ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 03/17/2015

ClinicalTrials.gov ID: NCT00542828

Study Identification

Unique Protocol ID:	ThymoHEM01206
Brief Title:	Rabbit Anti-thymocyte Globulin in the Treatment of Patients With Low to Intermediate-1 Risk Myelodysplastic Syndrome (RISE)
Official Title:	A Phase II Study of the Efficacy of Rabbit Anti-thymocyte Globulin (rATG) in Patients With Low and Intermediate-1 Risk Myelodysplastic Syndrome
Secondary IDs:	2007-002532-28 [EudraCT Number]

Study Status

Record Verification:	March 2015
Overall Status:	Terminated
Study Start:	October 2007
Primary Completion:	May 2009 [Actual]
Study Completion:	July 2009 [Actual]

Sponsor/Collaborators

Sponsor:	Genzyme, a Sanofi Company
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	Yes
IND/IDE Protocol?:	Yes

IND/IDE Information:	Grantor: CBER IND/IDE Number: 8999 Serial Number: 043 Has Expanded Access? No
Review Board:	Approval Status: Approved Approval Number: 07/H1102/83 Board Name: South East Research Ethics Committee Board Affiliation: King's College Hospital Research Ethics Committee (South London REC Office 2) Camberwell Building, King's College Hopsital, 94 Denmark Hill, London, SE5 9RS Phone: Email:
Data Monitoring?:	No
Oversight Authorities:	United States: Food and Drug Administration Germany: Paul-Ehrlich-Institut United Kingdom: Medicines and Healthcare Products Regulatory Agency France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) European Union: European Medicines Agency Netherlands: The Central Committee on Research Involving Human Subjects (CCMO)

Study Description

Brief Summary:	This is a Phase II, single-arm, open-label, multinational, multicenter study of rATG in patients with low or intermediate-1 risk MDS who have either failed 1 prior treatment with growth factor(s), hypomethylating agents (5-azacitidine or decitabine), or the antiangiogenic agents lenalidomide or thalidomide, or who have never been treated for MDS (i.e., treatment-naïve patients).
Detailed Description:	

Conditions

Conditions:	Myelodysplastic Syndrome (MDS)
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Intervention Model:	Single Group Assignment

Number of Arms: 1

Masking: Open Label

Allocation: Non-Randomized

Endpoint Classification: Efficacy Study

Enrollment: 16 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Thymoglobulin	Biological/Vaccine: Thymoglobulin®, Rabbit Anti-thymocyte Globulin (rATG) All patients were to be treated with rATG 3.75 mg/kg/day administered by intravenous (IV) infusion over ≥6 hours for 5 consecutive days (cumulative dose: 18.75 mg/kg) Other Names: • Rabbbit Anti-human thymocyte immunoglobulin

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age: 70 Years

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Patient provided signed written informed consent.
- Patient had pathologically confirmed low or intermediate-1 risk MDS at the time of MDS diagnosis and at the time of screening.
- Patient had received no more than 1 prior treatment for MDS.
- Patient exhibited at least 1 hematologic cytopenia (anemia, neutropenia, or thrombocytopenia) over a period of ≥1 week.
- Patient had documentation of any prior transfusion requirements.
- Patient had an Eastern Cooperative Oncology Group (ECOG) performance score of 0, 1, or 2.
- Patient was ≥18 and ≤70 years of age at time of signing the informed consent document (ICD).
- Patient was able to adhere to study visit schedule and all other protocol requirements.

- Patient was willing to practice a medically approved method of birth control during participation in the study (at least 12 months after the last infusion of rATG) (fertile male and female patients).

