ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 02/10/2014

ClinicalTrials.gov ID: NCT00103662

Study Identification

Unique Protocol ID: AMD3100-3102

Brief Title: Mobilization of Stem Cells With AMD3100 (Plerixafor) in Multiple Myeloma Patients

Official Title: A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Comparative Trial of AMD3100 Plus G-CSF Versus G-CSF Plus Placebo to Mobilize and Collect ≥ 6*10^6 CD34+ Cells/kg in Multiple Myeloma Patients for Autologous Transplantation

Secondary IDs: 2005-003599-39 [EudraCT Number]

Study Status

Record Verification: February 2014

Overall Status: Completed

Study Start: January 2005

Primary Completion: October 2006 [Actual]

Study Completion: January 2008 [Actual]

Sponsor/Collaborators

Sponsor: Genzyme, a Sanofi Company

Responsible Party:

Collaborators:

Oversight

FDA Regulated?: Yes

IND/IDE Protocol?: Yes

IND/IDE Information:	Grantor: CDER IND/IDE Number: 55,851 Serial Number: 0188 Has Expanded Access? No
Review Board:	Approval Status: Board Name: St Francis Hospital and Health Board Affiliation: Phone: Email:
Data Monitoring?:	No
Oversight Authorities:	United States: Food and Drug Administration Canada: Health Canada Germany: Bundesinstitut Arzneimittel und medizinprodukte (BfArM)

Study Description

Brief Summary: The purpose of this study is to determine whether the combination of AMD3100 (plerixafor) and granulocyte colony-stimulating factor (G-CSF, generic name of filgrastim) is better than G-CSF alone to mobilize and collect the optimal number of stem cells in multiple myeloma patients for autologous transplantation.

Detailed Description: A peripheral stem cell transplant may be able to replace blood-forming cells that were destroyed by chemotherapy. Currently filgrastim (G-CSF), a colony stimulating factor, is used to cause the growth and mobilization of stem cells from bone marrow to peripheral blood, which can then be collected from the peripheral blood by a process called apheresis. Plerixafor aids in the release of the stem cells from the bone marrow into the peripheral blood, possibly allowing for a more rapid collection of a larger number of stem cells from the peripheral blood. Larger stem cell doses for transplantation correlate to faster recovery times after high dose chemotherapy followed with stem cell transplantation. This study is intended to determine whether the combination of plerixafor with filgrastim (G-CSF)is better than filgrastim (G-CSF) alone in helping multiple myeloma patients collect at least 6 million stem cells in two or less apheresis sessions.

This study was previously posted by AnorMED, Inc. In November 2006, AnorMED, Inc. was acquired by Genzyme Corporation. Genzyme Corporation is the sponsor of the trial.

Conditions

Conditions: Multiple Myeloma

Keywords:

Study Design

Study Type: Interventional

Primary Purpose:	Treatment
Study Phase:	Phase 3
Intervention Model:	Parallel Assignment
Number of Arms:	2
Masking:	Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Allocation:	Randomized
Endpoint Classification:	Efficacy Study
Enrollment:	302 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: G-CSF plus plerixafor	Drug: Granulocyte colony-stimulating factor plus plerixafor Participants underwent mobilization with granulocyte colony-stimulating factor (G-CSF) (10 µg/kg/day) for 4 days, administered by subcutaneous (SC) injection. On the evening of Day 4, participants received plerixafor (240 µg/kg), administered by SC injection. On Day 5, participants received a morning dose of G-CSF (10 µg/kg) and underwent apheresis approx. 10 to 11 hours after the dose of plerixafor (within 60 minutes of G-CSF administration). Participants continued to receive an evening dose of plerixafor followed by a morning dose of G-CSF and apheresis for up to 4 aphereses or until ≥ 6*10^6 CD34+ cells/kg were collected. Participants who participated in the rescue procedure underwent an additional daily treatment with plerixafor (240 µg/kg) and apheresis for up to 4 days. Other Names: • Mozobil • AMD3100
Placebo Comparator: G-CSF plus placebo	Drug: Granulocyte colony-stimulating factor plus placebo Participants underwent mobilization with granulocyte colony-stimulating factor (G-CSF) (10 µg/kg/day) for 4 days, administered by subcutaneous (SC) injection. On the evening of Day 4, participants received placebo, administered by SC injection. On Day 5, participants received a morning dose of G-CSF (10 µg/kg) and underwent apheresis approx. 10 to 11 hours after the dose of placebo (within 60 minutes of G-CSF administration). Participants continued to receive an evening dose of placebo followed by a morning dose of G-CSF and apheresis for up to 4 aphereses or until ≥ 6*10^6 CD34+ cells/kg were collected. Participants

Arms	Assigned Interventions
	who participated in the rescue procedure underwent an additional daily treatment with plerixafor (240 µg/kg) and apheresis for up to 4 days.

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age: 78 Years

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Diagnosis of multiple myeloma in first or second complete or partial remission
- >= 4 weeks since last cycle of chemotherapy (thalidomide, dexamethasone, and Velcade were not considered prior chemotherapy for the purpose of this study)
- Recovered from all acute toxic effects of prior chemotherapy
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- White Blood Cell count (WBC) > 2.5*10^9/L
- Absolute polymorphonuclear leukocytes (PMN) count > 1.5*10^9/L
- Platelet (PLT) > 100*10^9/L
- Serum creatinine <=2.2 mg/dL
- Cardiac and pulmonary status sufficient to undergo apheresis and transplantation
- Negative for HIV

Exclusion Criteria):

- Failed previous stem cell collection
- Previous stem cell transplantation
- Brain metastases or myelomatous meningitis
- Radiation to ≥ 50% of the pelvis
- Abnormal electrocardiogram (ECG) with rhythm disturbance (ventricular arrhythmias) or other conduction abnormality
- Received bone-seeking radionuclides (e.g. holmium)
- A residual acute medical condition resulting from prior chemotherapy

Contacts/Locations

Study Officials: Medical Monitor

Genzyme

Locations: United States, Indiana
Indiana Blood and Marrow Transplantation Center
Beech Grove, Indiana, United States, 46107

United States, Missouri
Washington University School of Medicine, Division of Bone Marrow Transplantation and Leukemia
Saint Louis, Missouri, United States, 63110

United States, Iowa
University of Iowa Hosptials and Clinics
Iowa City, Iowa, United States, 52242

United States, Texas
University of Texas Health Science Center
San Antonio, Texas, United States, 78229

United States, Illinois
Loyola University Medical Center
Maywood, Illinois, United States, 60153

United States, Arizona
City of Hope Samaritan Bone Marrow Transplant Program
Phoenix, Arizona, United States, 85006

United States, Washington
Fred Hutchinson Cancer Research Center
Seattle, Washington, United States, 98109

United States, Colorado
Rocky Mountain Cancer Center
Denver, Colorado, United States, 80218

United States, Pennsylvania
Hospital of the University of Pennsylvania
Philadelphia, Pennsylvania, United States, 19104

