 (5.63%)	0/20 (0%)	0/4 (0%)
Nasopharyngitis [A] †	8/73 (10.96%)	5/71 (7.04%)	1/20 (5%)	0/4 (0%)
Oral Candidiasis [A] †	6/73 (8.22%)	4/71 (5.63%)	0/20 (0%)	0/4 (0%)
Peritonitis bacterial [A] †	0/73 (0%)	0/71 (0%)	1/20 (5%)	0/4 (0%)
Sinusitis [A] †	9/73 (12.33%)	4/71 (5.63%)	0/20 (0%)	0/4 (0%)
Upper Respiratory Tract Infection [A] †	21/73 (28.77%)	23/71 (32.39%)	1/20 (5%)	0/4 (0%)
Urinary Tract Infection [A] †	17/73 (23.29%)	20/71 (28.17%)	3/20 (15%)	0/4 (0%)
Injury, poisoning and procedural complications				
Contusion [A] †	5/73 (6.85%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Investigations				
Blood Potassium Decreased [A] †	1/73 (1.37%)	4/71 (5.63%)	0/20 (0%)	0/4 (0%)
Blood creatinine increased [A] †	0/73 (0%)	0/71 (0%)	1/20 (5%)	0/4 (0%)
Glomerular filtration rate decreased [A] †	0/73 (0%)	0/71 (0%)	1/20 (5%)	0/4 (0%)
Metabolism and nutrition disorders				
Hypercholesterolaemia [A] †	8/73 (10.96%)	3/71 (4.23%)	0/20 (0%)	0/4 (0%)
Hypokalaemia [A] †	10/73 (13.7%)	10/71 (14.08%)	0/20 (0%)	0/4 (0%)
Musculoskeletal and connective tissue disorders				
Arthralgia [A] †	16/73 (21.92%)	16/71 (22.54%)	0/20 (0%)	0/4 (0%)
Back Pain [A] †	6/73 (8.22%)	11/71 (15.49%)	0/20 (0%)	0/4 (0%)
Muscle Spasms [A] †	17/73 (23.29%)	18/71 (25.35%)	0/20 (0%)	0/4 (0%)

	Rituximab - Treatment and Safety Follow-up Periods	Placebo - Treatment and Safety Follow-up Periods	Rituximab - B Cell Follow-up Period	Placebo - B Cell Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Musculoskeletal Chest Pain [A] †	2/73 (2.74%)	4/71 (5.63%)	0/20 (0%)	0/4 (0%)
Myalgia [A] †	3/73 (4.11%)	6/71 (8.45%)	0/20 (0%)	0/4 (0%)
Neck Pain [A] †	6/73 (8.22%)	4/71 (5.63%)	0/20 (0%)	0/4 (0%)
Pain in Extremity [A] †	9/73 (12.33%)	9/71 (12.68%)	0/20 (0%)	0/4 (0%)
Nervous system disorders				
Dizziness [A] †	9/73 (12.33%)	5/71 (7.04%)	0/20 (0%)	0/4 (0%)
Dysgeusia [A] †	2/73 (2.74%)	5/71 (7.04%)	0/20 (0%)	0/4 (0%)
Headache [A] †	26/73 (35.62%)	19/71 (26.76%)	0/20 (0%)	0/4 (0%)
Hypoaesthesia [A] †	1/73 (1.37%)	5/71 (7.04%)	0/20 (0%)	0/4 (0%)
Tremor [A] †	3/73 (4.11%)	5/71 (7.04%)	0/20 (0%)	0/4 (0%)
Psychiatric disorders				
Anxiety [A] †	5/73 (6.85%)	8/71 (11.27%)	0/20 (0%)	0/4 (0%)
Depression [A] †	5/73 (6.85%)	6/71 (8.45%)	0/20 (0%)	0/4 (0%)
Insomnia [A] †	10/73 (13.7%)	14/71 (19.72%)	0/20 (0%)	0/4 (0%)
Renal and urinary disorders				
Pyelonephritis [A] †	0/73 (0%)	0/71 (0%)	1/20 (5%)	0/4 (0%)
Respiratory, thoracic and mediastinal disorders				
Cough [A] †	16/73 (21.92%)	13/71 (18.31%)	0/20 (0%)	0/4 (0%)
Dyspnoea [A] †	5/73 (6.85%)	7/71 (9.86%)	0/20 (0%)	0/4 (0%)
Epistaxis [A] †	2/73 (2.74%)	4/71 (5.63%)	0/20 (0%)	0/4 (0%)
Oropharyngeal Pain [A] †	2/73 (2.74%)	4/71 (5.63%)	0/20 (0%)	0/4 (0%)
Pleuritic Pain [A] †	1/73 (1.37%)	4/71 (5.63%)	0/20 (0%)	0/4 (0%)

	Rituximab - Treatment and Safety Follow-up Periods	Placebo - Treatment and Safety Follow-up Periods	Rituximab - B Cell Follow-up Period	Placebo - B Cell Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Rhinorrhoea [A] †	0/73 (0%)	4/71 (5.63%)	0/20 (0%)	0/4 (0%)
Throat Irritation [A] †	4/73 (5.48%)	0/71 (0%)	0/20 (0%)	0/4 (0%)
Skin and subcutaneous tissue disorders				
Acne [A] †	3/73 (4.11%)	8/71 (11.27%)	0/20 (0%)	0/4 (0%)
Alopecia [A] †	10/73 (13.7%)	6/71 (8.45%)	0/20 (0%)	0/4 (0%)
Rash [A] †	7/73 (9.59%)	8/71 (11.27%)	0/20 (0%)	0/4 (0%)
Swelling Face [A] †	4/73 (5.48%)	1/71 (1.41%)	0/20 (0%)	0/4 (0%)
Vascular disorders				
Hypertension [A] †	7/73 (9.59%)	7/71 (9.86%)	0/20 (0%)	0/4 (0%)
Hypotension [A] †	8/73 (10.96%)	3/71 (4.23%)	0/20 (0%)	0/4 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (Unspecified)

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The Study being conducted under this Agreement is part of the Overall Study. Investigator is free to publish in reputable journals or to present at professional conferences the results of the Study, but only after the first publication or presentation that involves the Overall Study. The Sponsor may request that Confidential Information be deleted and/or the publication be postponed in order to protect the Sponsor's intellectual property rights.

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