Exclusion Criteria:

- Patient was pregnant or lactating.
- Patient has had prior treatment with any ATG.
- Patient has received any immunomodulatory or immunosuppressing agents (excluding steroids) <12 weeks prior to the first infusion of rATG.
- Patient has had a prior hematopoietic stem cell transplantation and/or other organ transplant.
- Patient has had a prior allergic reaction to rabbit proteins or excipients.
- Patient had any of the following subtypes of MDS: refractory anemia with ringed sideroblasts (RARS); chronic myelomonocytic leukemia (CMML) if white blood counts >13x10^9/L; or other MDS/myeloproliferative diseases (MPD).
- Patient had MDS associated with a 5q chromosomal deletion unless the patient received prior lenalidomide treatment <4 weeks prior to the first infusion of rATG.
- Patient had MDS presumed secondary to exposure to chemicals or treatment with radiotherapy or chemotherapy.
- Patient received any investigational agents within 4 weeks prior to the first infusion of rATG.
- Patient has any of the following abnormalities: serum creatinine >1.5 x upper limit of normal (ULN); aspartate transaminase (AST) and alanine transaminase (ALT) >2.5 x ULN; or serum total bilirubin >1.5 x ULN, except for unconjugated hyperbilirubinemia related to the patient's MDS.
- Patient received any treatment with non-steroidal anti-inflammatory drugs (NSAIDs) within 14 days prior to the start of treatment.
- Patient was known to be human immunodeficiency virus (HIV) positive.
- Patient had any prior diagnosis of malignancy other than MDS, unless the patient had been disease-free for at least 5 years following the completion of curative intent therapy.
- Patient had any serious medical condition (other than MDS) that would limit survival to <2 years.
- Patient had active acute or chronic infection, including cytomegaloviremia (CMV) infection or deep tissue infection.
- Patient had any other serious medical condition, uncontrolled illness (including, but not limited to, symptomatic congestive heart failure, unstable angina pectoris, or cardiac arrhythmia), social condition, or psychiatric illness that would prevent the patient from signing the informed consent document (ICD), or would place the patient at unacceptable risk if he/she participated in the study, or that would limit compliance with study requirements.

Contacts/Locations

Study Officials: Medical Monitor
Genzyme Corporation

Locations: United Kingdom
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United Kingdom
St. James Hospital
Leeds, England, United Kingdom, LS9 7TF

References

Citations:

Links:

Study Results

Participant Flow

Recruitment Details	Enrollment period: 05 November 2007 through 06 May 2009. Study participants were enrolled at 7 study centers in Europe.
Pre-Assignment Details	Because the study was terminated early due to slow enrollment, only 16 participants were enrolled in the study. Of these, 14 participants went on to receive treatment with Thymoglobulin.

Reporting Groups

	Description
Thymoglobulin	Thymoglobulin 3.75 mg/kg/day for 5 consecutive days

Overall Study

	Thymoglobulin
Started	16 [1]
Completed	3 [2]
Not Completed	13
Physician Decision	1
Need for Prohibited Treatment	3
Study Prematurely Discontinued	7
Did Not Receive Thymoglobulin Treatment	2

[1] Number of participants enrolled in the study; of the 16 enrolled, 14 received study treatment.
[2] Number of participants who completed the 12-month study period.

Baseline Characteristics

Reporting Groups

	Description
Thymoglobulin	Thymoglobulin 3.75 mg/kg/day for 5 consecutive days

Baseline Measures

	Thymoglobulin
Number of Participants	14
Age, Continuous [units: years] Mean (Standard Deviation)	55.4 (7.67)
Age, Customized [units: participants]	
<60 years	10
>=60 years	4
Gender, Male/Female [units: participants]	
Female	7
Male	7

	Thymoglobulin
Race/Ethnicity, Customized [units: participants]	
Black	1
White	11
Not Reported	2

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Number of Participants Who Achieved Hematologic Improvement (HI)
Measure Description	This is a measure of HI in the erythroid, platelet, and neutrophil lineages. Note that HI was observed in the erythroid lineage only, which is defined as a participant who had a >=1.5 g/dL increase in hemoglobin from baseline (pretreatment value must have been <11 g/dL) and who had a relevant reduction of units of red blood cell (RBC) transfusions by an absolute number of >=4 RBC transfusions over 8 weeks as compared with the pretreatment transfusion number in the previous 8 weeks. These criteria were taken from the 2006 International Working Group criteria.
Time Frame	12 months
Safety Issue?	No

Analysis Population Description

Number of participants analyzed includes those who received treatment with Thymoglobulin and completed follow-up efficacy assessments. However, no formal efficacy analysis was conducted due to the small sample size and early study termination.