United States, New Jersey
The Cancer Center at Hackensack University Medical Center
Hackensack, New Jersey, United States, 07601

United States, Minnesota
Fairview-University Medical Center, University of Minnesota
Minneapolis, Minnesota, United States, 55455

United States, Connecticut
Yale University School of Medicine
New Haven, Connecticut, United States, 06520

United States, Ohio
Cleveland Clinic Foundation
Cleveland, Ohio, United States, 44195

United States, Florida
H. Lee Moffitt Cancer Center and Research Institute
Tampa, Florida, United States, 33612

United States, Missouri
Kansas City Cancer Center
Kansas City, Missouri, United States, 64111

United States, Minnesota
Mayo Clinic
Rochester, Minnesota, United States, 55905

United States, New York
University of Rochester Medical Center
Rochester, New York, United States, 14642

United States, Virginia
Virginia Commonwealth University
Richmond, Virginia, United States, 23298

United States, Arkansas
Myeloma Institute for Research and Therapy, University of Arkansas for Medical Sciences
Little Rock, Arkansas, United States, 72205

United States, North Carolina
Duke University Medical Center
Durham, North Carolina, United States, 27705

United States, Oregon
Oregon Health & Science University
Portland, Oregon, United States, 97239

United States, New York
Roswell Park Cancer Institute
Buffalo, New York, United States, 14263

United States, Texas
Texas Transplant Institute

San Antonio, Texas, United States, 78229

United States, Utah
Utah Blood and Marrow Transplant Program, University of Utah
San Antonio, Texas, United States, 84132

United States, Texas
The University of Texas MD Anderson Cancer Center
Houston, Texas, United States, 77030

Wilford Hall Medical Center
Lackland AFB, Texas, United States, 78236

United States, Ohio
Case Western Reserve University
Cleveland, Ohio, United States, 44106

United States, California
City of Hope National Medical Center
Duarte, California, United States, 91010

United States, New York
St. Vincent's Comprehensive Cancer Center
New York, New York, United States, 10011

United States, Ohio
Ohio State University
Columbus, Ohio, United States, 43210

United States, Pennsylvania
Thomas Jefferson University
Philadelphia, Pennsylvania, United States, 19107

United States, New York
Memorial Sloan Kettering
New York, New York, United States, 10065

United States, Georgia
Emory University
Atlanta, Georgia, United States, 30322

United States, California
Cedars-Sinai
Los Angeles, California, United States, 90048

United States, Florida

University of Florida
Gainesville, Florida, United States, 32611

United States, New York
New York Hospital
New York, New York, United States, 10032

United States, California
University of California
Los Angeles, California, United States, 90095

Canada, British Columbia
Vancouver General Hospital
Vancouver, British Columbia, Canada, V5Z 1M9

Germany
Universitätsklinikum Heidelberg,
Heidelberg, Germany, 69120

References

Citations: [Study Results] DiPersio JF, Stadtmauer EA, Nademanee A, Micallef IN, Stiff PJ, Kaufman JL, Maziarz RT, Hosing C, Früehauf S, Horwitz M, Cooper D, Bridger G, Calandra G; 3102 Investigators. Plerixafor and G-CSF versus placebo and G-CSF to mobilize hematopoietic stem cells for autologous stem cell transplantation in patients with multiple myeloma. Blood. 2009 Jun 4;113(23):5720-6. Epub 2009 Apr 10. PMID: 19363221

Links: URL: http://www.nci.nih.gov/cancertopics/types/myeloma
Description Further information on multiple myeloma from the National Cancer Institute

---

Study Results

Participant Flow

Recruitment Details	Participants with multiple myeloma (MM) eligible for autologous hematopoietic stem cell transplant were recruited from 40 centers (38 in the U.S., 1 in Germany, 1 in Canada). The first participant was randomized on 04 February 2005 and the last participant's last study visit occurred on 22 January 2008. A total of 302 participants were randomized.

Reporting Groups

	Description
G-CSF Plus Plerixafor	Participants underwent mobilization with G-CSF for 4 days. On the evening of Day 4, participants received a dose of plerixafor. On each subsequent day, participants received a morning dose of G-CSF followed by apheresis and an evening dose of plerixafor for a maximum of 4 aphereses or until ≥ 6*10^6 CD34+ cells/kg were collected.
G-CSF Plus Placebo	Participants underwent mobilization with G-CSF for 4 days. On the evening of Day 4, participants received a dose of placebo. On each subsequent day, participants received a morning dose of G-CSF followed by apheresis and an evening dose of placebo for a maximum of 4 aphereses or until ≥ 6*10^6 CD34+ cells/kg were collected.

Overall Study

	G-CSF Plus Plerixafor	G-CSF Plus Placebo
Started	148	154
Completed	129 [1]	121 [1]
Not Completed	19	33
Entered Rescue Procedure	0	7
Death	7	7
Elective Withdrawal	5	5
Lost to Follow-up	0	1
Other	6	9
Failed mobilization	0	4
Intercurrent illness	1	0

[1] 1 participant was wrongly terminated due to 'other'; the participant stayed on study until death.

Baseline Characteristics

Reporting Groups

	Description
G-CSF Plus Plerixafor	Participants underwent mobilization with G-CSF for 4 days. On the evening of Day 4, participants received a dose of plerixafor. On each subsequent day, participants received a morning dose of G-CSF followed by apheresis and an evening dose of plerixafor for a maximum of 4 aphereses or until ≥ 6*10^6 CD34+ cells/kg were collected.

	Description
G-CSF Plus Placebo	Participants underwent mobilization with G-CSF for 4 days. On the evening of Day 4, participants received a dose of placebo. On each subsequent day, participants received a morning dose of G-CSF followed by apheresis and an evening dose of placebo for a maximum of 4 aphereses or until ≥ 6*10^6 CD34+ cells/kg were collected.

Baseline Measures

	G-CSF Plus Plerixafor	G-CSF Plus Placebo	Total
Number of Participants	148	154	302
Age, Continuous [units: years] Mean (Standard Deviation)	58.2 (8.4)	58.4 (8.6)	58.3 (8.5)
Gender, Male/Female [units: participants]			
Female	48	47	95
Male	100	107	207
Race/Ethnicity, Customized [units: participants]			
Caucasian	117	128	245
African-American	18	14	32
Asian	1	3	4
Hispanic/Latino	11	4	15
Other	1	5	6

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Proportion of Participants Achieving a Target of ≥ 6*10^6 CD34+ Cells/kg in 2 or Fewer Days of Apheresis.
Measure Description	Proportion of participants achieving a target of ≥ 6*10^6 CD34+ cells/kg in 2 or fewer days of apheresis. Central lab data were taken from Days 5 to 6 of the Treatment/Apheresis period. Each participant's value was calculated as the sum of all daily values collected over the 2 apheresis days.
Time Frame	up to Day 6
Safety Issue?	No

Analysis Population Description
Intent-to-Treat Population

Reporting Groups

	Description
G-CSF Plus Plerixafor	Participants underwent mobilization with G-CSF for 4 days. On the evening of Day 4, participants received a dose of plerixafor. On each subsequent day, participants received a morning dose of G-CSF followed by apheresis and an evening dose of plerixafor for a maximum of 4 aphereses or until ≥ 6*10^6 CD34+ cells/kg were collected.
G-CSF Plus Placebo	Participants underwent mobilization with G-CSF for 4 days. On the evening of Day 4, participants received a dose of placebo. On each subsequent day, participants received a morning dose of G-CSF followed by apheresis and an evening dose of placebo for a maximum of 4 aphereses or until ≥ 6*10^6 CD34+ cells/kg were collected.