Reporting Groups

	Description
Thymoglobulin	Thymoglobulin 3.75 mg/kg/day for 5 consecutive days

Measured Values

	Thymoglobulin
Number of Participants Analyzed	13
Number of Participants Who Achieved Hematologic Improvement (HI) [units: participants]	3

2. Secondary Outcome Measure:

Measure Title	Number of Participants With Duration of HI
Measure Description	This is a measure of the duration of HI for those participants who achieved HI. Duration of HI is defined as the time from confirmation of HI response to the date of first documentation of HI relapse or death due to any cause, whichever occurs first.
Time Frame	36 months
Safety Issue?	No

Analysis Population Description

This secondary outcome measure was not formally analyzed or assessed due to the small sample size and early study termination (i.e., no study participants reached the 36-month time point).

Reporting Groups

	Description
Thymoglobulin	Thymoglobulin 3.75 mg/kg/day for 5 consecutive days

Measured Values

	Thymoglobulin
Number of Participants Analyzed	0

No data displayed because Outcome Measure has zero total participants analyzed.

3. Secondary Outcome Measure:

Measure Title	Number of Participants Who Achieved Disease Remission
Measure Description	Disease remission is defined as a participant whose best response to therapy was a complete remission or partial remission. A complete remission is defined as: bone marrow <=5% myeloblasts with normal maturation of all cell lines; persistent dysplasia noted; and peripheral blood hemoglobin >=11 g/dL, platelets >=100 x 10^9/L, neutrophils >=1.0 x 10^9/L, and blasts 0%. Partial remission is defined as: all complete remission criteria if abnormal before treatment, except bone marrow blasts decreased by >=50% over pretreatment, but still >5%; and cellularity and morphology not relevant.
Time Frame	36 months
Safety Issue?	No

Analysis Population Description

This secondary outcome measure was not formally analyzed or assessed due to the small sample size and early study termination (i.e., no study participants reached the 36-month time point).

Reporting Groups

	Description
Thymoglobulin	Thymoglobulin 3.75 mg/kg/day for 5 consecutive days

Measured Values

	Thymoglobulin
Number of Participants Analyzed	0

No data displayed because Outcome Measure has zero total participants analyzed.

4. Secondary Outcome Measure:

Measure Title	Duration of Disease Remission
Measure Description	This is a measure of the duration of overall disease remission only for those participants who achieved an overall remission. Duration of overall remission is defined as the time from first documentation of overall remission to the date of first documentation of disease relapse or death due to any cause, whichever occurs first.
Time Frame	36 months
Safety Issue?	No

Analysis Population Description

This secondary outcome measure was not formally analyzed or assessed due to the small sample size and early study termination (i.e., no study participants reached the 36-month time point).

Reporting Groups

	Description
Thymoglobulin	Thymoglobulin 3.75 mg/kg/day for 5 consecutive days

Measured Values

	Thymoglobulin
Number of Participants Analyzed	0

No data displayed because Outcome Measure has zero total participants analyzed.

5. Secondary Outcome Measure:

Measure Title	Number of Participants Who Achieved Transfusion Independence

Measure Description	This is a measure of transfusion independence, which is defined as a participant with no transfusions for a period of 8 consecutive calendar weeks after first dose. Transfusion independence was to be calculated only for those participants who had documented transfusions during the 8 weeks prior to enrollment.
Time Frame	36 months
Safety Issue?	No

Analysis Population Description

This secondary outcome measure was not formally analyzed or assessed due to the small sample size and early study termination (i.e., no study participants reached the 36-month time point).

Reporting Groups

	Description
Thymoglobulin	Thymoglobulin 3.75 mg/kg/day for 5 consecutive days

Measured Values

	Thymoglobulin
Number of Participants Analyzed	0

No data displayed because Outcome Measure has zero total participants analyzed.

6. Secondary Outcome Measure:

Measure Title	Number of Participants With Duration of Transfusion Independence
Measure Description	This is a measure of the duration of transfusion independence only for those participants who achieved transfusion independence. Duration of transfusion independence is defined as the longest period of time during which a participant requires no transfusions.
Time Frame	36 months
Safety Issue?	No

Analysis Population Description

This secondary outcome measure was not formally analyzed or assessed due to the small sample size and early study termination (i.e., no study participants reached the 36-month time point).

Reporting Groups

	Description
Thymoglobulin	Thymoglobulin 3.75 mg/kg/day for 5 consecutive days

Measured Values

	Thymoglobulin
Number of Participants Analyzed	0

No data displayed because Outcome Measure has zero total participants analyzed.

7. Secondary Outcome Measure:

Measure Title	Number of Participants With a Relapse Following HI
Measure Description	This is a measure of relapse following HI, which is defined as a participant who experiences at least one of the following: >=50% decrease from maximum response levels in granulocytes or platelets; >=1.5 g/dL reduction in hemoglobin; or transfusion dependence.
Time Frame	36 months
Safety Issue?	No

Analysis Population Description

This secondary outcome measure was not formally analyzed or assessed due to the small sample size and early study termination (i.e., no study participants reached the 36-month time point).

Reporting Groups

	Description
Thymoglobulin	Thymoglobulin 3.75 mg/kg/day for 5 consecutive days

Measured Values

	Thymoglobulin
Number of Participants Analyzed	0

No data displayed because Outcome Measure has zero total participants analyzed.

8. Secondary Outcome Measure:

Measure Title	Number of Participants With a Relapse Following Overall Remission
Measure Description	This is a measure of relapse following an overall remission only for participants who experienced either a complete or partial remission. Relapse following an overall remission is defined as a participant who meets any of the following criteria: a return to pretreatment bone marrow blast percentage; decrease of >=50% from maximum remission levels in neutrophils or platelets; reduction in hemoglobin concentration by >=1.5 g/dL from maximum remission levels; or transfusion dependence.
Time Frame	36 months

Safety Issue?	No

Analysis Population Description

Secondary outcome measure was not formally analyzed or assessed due to early study termination and small sample size (i.e., no study participants reached the 36-month time point)

Reporting Groups

	Description
Thymoglobulin	Thymoglobulin 3.75 mg/kg/day for 5 consecutive days

Measured Values

	Thymoglobulin
Number of Participants Analyzed	0

No data displayed because Outcome Measure has zero total participants analyzed.

9. Secondary Outcome Measure:

Measure Title	Number of Participants With Progression-free Survival
Measure Description	This is a measure of a progression-free survival which is defined as the time from the participant’s first dose to the date of disease progression, lost to follow-up or death due to any cause, whichever occurs first.
Time Frame	36 months
Safety Issue?	No

Analysis Population Description

This secondary outcome measure was not formally analyzed or assessed due to the small sample size and early study termination (i.e., no study participants reached the 36-month time point).

Reporting Groups

	Description
Thymoglobulin	Thymoglobulin 3.75 mg/kg/day for 5 consecutive days

Measured Values

	Thymoglobulin
Number of Participants Analyzed	0

No data displayed because Outcome Measure has zero total participants analyzed.

10. Secondary Outcome Measure:

Measure Title	Number of Participants With Transformation to Acute Myeloid Leukemia
Measure Description	This is a measure of transformation to acute myeloid leukemia only for participants who have bone marrow assessments. Transformation to acute myeloid leukemia is defined as the earliest date a participant experiences bone marrow blasts of >=20% after the start of treatment.
Time Frame	36 months
Safety Issue?	No

Analysis Population Description

This secondary outcome measure was not formally analyzed or assessed due to the small sample size and early study termination (i.e., no study participants reached the 36-month time point).