Measured Values

	G-CSF Plus Plerixafor	G-CSF Plus Placebo
Number of Participants Analyzed	148	154
Proportion of Participants Achieving a Target of ≥ 6*10^6 CD34+ Cells/kg in 2 or Fewer Days of Apheresis. [units: proportion of participants]		
Proportion achieving target in ≤2 days	0.716	0.344
Proportion not achieving target in ≤2 days	0.284	0.656

2. Secondary Outcome Measure:

Measure Title	Number of Participants With Adverse Events
Measure Description	Number of participants with treatment emergent adverse events (AEs). The timeframe for treatment emergent AEs is defined as Day 1 (start of G-CSF Mobilization) to the day before starting chemotherapy (approximately 38 days later). AEs were reported regardless of relationship to study treatment. The investigator graded each AE using the World Health Organization (WHO) Adverse Event Grading Scale. AEs of Grade 3 were considered severe and Grade 4 were considered life-threatening.
Time Frame	up to Day 38
Safety Issue?	Yes

Analysis Population Description

Primary Safety population of all participants who received at least 1 mobilization dose of G-CSF or study treatment (plerixafor or placebo). Four participants did not receive G-CSF or any study treatment and were excluded from the safety analyses.

Reporting Groups

	Description
G-CSF Plus Plerixafor	Participants underwent mobilization with G-CSF for 4 days. On the evening of Day 4, participants received a dose of plerixafor. On each subsequent day, participants received a morning dose of G-CSF followed by apheresis and an evening dose of plerixafor for a maximum of 4 aphereses or until ≥ 6*10^6 CD34+ cells/kg were collected.
G-CSF Plus Placebo	Participants underwent mobilization with G-CSF for 4 days. On the evening of Day 4, participants received a dose of placebo. On each subsequent day, participants received a morning dose of G-CSF followed by apheresis and an evening dose of placebo for a maximum of 4 aphereses or until ≥ 6*10^6 CD34+ cells/kg were collected.

Measured Values

	G-CSF Plus Plerixafor	G-CSF Plus Placebo
Number of Participants Analyzed	147	151
Number of Participants With Adverse Events [units: participants]		
Adverse Events (AEs)	140	140
Related AEs	95	67
AEs Leading to early treatment termination	1	2
AEs Leading to early termination	3	0
Grade 3 (severe) or 4 (life-threatening) AEs	11	11
Serious Adverse Events (SAEs)	4	6

3. Secondary Outcome Measure:

Measure Title	Proportion of Participants Achieving a Target of ≥ 6*10^6 CD34+ Cells/kg in 4 or Fewer Days of Apheresis.
Measure Description	Proportion of participants achieving a target of ≥ 6*10^6 CD34+ cells/kg in 4 or fewer days of apheresis. Central lab data were taken from Days 5 to 8 of the Treatment/Apheresis period. Each participant's value was calculated as the sum of all daily values collected over the 4 apheresis days.
Time Frame	up to Day 8

Safety Issue?	No

Analysis Population Description
Intent-to-Treat Population

Reporting Groups

	Description
G-CSF Plus Plerixafor	Participants underwent mobilization with G-CSF for 4 days. On the evening of Day 4, participants received a dose of plerixafor. On each subsequent day, participants received a morning dose of G-CSF followed by apheresis and an evening dose of plerixafor for a maximum of 4 aphereses or until ≥ 6*10^6 CD34+ cells/kg were collected.
G-CSF Plus Placebo	Participants underwent mobilization with G-CSF for 4 days. On the evening of Day 4, participants received a dose of placebo. On each subsequent day, participants received a morning dose of G-CSF followed by apheresis and an evening dose of placebo for a maximum of 4 aphereses or until ≥ 6*10^6 CD34+ cells/kg were collected.

Measured Values

	G-CSF Plus Plerixafor	G-CSF Plus Placebo
Number of Participants Analyzed	148	154
Proportion of Participants Achieving a Target of ≥ 6*10^6 CD34+ Cells/kg in 4 or Fewer Days of Apheresis. [units: proportion of participants]		
Proportion achieving target in ≤4 days	0.757	0.513
Proportion not achieving target in ≤4 days	0.243	0.487

4. Secondary Outcome Measure:

Measure Title	Proportion of Participants Achieving a Target of ≥ 2*10^6 CD34+ Cells/kg in 4 or Fewer Days of Apheresis.
Measure Description	Proportion of participants achieving a target of ≥ 2*10^6 CD34+ cells/kg in 4 or fewer days of apheresis. Central lab data were taken from Days 5 to 8 of the Treatment/Apheresis period. Each participant's value was calculated as the sum of all daily values collected over the 4 apheresis days.
Time Frame	up to Day 8
Safety Issue?	No

Analysis Population Description
Intent-to-Treat Population

Reporting Groups

	Description
G-CSF Plus Plerixafor	Participants underwent mobilization with G-CSF for 4 days. On the evening of Day 4, participants received a dose of plerixafor. On each subsequent day, participants received a morning dose of G-CSF followed by apheresis and an evening dose of plerixafor for a maximum of 4 aphereses or until ≥ 6*10^6 CD34+ cells/kg were collected.
G-CSF Plus Placebo	Participants underwent mobilization with G-CSF for 4 days. On the evening of Day 4, participants received a dose of placebo. On each subsequent day, participants received a morning dose of G-CSF followed by apheresis and an evening dose of placebo for a maximum of 4 aphereses or until ≥ 6*10^6 CD34+ cells/kg were collected.

Measured Values

	G-CSF Plus Plerixafor	G-CSF Plus Placebo
Number of Participants Analyzed	148	154
Proportion of Participants Achieving a Target of ≥ 2*10^6 CD34+ Cells/kg in 4 or Fewer Days of Apheresis. [units: proportion of participants]		
Proportion achieving target in ≤4 days	0.953	0.883
Proportion not achieving target in ≤4 days	0.047	0.117

5. Secondary Outcome Measure:

Measure Title	Median Number of Days to ≥6*10^6 CD34+ Cells/kg
Measure Description	The Kaplan Meier estimate of median number of days (number of days at which 50% of participants have experienced the event, accounting for censored values) in each treatment arm to collect an optimum number of cells (≥6*10^6 CD34+ cells/kg) for transplantation.
Time Frame	up to Day 8
Safety Issue?	No

Analysis Population Description
Intent-to-treat population

Reporting Groups

	Description
G-CSF Plus Plerixafor	Participants underwent mobilization with G-CSF for 4 days. On the evening of Day 4, participants received a dose of plerixafor. On each subsequent day, participants received a morning dose of G-CSF followed by apheresis and an evening dose of plerixafor for a maximum of 4 aphereses or until ≥ 6*10^6 CD34+ cells/kg were collected.
G-CSF Plus Placebo	Participants underwent mobilization with G-CSF for 4 days. On the evening of Day 4, participants received a dose of placebo. On each subsequent day, participants received a morning dose of G-CSF followed by apheresis and an evening dose of placebo for a maximum of 4 aphereses or until ≥ 6*10^6 CD34+ cells/kg were collected.

Measured Values

	G-CSF Plus Plerixafor	G-CSF Plus Placebo
Number of Participants Analyzed	144	150
Median Number of Days to ≥6*10^6 CD34+ Cells/kg [units: Days] Median (Inter-Quartile Range)	1.0 (1.0 to 2.0)	4.0 (2.0 to NA) [1]

[1] Not enough participants reached the threshold to support estimating the upper range.

6. Secondary Outcome Measure:

Measure Title	Median Number of Days to Polymorphonuclear (PMN) Cell Engraftment
Measure Description	The Kaplan Meier estimate of median number of days to PMN engraftment (number of days at which 50% of participants have experienced the event, accounting for censored values) was a secondary efficacy endpoint. Engraftment was defined as PMN counts ≥ 0.5*10^9/L for 3 consecutive days or ≥ 1.0*10^9/L for 1 day. Time to engraftment corresponded to the first day that the criteria were met and was evaluated up to 12 months post transplant.
Time Frame	Up to Month 13
Safety Issue?	No

Analysis Population Description

Participants who received a stem cell transplant.

Reporting Groups

	Description
G-CSF Plus Plerixafor	Participants underwent mobilization with G-CSF for 4 days. On the evening of Day 4, participants received a dose of plerixafor. On each subsequent day, participants received a morning dose of G-CSF followed by apheresis and an evening dose of plerixafor for a maximum of 4 aphereses or until ≥ 6*10^6 CD34+ cells/kg were collected.
G-CSF Plus Placebo	Participants underwent mobilization with G-CSF for 4 days. On the evening of Day 4, participants received a dose of placebo. On each subsequent day, participants received a morning dose of G-CSF followed by apheresis and an evening dose of placebo for a maximum of 4 aphereses or until ≥ 6*10^6 CD34+ cells/kg were collected.

Measured Values

	G-CSF Plus Plerixafor	G-CSF Plus Placebo
Number of Participants Analyzed	142	136
Median Number of Days to Polymorphonuclear (PMN) Cell Engraftment [units: Days] Median (Inter-Quartile Range)	11.0 (10.0 to 12.0)	11.0 (11.0 to 12.0)

7. Secondary Outcome Measure:

Measure Title	Median Number of Days to Platelet (PLT) Engraftment
Measure Description	The Kaplan Meier estimate of median number of days to PLT engraftment (number of days at which 50% of participants have experienced the event, accounting for censored values) was a secondary efficacy endpoint. Engraftment was defined as ≥ 20*10^9/L without transfusion for the preceding 7 days. Time to engraftment corresponded to the first day that the criteria were met and was evaluated up to 12 months post transplant.
Time Frame	Up to Month 13
Safety Issue?	No

Analysis Population Description

Participants who received a stem cell transplant

Reporting Groups

	Description
G-CSF Plus Plerixafor	Participants underwent mobilization with G-CSF for 4 days. On the evening of Day 4, participants received a dose of plerixafor. On each subsequent day, participants received a morning dose of G-CSF followed by apheresis and an evening dose of plerixafor for a maximum of 4 aphereses or until ≥ 6*10^6 CD34+ cells/kg were collected.
G-CSF Plus Placebo	Participants underwent mobilization with G-CSF for 4 days. On the evening of Day 4, participants received a dose of placebo. On each subsequent day, participants received a morning dose of G-CSF followed by apheresis and an evening dose of placebo for a maximum of 4 aphereses or until ≥ 6*10^6 CD34+ cells/kg were collected.

Measured Values

	G-CSF Plus Plerixafor	G-CSF Plus Placebo
Number of Participants Analyzed	142	136
Median Number of Days to Platelet (PLT) Engraftment [units: Days] Median (Inter-Quartile Range)	18.0 (16.0 to 22.0)	18.0 (16.0 to 21.0)

8. Secondary Outcome Measure:

Measure Title	Graft Durability at 100 Days Post Transplantation
Measure Description	The proportion of participants maintaining a durable graft at 100 days post-transplantation by at least 2 of the following criteria (without erythropoietin (EPO), G-CSF, or transfusions): (1) a platelet count >50000/μL without transfusion for at least 2 weeks, (2) hemoglobin >=10g/dL for at least 1 month, (3) and absolute neutrophil count >1000/μL for at least 1 week.
Time Frame	approximately Day 138
Safety Issue?	No

Analysis Population Description

Participants who received a stem cell transplant and were evaluable at 100 days post-transplant

Reporting Groups

	Description
G-CSF Plus Plerixafor	Participants underwent mobilization with G-CSF for 4 days. On the evening of Day 4, participants received a dose of plerixafor. On each subsequent day, participants received a morning dose of G-CSF followed by apheresis and an evening dose of plerixafor for a maximum of 4 aphereses or until ≥ 6*10^6 CD34+ cells/kg were collected.

	Description
G-CSF Plus Placebo	Participants underwent mobilization with G-CSF for 4 days. On the evening of Day 4, participants received a dose of placebo. On each subsequent day, participants received a morning dose of G-CSF followed by apheresis and an evening dose of placebo for a maximum of 4 aphereses or until ≥ 6*10^6 CD34+ cells/kg were collected.

Measured Values

	G-CSF Plus Plerixafor	G-CSF Plus Placebo
Number of Participants Analyzed	142	136
Graft Durability at 100 Days Post Transplantation [units: proportion of participants]		
Proportion of participants with a durable graft	0.986	0.978
Proportion of participants without a durable graft	0.014	0.022

9. Secondary Outcome Measure:

Measure Title	Graft Durability at 6 Months Post Transplantation
Measure Description	The proportion of participants maintaining a durable graft at 6 months post-transplantation by at least 2 of the following criteria (without erythropoietin (EPO), G-CSF, or transfusions): (1) a platelet count >50000/μL without transfusion for at least 2 weeks, (2) hemoglobin >=10g/dL for at least 1 month, (3) and absolute neutrophil count >1000/μL for at least 1 week.
Time Frame	approximately Month 7
Safety Issue?	No

Analysis Population Description

Participants who received a stem cell transplant and were evaluable at 6 months post-transplant

Reporting Groups

	Description
G-CSF Plus Plerixafor	Participants underwent mobilization with G-CSF for 4 days. On the evening of Day 4, participants received a dose of plerixafor. On each subsequent day, participants received a morning dose of G-CSF followed by apheresis and an evening dose of plerixafor for a maximum of 4 aphereses or until ≥ 6*10^6 CD34+ cells/kg were collected.