Reporting Groups

	Description
Thymoglobulin	Thymoglobulin 3.75 mg/kg/day for 5 consecutive days

Measured Values

	Thymoglobulin
Number of Participants Analyzed	0

No data displayed because Outcome Measure has zero total participants analyzed.

11. Secondary Outcome Measure:

Measure Title	Number of Participants With a Cytogenetic Response
Measure Description	This is a measure of cytogenic response for participants whose best response to therapy is a either a complete or partial cytogenetic response. A complete cytogenetic response is defined as the disappearance of the chromosomal abnormality without appearance of new ones. A partial cytogenetic response is defined as at least 50% reduction of the chromosomal abnormality.
Time Frame	36 months
Safety Issue?	No

Analysis Population Description

This secondary outcome measure was not formally analyzed or assessed due to the small sample size and early study termination (i.e., no study participants reached the 36-month time point).

Reporting Groups

	Description
Thymoglobulin	Thymoglobulin 3.75 mg/kg/day for 5 consecutive days

Measured Values

	Thymoglobulin
Number of Participants Analyzed	0

No data displayed because Outcome Measure has zero total participants analyzed.

12. Secondary Outcome Measure:

Measure Title	Number of Participants With a Marrow Remission
Measure Description	This is a measure of bone marrow complete remission for participants who experience a remission. Bone marrow complete remission is defined as a bone marrow assessment of <=5% myeloblasts and decrease by >=50% over pretreatment.
Time Frame	36 months
Safety Issue?	No

Analysis Population Description

This secondary outcome measure was not formally analyzed or assessed due to the small sample size and early study termination (i.e., no study participants reached the 36-month time point).

Reporting Groups

	Description
Thymoglobulin	Thymoglobulin 3.75 mg/kg/day for 5 consecutive days

Measured Values

	Thymoglobulin
Number of Participants Analyzed	0

No data displayed because Outcome Measure has zero total participants analyzed.

Reported Adverse Events

Time Frame	Adverse events were collected for approximately 19 months (includes all events which presented after the start of treatment through the end of study).
Additional Description	In the event a single participant has experienced both a serious and a non-serious form of the same adverse event term, the individual has been included in the numerator ("number of affected participants") of both adverse event tables.

Reporting Groups

	Description
Thymoglobulin	Thymoglobulin 3.75 mg/kg/day for 5 consecutive days

Serious Adverse Events

	Thymoglobulin
	Affected/At Risk (%)
Total	7/14 (50%)
Cardiac disorders	
Bradycardia [A] †	1/14 (7.14%)
Gastrointestinal disorders	
Constipation [A] †	1/14 (7.14%)
Intestinal perforation [A] †	1/14 (7.14%)
Rectal haemorrhage [A] †	2/14 (14.29%)
General disorders	
Oedema peripheral [A] †	1/14 (7.14%)
Pyrexia [A] †	1/14 (7.14%)
Immune system disorders	
Serum sickness [A] †	2/14 (14.29%)
Infections and infestations	
Cellulitis [A] †	1/14 (7.14%)

	Thymoglobulin
	Affected/At Risk (%)
Influenza [A] †	1/14 (7.14%)
Sepsis [A] †	1/14 (7.14%)
Musculoskeletal and connective tissue disorders	
Myalgia [A] †	1/14 (7.14%)
Myositis [A] †	1/14 (7.14%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
Myelodysplastic syndrome [A] †	1/14 (7.14%)
Renal and urinary disorders	
Renal failure acute [A] †	1/14 (7.14%)
Respiratory, thoracic and mediastinal disorders	
Pulmonary embolism [A] †	1/14 (7.14%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 12.0

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 0%

	Thymoglobulin
	Affected/At Risk (%)
Total	14/14 (100%)
Blood and lymphatic system disorders	
Anaemia [A] †	2/14 (14.29%)
Febrile neutropenia [A] †	1/14 (7.14%)
Neutropenia [A] †	2/14 (14.29%)
Pancytopenia [A] †	1/14 (7.14%)
Thrombocytopenia [A] †	2/14 (14.29%)