	Description
G-CSF Plus Placebo	Participants underwent mobilization with G-CSF for 4 days. On the evening of Day 4, participants received a dose of placebo. On each subsequent day, participants received a morning dose of G-CSF followed by apheresis and an evening dose of placebo for a maximum of 4 aphereses or until ≥ 6*10^6 CD34+ cells/kg were collected.

Measured Values

	G-CSF Plus Plerixafor	G-CSF Plus Placebo
Number of Participants Analyzed	135	127
Graft Durability at 6 Months Post Transplantation [units: proportion of participants]		
Proportion of participants with a durable graft	0.985	0.984
Proportion of participants without a durable graft	0.015	0.016

10. Secondary Outcome Measure:

Measure Title	Graft Durability at 12 Months Post Transplantation
Measure Description	The proportion of participants maintaining a durable graft at 12 months post-transplantation by at least 2 of the following criteria (without erythropoietin (EPO), G-CSF, or transfusions): (1) a platelet count >50000/μL without transfusion for at least 2 weeks, (2) hemoglobin >=10g/dL for at least 1 month, (3) and absolute neutrophil count >1000/μL for at least 1 week.
Time Frame	approximately Month 13
Safety Issue?	No

Analysis Population Description

Participants who received a stem cell transplant and were evaluable at 12 months post-transplant

Reporting Groups

	Description
G-CSF Plus Plerixafor	Participants underwent mobilization with G-CSF for 4 days. On the evening of Day 4, participants received a dose of plerixafor. On each subsequent day, participants received a morning dose of G-CSF followed by apheresis and an evening dose of plerixafor for a maximum of 4 aphereses or until ≥ 6*10^6 CD34+ cells/kg were collected.

	Description
G-CSF Plus Placebo	Participants underwent mobilization with G-CSF for 4 days. On the evening of Day 4, participants received a dose of placebo. On each subsequent day, participants received a morning dose of G-CSF followed by apheresis and an evening dose of placebo for a maximum of 4 aphereses or until ≥ 6*10^6 CD34+ cells/kg were collected.

Measured Values

	G-CSF Plus Plerixafor	G-CSF Plus Placebo
Number of Participants Analyzed	128	120
Graft Durability at 12 Months Post Transplantation [units: proportion of participants]		
Proportion of participants with a durable graft	0.992	0.992
Proportion of participants without a durable graft	0.008	0.008

Reported Adverse Events

Time Frame	Day 1 (start of G-CSF Mobilization plus Treatment/Apheresis) to the day before starting chemotherapy. Chemotherapy typically started within 30 days of the last apheresis (which may have occurred on Day 5, 6, 7, or 8).
Additional Description	Four participants did not receive any study treatment and were excluded from the safety analyses. In the event a participant experienced both a serious and a non-serious form of the same AE, they were included in the numerator of both AE tables. Each AE table includes all events, regardless of reported relationship to study treatment or grade.

Reporting Groups

	Description
G-CSF Plus Plerixafor	Participants underwent mobilization with G-CSF for 4 days. On the evening of Day 4, participants received a dose of plerixafor. On each subsequent day, participants received a morning dose of G-CSF followed by apheresis and an evening dose of plerixafor for a maximum of 4 aphereses or until ≥ 6*10^6 CD34+ cells/kg were collected.

	Description
G-CSF Plus Placebo	Participants underwent mobilization with G-CSF for 4 days. On the evening of Day 4, participants received a dose of placebo. On each subsequent day, participants received a morning dose of G-CSF followed by apheresis and an evening dose of placebo for a maximum of 4 aphereses or until ≥ 6*10^6 CD34+ cells/kg were collected.

Serious Adverse Events

	G-CSF Plus Plerixafor	G-CSF Plus Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Total	4/147 (2.72%)	6/151 (3.97%)
Cardiac disorders		
Atrial fibrillation [A] †	1/147 (0.68%)	0/151 (0%)
Gastrointestinal disorders		
Nausea [A] †	0/147 (0%)	2/151 (1.32%)
Vomiting [A] †	0/147 (0%)	1/151 (0.66%)
Infections and infestations		
Enterobacter bacteraemia [A] †	0/147 (0%)	1/151 (0.66%)
Metabolism and nutrition disorders		
Dehydration [A] †	0/147 (0%)	1/151 (0.66%)
Musculoskeletal and connective tissue disorders		
Bone pain [A] †	1/147 (0.68%)	1/151 (0.66%)
Nervous system disorders		
Hemiparesis [A] †	1/147 (0.68%)	0/151 (0%)
Muscle spasticity [A] †	0/147 (0%)	1/151 (0.66%)
Psychiatric disorders		
Agitation [A] †	0/147 (0%)	1/151 (0.66%)
Respiratory, thoracic and mediastinal disorders		
Pneumothorax [A] †	0/147 (0%)	1/151 (0.66%)

	G-CSF Plus Plerixafor	G-CSF Plus Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Vascular disorders		
Deep vein thrombosis [A] †	1/147 (0.68%)	0/151 (0%)
Jugular vein thrombosis [A] †	0/147 (0%)	1/151 (0.66%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 10.0

Other Adverse Events

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

	G-CSF Plus Plerixafor	G-CSF Plus Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Total	140/147 (95.24%)	140/151 (92.72%)
Blood and lymphatic system disorders		
Anaemia [A] †	2/147 (1.36%)	4/151 (2.65%)
Lymphadenopathy [A] †	1/147 (0.68%)	0/151 (0%)
Lymphopenia [A] †	1/147 (0.68%)	1/151 (0.66%)
Splenomegaly [A] †	0/147 (0%)	1/151 (0.66%)
Thrombocytopenia [A] †	2/147 (1.36%)	4/151 (2.65%)
Cardiac disorders		
Angina pectoris [A] †	0/147 (0%)	1/151 (0.66%)
Arrhythmia [A] †	0/147 (0%)	1/151 (0.66%)
Atrioventricular block first degree [A] †	1/147 (0.68%)	0/151 (0%)
Extrasystoles [A] †	0/147 (0%)	1/151 (0.66%)
Myocardial ischaemia [A] †	0/147 (0%)	1/151 (0.66%)
Palpitations [A] †	2/147 (1.36%)	4/151 (2.65%)
Sinus tachycardia [A] †	1/147 (0.68%)	1/151 (0.66%)

	G-CSF Plus Plerixafor	G-CSF Plus Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Supraventricular tachycardia [A] †	0/147 (0%)	1/151 (0.66%)
Tachycardia [A] †	2/147 (1.36%)	4/151 (2.65%)
Ventricular extrasystoles [A] †	1/147 (0.68%)	0/151 (0%)
Congenital, familial and genetic disorders		
Atrial septal defect [A] †	1/147 (0.68%)	0/151 (0%)
Ear and labyrinth disorders		
Deafness [A] †	1/147 (0.68%)	0/151 (0%)
Ear pain [A] †	0/147 (0%)	2/151 (1.32%)
Tinnitus [A] †	1/147 (0.68%)	0/151 (0%)
Eye disorders		
Eye irritation [A] †	0/147 (0%)	1/151 (0.66%)
Eye pruritus [A] †	0/147 (0%)	1/151 (0.66%)
Ocular hyperaemia [A] †	1/147 (0.68%)	0/151 (0%)
Vision blurred [A] †	3/147 (2.04%)	0/151 (0%)
Gastrointestinal disorders		
Abdominal distension [A] †	3/147 (2.04%)	5/151 (3.31%)
Abdominal mass [A] †	0/147 (0%)	1/151 (0.66%)
Abdominal pain [A] †	3/147 (2.04%)	3/151 (1.99%)
Abdominal pain upper [A] †	0/147 (0%)	4/151 (2.65%)
Constipation [A] †	9/147 (6.12%)	5/151 (3.31%)
Dental discomfort [A] †	1/147 (0.68%)	0/151 (0%)
Diarrhoea [A] †	47/147 (31.97%)	29/151 (19.21%)
Dry mouth [A] †	6/147 (4.08%)	6/151 (3.97%)

	G-CSF Plus Plerixafor	G-CSF Plus Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Duodenogastric reflux [A] †	0/147 (0%)	1/151 (0.66%)
Dyspepsia [A] †	2/147 (1.36%)	1/151 (0.66%)
Dysphagia [A] †	2/147 (1.36%)	1/151 (0.66%)
Eructation [A] †	1/147 (0.68%)	0/151 (0%)
Faeces discoloured [A] †	1/147 (0.68%)	0/151 (0%)
Flatulence [A] †	9/147 (6.12%)	4/151 (2.65%)
Frequent bowel movements [A] †	6/147 (4.08%)	5/151 (3.31%)
Gastritis [A] †	0/147 (0%)	1/151 (0.66%)
Gastrooesophageal reflux disease [A] †	0/147 (0%)	1/151 (0.66%)
Haemorrhoids [A] †	0/147 (0%)	1/151 (0.66%)
Hypoaesthesia oral [A] †	3/147 (2.04%)	1/151 (0.66%)
Localised intraabdominal fluid collection [A] †	1/147 (0.68%)	1/151 (0.66%)
Mouth ulceration [A] †	0/147 (0%)	1/151 (0.66%)
Nausea [A] †	51/147 (34.69%)	39/151 (25.83%)
Oral soft tissue disorder [A] †	0/147 (0%)	1/151 (0.66%)
Paraesthesia oral [A] †	11/147 (7.48%)	13/151 (8.61%)
Retching [A] †	1/147 (0.68%)	0/151 (0%)
Stomach discomfort [A] †	2/147 (1.36%)	1/151 (0.66%)
Stomatitis [A] †	3/147 (2.04%)	0/151 (0%)
Tongue haematoma [A] †	1/147 (0.68%)	0/151 (0%)
Toothache [A] †	1/147 (0.68%)	0/151 (0%)
Vomiting [A] †	17/147 (11.56%)	9/151 (5.96%)

	G-CSF Plus Plerixafor	G-CSF Plus Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
General disorders		
Asthenia [A] †	5/147 (3.4%)	3/151 (1.99%)
Catheter related complication [A] †	1/147 (0.68%)	5/151 (3.31%)
Catheter site discharge [A] †	1/147 (0.68%)	1/151 (0.66%)
Catheter site erythema [A] †	1/147 (0.68%)	4/151 (2.65%)
Catheter site haematoma [A] †	2/147 (1.36%)	0/151 (0%)
Catheter site haemorrhage [A] †	6/147 (4.08%)	6/151 (3.97%)
Catheter site inflammation [A] †	1/147 (0.68%)	0/151 (0%)
Catheter site oedema [A] †	0/147 (0%)	1/151 (0.66%)
Catheter site pain [A] †	14/147 (9.52%)	19/151 (12.58%)
Catheter site pruritus [A] †	1/147 (0.68%)	1/151 (0.66%)
Catheter site related reaction [A] †	7/147 (4.76%)	4/151 (2.65%)
Chest discomfort [A] †	3/147 (2.04%)	2/151 (1.32%)
Chest pain [A] †	2/147 (1.36%)	2/151 (1.32%)
Chills [A] †	4/147 (2.72%)	4/151 (2.65%)
Discomfort [A] †	0/147 (0%)	1/151 (0.66%)
Fatigue [A] †	40/147 (27.21%)	41/151 (27.15%)
Feeling abnormal [A] †	0/147 (0%)	1/151 (0.66%)
Feeling cold [A] †	2/147 (1.36%)	2/151 (1.32%)
Feeling hot [A] †	0/147 (0%)	1/151 (0.66%)
Gait disturbance [A] †	0/147 (0%)	1/151 (0.66%)
Influenza like illness [A] †	3/147 (2.04%)	1/151 (0.66%)

	G-CSF Plus Plerixafor	G-CSF Plus Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Infusion site mass [A] †	1/147 (0.68%)	0/151 (0%)
Infusion site thrombosis [A] †	0/147 (0%)	1/151 (0.66%)
Injection site bruising [A] †	3/147 (2.04%)	2/151 (1.32%)
Injection site discharge [A] †	1/147 (0.68%)	0/151 (0%)
Injection site erythema [A] †	32/147 (21.77%)	5/151 (3.31%)
Injection site haemorrhage [A] †	4/147 (2.72%)	1/151 (0.66%)
Injection site induration [A] †	1/147 (0.68%)	0/151 (0%)
Injection site irritation [A] †	3/147 (2.04%)	3/151 (1.99%)
Injection site pain [A] †	3/147 (2.04%)	1/151 (0.66%)
Injection site paraesthesia [A] †	1/147 (0.68%)	0/151 (0%)
Injection site pruritus [A] †	5/147 (3.4%)	1/151 (0.66%)
Injection site rash [A] †	2/147 (1.36%)	0/151 (0%)
Injection site reaction [A] †	1/147 (0.68%)	0/151 (0%)
Injection site swelling [A] †	1/147 (0.68%)	1/151 (0.66%)
Irritability [A] †	1/147 (0.68%)	0/151 (0%)
Malaise [A] †	5/147 (3.4%)	1/151 (0.66%)
Mucosal inflammation [A] †	0/147 (0%)	1/151 (0.66%)
Non-cardiac chest pain [A] †	1/147 (0.68%)	0/151 (0%)
Oedema peripheral [A] †	12/147 (8.16%)	10/151 (6.62%)
Pain [A] †	11/147 (7.48%)	11/151 (7.28%)
Peripheral coldness [A] †	0/147 (0%)	1/151 (0.66%)
Pitting oedema [A] †	0/147 (0%)	1/151 (0.66%)