	Thymoglobulin
	Affected/At Risk (%)
Cardiac disorders	
Arrhythmia [A] †	1/14 (7.14%)
Tachycardia [A] †	1/14 (7.14%)
Ear and labyrinth disorders	
Deafness [A] †	1/14 (7.14%)
Eye disorders	
Conjunctival haemorrhage [A] †	1/14 (7.14%)
Eye pain [A] †	1/14 (7.14%)
Scleral hyperaemia [A] †	1/14 (7.14%)
Visual impairment [A] †	1/14 (7.14%)
Gastrointestinal disorders	
Abdominal distension [A] †	1/14 (7.14%)
Abdominal pain [A] †	2/14 (14.29%)
Abdominal tenderness [A] †	1/14 (7.14%)
Diarrhoea [A] †	10/14 (71.43%)
Dry mouth [A] †	3/14 (21.43%)
Dysphagia [A] †	1/14 (7.14%)
Haemorrhoidal haemorrhage [A] †	1/14 (7.14%)
Mouth haemorrhage [A] †	1/14 (7.14%)
Mouth ulceration [A] †	1/14 (7.14%)
Nausea [A] †	5/14 (35.71%)
Oral pain [A] †	1/14 (7.14%)
Rectal haemorrhage [A] †	1/14 (7.14%)

	Thymoglobulin
	Affected/At Risk (%)
Toothache [A] †	1/14 (7.14%)
Vomiting [A] †	4/14 (28.57%)
General disorders	
Catheter site pain [A] †	1/14 (7.14%)
Chills [A] †	3/14 (21.43%)
Fatigue [A] †	3/14 (21.43%)
Injection site reaction [A] †	1/14 (7.14%)
Local swelling [A] †	1/14 (7.14%)
Non-cardiac chest pain [A] †	1/14 (7.14%)
Oedema [A] †	1/14 (7.14%)
Oedema peripheral [A] †	3/14 (21.43%)
Pyrexia [A] †	9/14 (64.29%)
Immune system disorders	
Cytokine release syndrome [A] †	1/14 (7.14%)
Serum sickness [A] †	3/14 (21.43%)
Infections and infestations	
Central line infection [A] †	1/14 (7.14%)
Epstein-Barr virus infection [A] †	1/14 (7.14%)
Folliculitis [A] †	1/14 (7.14%)
Gastroenteritis [A] †	1/14 (7.14%)
Lower respiratory tract infection [A] †	1/14 (7.14%)
Nasopharyngitis [A] †	2/14 (14.29%)

	Thymoglobulin
	Affected/At Risk (%)
Staphylococcal infection [A] †	1/14 (7.14%)
Upper respiratory tract infection [A] †	1/14 (7.14%)
Injury, poisoning and procedural complications	
Transfusion reaction [A] †	1/14 (7.14%)
Investigations	
Blood glucose increased [A] †	1/14 (7.14%)
Blood lactate dehydrogenase increased [A] †	1/14 (7.14%)
Blood phosphorus decreased [A] †	1/14 (7.14%)
Blood potassium decreased [A] †	1/14 (7.14%)
Blood sodium increased [A] †	1/14 (7.14%)
Blood urine present [A] †	1/14 (7.14%)
Hepatic enzyme increased [A] †	1/14 (7.14%)
Liver function test abnormal [A] †	1/14 (7.14%)
Neutrophil count decreased [A] †	1/14 (7.14%)
Platelet count decreased [A] †	2/14 (14.29%)
Protein urine present [A] †	1/14 (7.14%)
Weight increased [A] †	2/14 (14.29%)
Metabolism and nutrition disorders	
Anorexia [A] †	1/14 (7.14%)
Decreased appetite [A] †	1/14 (7.14%)
Hyperglycaemia [A] †	3/14 (21.43%)
Hypocalcaemia [A] †	1/14 (7.14%)

	Thymoglobulin
	Affected/At Risk (%)
Hypokalaemia [A] †	4/14 (28.57%)
Hypomagnesaemia [A] †	1/14 (7.14%)
Hypophosphataemia [A] †	1/14 (7.14%)
Musculoskeletal and connective tissue disorders	
Arthralgia [A] †	5/14 (35.71%)
Arthritis [A] †	1/14 (7.14%)
Back pain [A] †	1/14 (7.14%)
Bone pain [A] †	1/14 (7.14%)
Flank pain [A] †	1/14 (7.14%)
Muscle spasms [A] †	1/14 (7.14%)
Musculoskeletal chest pain [A] †	1/14 (7.14%)
Musculoskeletal pain [A] †	1/14 (7.14%)
Myalgia [A] †	1/14 (7.14%)
Neck pain [A] †	1/14 (7.14%)
Pain in extremity [A] †	3/14 (21.43%)
Pain in jaw [A] †	1/14 (7.14%)
Nervous system disorders	
Benign intracranial hypertension [A] †	1/14 (7.14%)
Dizziness [A] †	1/14 (7.14%)
Dysgeusia [A] †	1/14 (7.14%)
Headache [A] †	6/14 (42.86%)
Lethargy [A] †	3/14 (21.43%)

	Thymoglobulin
	Affected/At Risk (%)
Paraesthesia [A] †	2/14 (14.29%)
Syncope [A] †	1/14 (7.14%)
Tremor [A] †	1/14 (7.14%)
Psychiatric disorders	
Insomnia [A] †	1/14 (7.14%)
Reproductive system and breast disorders	
Genital ulceration [A] †	1/14 (7.14%)
Menorrhagia [A] †	1/14 (7.14%)
Menstrual disorder [A] †	1/14 (7.14%)
Sexual dysfunction [A] †	1/14 (7.14%)
Vaginal haemorrhage [A] †	2/14 (14.29%)
Respiratory, thoracic and mediastinal disorders	
Cough [A] †	1/14 (7.14%)
Dyspnoea [A] †	1/14 (7.14%)
Dyspnoea exertional [A] †	1/14 (7.14%)
Epistaxis [A] †	4/14 (28.57%)
Hypoxia [A] †	1/14 (7.14%)
Oropharyngeal pain [A] †	3/14 (21.43%)
Skin and subcutaneous tissue disorders	
Alopecia [A] †	2/14 (14.29%)
Dermatitis allergic [A] †	1/14 (7.14%)
Dry skin [A] †	2/14 (14.29%)
Ecchymosis [A] †	1/14 (7.14%)

	Thymoglobulin
	Affected/At Risk (%)
Eczema [A] †	2/14 (14.29%)
Erythema [A] †	1/14 (7.14%)
Hyperhidrosis [A] †	1/14 (7.14%)
Pain of skin [A] †	1/14 (7.14%)
Petechiae [A] †	2/14 (14.29%)
Pruritus [A] †	2/14 (14.29%)
Pruritus generalised [A] †	1/14 (7.14%)
Purpura [A] †	1/14 (7.14%)
Rash [A] †	5/14 (35.71%)
Rash erythematous [A] †	2/14 (14.29%)
Rash macular [A] †	2/14 (14.29%)
Rash maculo-papular [A] †	1/14 (7.14%)
Rash pruritic [A] †	1/14 (7.14%)
Skin chapped [A] †	1/14 (7.14%)
Skin exfoliation [A] †	1/14 (7.14%)
Skin lesion [A] †	1/14 (7.14%)
Stasis dermatitis [A] †	1/14 (7.14%)
Swelling face [A] †	1/14 (7.14%)
Vascular disorders	
Cardiovascular insufficiency [A] †	1/14 (7.14%)
Flushing [A] †	2/14 (14.29%)
Hypertension [A] †	3/14 (21.43%)

	Thymoglobulin
	Affected/At Risk (%)
Hypotension [A] †	4/14 (28.57%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 12.0

Limitations and Caveats

The study was terminated early due to a slow enrollment rate; therefore, only safety data were collected from participants for 45 days following the last day of infusion (Day 5).

More Information

Certain Agreements:

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

The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is less than or equal to 60 days from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.

Results Point of Contact:

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