	G-CSF Plus Plerixafor	G-CSF Plus Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Pyrexia [A] †	8/147 (5.44%)	11/151 (7.28%)
Sensation of pressure [A] †	0/147 (0%)	1/151 (0.66%)
Vessel puncture site haematoma [A] †	0/147 (0%)	1/151 (0.66%)
Infections and infestations		
Bacteraemia [A] †	0/147 (0%)	1/151 (0.66%)
Bronchopneumonia [A] †	1/147 (0.68%)	0/151 (0%)
Bronchopulmonary aspergillosis [A] †	1/147 (0.68%)	0/151 (0%)
Catheter site infection [A] †	0/147 (0%)	1/151 (0.66%)
Herpes zoster [A] †	1/147 (0.68%)	0/151 (0%)
Nasopharyngitis [A] †	2/147 (1.36%)	0/151 (0%)
Oral candidiasis [A] †	1/147 (0.68%)	0/151 (0%)
Pneumonia fungal [A] †	1/147 (0.68%)	0/151 (0%)
Respiratory tract infection [A] †	0/147 (0%)	1/151 (0.66%)
Rhinitis [A] †	1/147 (0.68%)	0/151 (0%)
Sinusitis [A] †	1/147 (0.68%)	0/151 (0%)
Tinea manuum [A] †	0/147 (0%)	1/151 (0.66%)
Tinea pedis [A] †	1/147 (0.68%)	0/151 (0%)
Tooth abscess [A] †	0/147 (0%)	1/151 (0.66%)
Upper respiratory tract infection [A] †	3/147 (2.04%)	4/151 (2.65%)
Urinary tract infection [A] †	0/147 (0%)	2/151 (1.32%)
Injury, poisoning and procedural complications		
Arthropod bite [A] †	1/147 (0.68%)	0/151 (0%)

	G-CSF Plus Plerixafor	G-CSF Plus Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Citrate toxicity [A] †	6/147 (4.08%)	4/151 (2.65%)
Contusion [A] †	4/147 (2.72%)	5/151 (3.31%)
Post procedural discomfort [A] †	0/147 (0%)	1/151 (0.66%)
Procedural hypertension [A] †	1/147 (0.68%)	0/151 (0%)
Procedural nausea [A] †	1/147 (0.68%)	0/151 (0%)
Procedural pain [A] †	1/147 (0.68%)	1/151 (0.66%)
Skin laceration [A] †	0/147 (0%)	1/151 (0.66%)
Tooth fracture [A] †	0/147 (0%)	1/151 (0.66%)
Tooth injury [A] †	1/147 (0.68%)	0/151 (0%)
Investigations		
Aspartate aminotransferase increased [A] †	1/147 (0.68%)	0/151 (0%)
Blood alkaline phosphatase increased [A] †	3/147 (2.04%)	3/151 (1.99%)
Blood calcium decreased [A] †	0/147 (0%)	1/151 (0.66%)
Blood glucose decreased [A] †	0/147 (0%)	1/151 (0.66%)
Blood magnesium decreased [A] †	1/147 (0.68%)	1/151 (0.66%)
Blood potassium decreased [A] †	2/147 (1.36%)	1/151 (0.66%)
Blood pressure increased [A] †	0/147 (0%)	1/151 (0.66%)
Blood uric acid increased [A] †	6/147 (4.08%)	6/151 (3.97%)
Body temperature increased [A] †	1/147 (0.68%)	0/151 (0%)
C-reactive protein increased [A] †	1/147 (0.68%)	0/151 (0%)
Cardiac murmur [A] †	1/147 (0.68%)	0/151 (0%)
Culture positive [A] †	0/147 (0%)	1/151 (0.66%)

	G-CSF Plus Plerixafor	G-CSF Plus Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Haemoglobin decreased [A] †	0/147 (0%)	1/151 (0.66%)
Heart rate increased [A] †	0/147 (0%)	1/151 (0.66%)
Heart rate irregular [A] †	1/147 (0.68%)	4/151 (2.65%)
Lymph node palpable [A] †	1/147 (0.68%)	0/151 (0%)
Oxygen saturation decreased [A] †	0/147 (0%)	2/151 (1.32%)
Platelet count decreased [A] †	0/147 (0%)	1/151 (0.66%)
Weight decreased [A] †	1/147 (0.68%)	0/151 (0%)
Weight increased [A] †	1/147 (0.68%)	1/151 (0.66%)
Metabolism and nutrition disorders		
Anorexia [A] †	6/147 (4.08%)	6/151 (3.97%)
Decreased appetite [A] †	6/147 (4.08%)	5/151 (3.31%)
Hyperuricaemia [A] †	0/147 (0%)	3/151 (1.99%)
Hypocalcaemia [A] †	6/147 (4.08%)	6/151 (3.97%)
Hypokalaemia [A] †	19/147 (12.93%)	29/151 (19.21%)
Hypomagnesaemia [A] †	9/147 (6.12%)	16/151 (10.6%)
Hyponatraemia [A] †	1/147 (0.68%)	0/151 (0%)
Hypophosphataemia [A] †	0/147 (0%)	1/151 (0.66%)
Tetany [A] †	1/147 (0.68%)	0/151 (0%)
Musculoskeletal and connective tissue disorders		
Arthralgia [A] †	16/147 (10.88%)	17/151 (11.26%)
Back pain [A] †	23/147 (15.65%)	34/151 (22.52%)
Bone pain [A] †	53/147 (36.05%)	64/151 (42.38%)

	G-CSF Plus Plerixafor	G-CSF Plus Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Flank pain [A] †	0/147 (0%)	1/151 (0.66%)
Jaw disorder [A] †	0/147 (0%)	1/151 (0.66%)
Joint swelling [A] †	1/147 (0.68%)	0/151 (0%)
Muscle disorder [A] †	1/147 (0.68%)	0/151 (0%)
Muscle spasms [A] †	5/147 (3.4%)	8/151 (5.3%)
Muscle twitching [A] †	1/147 (0.68%)	0/151 (0%)
Muscular weakness [A] †	1/147 (0.68%)	0/151 (0%)
Musculoskeletal chest pain [A] †	8/147 (5.44%)	5/151 (3.31%)
Musculoskeletal discomfort [A] †	0/147 (0%)	1/151 (0.66%)
Musculoskeletal pain [A] †	7/147 (4.76%)	5/151 (3.31%)
Musculoskeletal stiffness [A] †	3/147 (2.04%)	2/151 (1.32%)
Myalgia [A] †	2/147 (1.36%)	0/151 (0%)
Neck pain [A] †	5/147 (3.4%)	0/151 (0%)
Pain in extremity [A] †	8/147 (5.44%)	11/151 (7.28%)
Pain in jaw [A] †	1/147 (0.68%)	0/151 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Bone neoplasm malignant [A] †	1/147 (0.68%)	0/151 (0%)
Lentigo [A] †	0/147 (0%)	1/151 (0.66%)
Prostate cancer [A] †	1/147 (0.68%)	0/151 (0%)
Nervous system disorders		
Balance disorder [A] †	1/147 (0.68%)	1/151 (0.66%)
Burning sensation [A] †	1/147 (0.68%)	0/151 (0%)

	G-CSF Plus Plerixafor	G-CSF Plus Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Coordination abnormal [A] †	1/147 (0.68%)	0/151 (0%)
Dizziness [A] †	17/147 (11.56%)	10/151 (6.62%)
Dysgeusia [A] †	7/147 (4.76%)	2/151 (1.32%)
Dyskinesia [A] †	0/147 (0%)	1/151 (0.66%)
Headache [A] †	30/147 (20.41%)	35/151 (23.18%)
Hypoaesthesia [A] †	8/147 (5.44%)	7/151 (4.64%)
Lethargy [A] †	0/147 (0%)	1/151 (0.66%)
Neuropathy peripheral [A] †	0/147 (0%)	1/151 (0.66%)
Paraesthesia [A] †	33/147 (22.45%)	34/151 (22.52%)
Parosmia [A] †	1/147 (0.68%)	0/151 (0%)
Restless legs syndrome [A] †	2/147 (1.36%)	2/151 (1.32%)
Sensory disturbance [A] †	1/147 (0.68%)	0/151 (0%)
Sinus headache [A] †	0/147 (0%)	1/151 (0.66%)
Somnolence [A] †	0/147 (0%)	1/151 (0.66%)
Tremor [A] †	3/147 (2.04%)	3/151 (1.99%)
Psychiatric disorders		
Abnormal dreams [A] †	0/147 (0%)	1/151 (0.66%)
Anticipatory anxiety [A] †	1/147 (0.68%)	0/151 (0%)
Anxiety [A] †	9/147 (6.12%)	6/151 (3.97%)
Confusional state [A] †	1/147 (0.68%)	0/151 (0%)
Depression [A] †	1/147 (0.68%)	1/151 (0.66%)
Emotional distress [A] †	0/147 (0%)	1/151 (0.66%)

	G-CSF Plus Plerixafor	G-CSF Plus Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Insomnia [A] †	10/147 (6.8%)	11/151 (7.28%)
Restlessness [A] †	2/147 (1.36%)	0/151 (0%)
Renal and urinary disorders		
Haematuria [A] †	0/147 (0%)	2/151 (1.32%)
Nocturia [A] †	1/147 (0.68%)	0/151 (0%)
Pollakiuria [A] †	2/147 (1.36%)	1/151 (0.66%)
Proteinuria [A] †	1/147 (0.68%)	0/151 (0%)
Reproductive system and breast disorders		
Pelvic pain [A] †	0/147 (0%)	1/151 (0.66%)
Vaginal pain [A] †	0/147 (0%)	1/151 (0.66%)
Respiratory, thoracic and mediastinal disorders		
Cough [A] †	1/147 (0.68%)	3/151 (1.99%)
Dyspnoea [A] †	3/147 (2.04%)	4/151 (2.65%)
Dyspnoea exertional [A] †	2/147 (1.36%)	4/151 (2.65%)
Nasal congestion [A] †	1/147 (0.68%)	0/151 (0%)
Nasal mucosal disorder [A] †	1/147 (0.68%)	0/151 (0%)
Paranasal sinus hypersecretion [A] †	0/147 (0%)	3/151 (1.99%)
Pharyngolaryngeal pain [A] †	3/147 (2.04%)	6/151 (3.97%)
Postnasal drip [A] †	1/147 (0.68%)	1/151 (0.66%)
Productive cough [A] †	1/147 (0.68%)	1/151 (0.66%)
Rhinorrhoea [A] †	1/147 (0.68%)	2/151 (1.32%)
Rhonchi [A] †	1/147 (0.68%)	0/151 (0%)

	G-CSF Plus Plerixafor	G-CSF Plus Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Sinus congestion [A] †	2/147 (1.36%)	0/151 (0%)
Wheezing [A] †	0/147 (0%)	1/151 (0.66%)
Skin and subcutaneous tissue disorders		
Actinic keratosis [A] †	1/147 (0.68%)	0/151 (0%)
Alopecia [A] †	1/147 (0.68%)	0/151 (0%)
Cold sweat [A] †	2/147 (1.36%)	0/151 (0%)
Dermatitis contact [A] †	1/147 (0.68%)	1/151 (0.66%)
Dry skin [A] †	1/147 (0.68%)	2/151 (1.32%)
Ecchymosis [A] †	2/147 (1.36%)	2/151 (1.32%)
Eczema [A] †	1/147 (0.68%)	0/151 (0%)
Ephelides [A] †	1/147 (0.68%)	0/151 (0%)
Erythema [A] †	3/147 (2.04%)	1/151 (0.66%)
Erythema nodosum [A] †	0/147 (0%)	1/151 (0.66%)
Hyperhidrosis [A] †	4/147 (2.72%)	5/151 (3.31%)
Hypoaesthesia facial [A] †	5/147 (3.4%)	0/151 (0%)
Ingrowing nail [A] †	0/147 (0%)	1/151 (0.66%)
Night sweats [A] †	4/147 (2.72%)	2/151 (1.32%)
Pruritus [A] †	4/147 (2.72%)	2/151 (1.32%)
Rash [A] †	3/147 (2.04%)	2/151 (1.32%)
Rash generalised [A] †	0/147 (0%)	1/151 (0.66%)
Scar [A] †	0/147 (0%)	1/151 (0.66%)
Skin irritation [A] †	4/147 (2.72%)	1/151 (0.66%)

	G-CSF Plus Plerixafor	G-CSF Plus Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Skin lesion [A] †	0/147 (0%)	1/151 (0.66%)
Vascular disorders		
Flushing [A] †	2/147 (1.36%)	1/151 (0.66%)
Hot flush [A] †	2/147 (1.36%)	1/151 (0.66%)
Hypertension [A] †	2/147 (1.36%)	5/151 (3.31%)
Hypotension [A] †	2/147 (1.36%)	5/151 (3.31%)
Orthostatic hypotension [A] †	1/147 (0.68%)	0/151 (0%)
Pallor [A] †	0/147 (0%)	1/151 (0.66%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 10.0

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.

In multi-site studies, PI can publish after Genzyme publishes or 18 months after study completion. PI gives Genzyme a draft 60 days before publication. Genzyme can ask that confidential information be removed, and can defer publication another 60 days upon notifying PI that it will file a patent application on inventions contained in the draft.

Results Point of Contact:

Name/Official Title: Genzyme Medical Information
Organization: Genzyme Corporation
Phone: 800-745-4447

Email: