



Clinical trial results:

A Pilot, Exploratory, Randomized, Phase 2 Safety Study Evaluating Tumor Cell (Plasma Cell) Mobilization and Apheresis Product Contamination in Plerixafor Plus Non-Pegylated Granulocyte Colony-Stimulating Factor (G-CSF) Mobilized Patients and in Non-Pegylated G-CSF Alone Mobilized Patients

Summary

EudraCT number	2011-004783-30
Trial protocol	BE LT SE EE
Global end of trial date	28 September 2016

Results information

Result version number	v1 (current)
This version publication date	14 October 2017
First version publication date	14 October 2017

Trial information

Trial identification

Sponsor protocol code	ARD12858-MOZ23510
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01753453
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Sanofi Genzyme Corporation
Sponsor organisation address	500 Kendall Street , Cambridge, MA, United States, 02142
Public contact	Trial Transparency Team, Sanofi aventis recherche & développement, Contact-US@sanofi.com
Scientific contact	Trial Transparency Team, Sanofi aventis recherche & développement, Contact-US@sanofi.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	18 October 2016
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	28 September 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate tumor cell mobilization (TCM) with non-pegylated granulocyte colony-stimulating factor (G-CSF) alone compared with non-pegylated G-CSF plus plerixafor in subjects with multiple myeloma (MM) who are potentially poor mobilizers of hematopoietic stem cells (HSC).

Protection of trial subjects:

Subjects were fully informed of all pertinent aspects of the clinical trial as well as the possibility to discontinue at any time in language and terms appropriate for the subject and considering the local culture. During the course of the trial, subjects were provided with individual subject cards indicating the nature of the trial the subject is participating, contact details and any information needed in the event of a medical emergency.

Collected personal data and human biological samples were processed in compliance with the Sanofi-Aventis Group Personal Data Protection Charter ensuring that the Group abides by the laws governing personal data protection in force in all countries in which it operates.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 June 2013
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	2 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Sweden: 8
Country: Number of subjects enrolled	Estonia: 5
Country: Number of subjects enrolled	Lithuania: 7
Worldwide total number of subjects	20
EEA total number of subjects	20

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0

Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	13
From 65 to 84 years	7
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 5 centres in 3 countries. A total of 28 subjects were screened between 4 June 2013 and 28 September 2016, of whom 20 subjects were randomized in the study.

Pre-assignment

Screening details:

Subjects were randomized in 1:1 ratio to receive either G-CSF alone or G-CSF plus plerixafor.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	G-CSF Alone

Arm description:

G-CSF (non-pegylated only) 10 mcg/kg once daily (qd) in the morning for 5 consecutive days. Morning doses of G-CSF was followed by apheresis and continued for up to a maximum of 4 apheresis or until $\geq 6 \times 10^6$ CD34+ cells/kg were collected.

Arm type	Non-Investigational Medicinal Product (IMP)
Investigational medicinal product name	Non-IMP: Granulocyte Colony-Stimulating Factor (G-CSF)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

The dose of G-CSF was based on the subject's actual body weight and G-CSF was administered approximately 1 hour prior to apheresis.

Arm title	G-CSF + Plerixafor
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Arm description:

G-CSF (non-pegylated only) 10 mcg/kg qd in the morning for 4 consecutive days, Plerixafor 240 mcg/kg in the evening of Day 4, and G-CSF (non-pegylated only) 10 mcg/kg in the morning on Day 5. Evening doses of plerixafor and morning doses of G-CSF was followed by apheresis and continued for up to a maximum of 4 apheresis or until $\geq 6 \times 10^6$ CD34+ cells/kg were collected.

Arm type	Experimental
Investigational medicinal product name	Non IMP: Granulocyte Colony-Stimulating Factor (G-CSF)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

The dose of G-CSF was based on the subject's actual body weight and G-CSF was administered approximately 1 hour prior to apheresis.

Investigational medicinal product name	Plerixafor
Investigational medicinal product code	AMD3100
Other name	Mozobil®

Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Plerixafor 240 mcg/kg was administered 10 to 11 hours prior to the initiation of apheresis.

Number of subjects in period 1	G-CSF Alone	G-CSF + Plerixafor
Started	10	10
Completed	9	10
Not completed	1	0
Consent withdrawn by subject	1	-

Baseline characteristics

Reporting groups

Reporting group title	G-CSF Alone
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Reporting group description:

G-CSF (non-pegylated only) 10 mcg/kg once daily (qd) in the morning for 5 consecutive days. Morning doses of G-CSF was followed by apheresis and continued for up to a maximum of 4 apheresis or until $\geq 6 \times 10^6$ CD34+ cells/kg were collected.

Reporting group title	G-CSF + Plerixafor
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Reporting group description:

G-CSF (non-pegylated only) 10 mcg/kg qd in the morning for 4 consecutive days, Plerixafor 240 mcg/kg in the evening of Day 4, and G-CSF (non-pegylated only) 10 mcg/kg in the morning on Day 5. Evening doses of plerixafor and morning doses of G-CSF was followed by apheresis and continued for up to a maximum of 4 apheresis or until $\geq 6 \times 10^6$ CD34+ cells/kg were collected.

Reporting group values	G-CSF Alone	G-CSF + Plerixafor	Total
Number of subjects	10	10	20
Age categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	58.3 ± 9.06	59.1 ± 8.77	-
Gender categorical Units: Subjects			
Female	4	6	10
Male	6	4	10

End points

End points reporting groups

Reporting group title	G-CSF Alone
Reporting group description: G-CSF (non-pegylated only) 10 mcg/kg once daily (qd) in the morning for 5 consecutive days. Morning doses of G-CSF was followed by apheresis and continued for up to a maximum of 4 apheresis or until $\geq 6 \times 10^6$ CD34+ cells/kg were collected.	
Reporting group title	G-CSF + Plerixafor
Reporting group description: G-CSF (non-pegylated only) 10 mcg/kg qd in the morning for 4 consecutive days, Plerixafor 240 mcg/kg in the evening of Day 4, and G-CSF (non-pegylated only) 10 mcg/kg in the morning on Day 5. Evening doses of plerixafor and morning doses of G-CSF was followed by apheresis and continued for up to a maximum of 4 apheresis or until $\geq 6 \times 10^6$ CD34+ cells/kg were collected.	

Primary: Percentage of Myeloma Tumor Cells/CD34+ Cell Count in Peripheral Blood

End point title	Percentage of Myeloma Tumor Cells/CD34+ Cell Count in Peripheral Blood ^[1]
End point description: The presence of myeloma tumor cells in peripheral blood was detected by flow cytometry analysis. Overall data from Day 5 pre-G-CSF administration up to Day 8 pre-G-CSF administration was calculated as sum of total myeloma tumors cells count/total CD34+ cells count from Day 5 up to Day 8. Analysis was performed on ITT population defined as all randomized population analyzed according to the treatment group allocated by randomization regardless of whether subjects received any study drug or received a different study drug from which they were randomized.	
End point type	Primary
End point timeframe: Day 5 up to Day 8	
Notes: [1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.	

End point values	G-CSF Alone	G-CSF + Plerixafor		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: percentage of myeloma tumor cells				
arithmetic mean (standard deviation)	0 ($\pm$ 0)	0 ($\pm$ 0)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Myeloma Tumor Cells/CD34+ Cells Count Per Cumulative G-CSF Dose (mcg/kg) in Peripheral Blood

End point title	Percentage of Myeloma Tumor Cells/CD34+ Cells Count Per Cumulative G-CSF Dose (mcg/kg) in Peripheral Blood ^[2]
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End point description:

The presence of myeloma tumor cells in peripheral blood was detected by flow cytometry analysis. Overall data from Day 5 pre-G-CSF administration up to Day 8 pre-G-CSF administration was calculated as: (total cumulative myeloma tumors cells count/total cumulative CD34+ cells count) divided by (cumulative G-CSF dose since Day 1/Body weight in kg), where G-CSF cumulative dose was the sum of all doses of G-CSF from the 1st administration to the last dose received prior the peripheral blood sample analyzed. The value of the body weight was the last available value before the start of first planned G-CSF. Analysis was performed on ITT population.

End point type	Primary
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End point timeframe:

Day 5 up to Day 8

Notes:

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

Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

End point values	G-CSF Alone	G-CSF + Plerixafor		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: percentage of cells per mcg/kg				
arithmetic mean (standard deviation)	0 (± 0)	0 (± 0)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Myeloma Tumor Cells/CD34+ Cells Count per Cumulative Plerixafor Dose (mcg/kg) in Peripheral Blood

End point title	Percentage of Myeloma Tumor Cells/CD34+ Cells Count per Cumulative Plerixafor Dose (mcg/kg) in Peripheral Blood ^[3] ^[4]
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End point description:

The presence of myeloma tumor cells in peripheral blood was detected by flow cytometry analysis. Overall data from Day 5 pre-G-CSF administration up to Day 8 pre-G-CSF administration was calculated as: (total cumulative myeloma tumors cells count/total cumulative CD34+ cells count) divided by (cumulative Plerixafor dose since Day 4/Body weight in kg), where plerixafor cumulative dose was the sum of all doses of plerixafor from the 1st administration of plerixafor (Day 4) to the last dose of plerixafor received prior the peripheral blood sample analyzed. The value of the body weight was the last available value before the start of first planned G-CSF. Analysis was performed on ITT population.

End point type	Primary
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End point timeframe:

Day 5 up to Day 8

Notes:

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

Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The end point is reporting results only for the arm in which Plerixafor was administered.

End point values	G-CSF + Plerixafor			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: percentage of cells per mcg/kg				
arithmetic mean (standard deviation)	0 (± 0)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from Day 4 in Tumor Cell Mobilization (TCM) in Peripheral Blood at Day 5

End point title	Change from Day 4 in Tumor Cell Mobilization (TCM) in Peripheral Blood at Day 5 ^[5]
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End point description:

The Change in TCM was calculated as: TCM value at Day 5 (pre-G-CSF administration) minus TCM value at Day 4 (pre-G-CSF administration). Analysis was performed on ITT population. Number of subjects analyzed=subjects with available data for this endpoint.

End point type	Primary
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End point timeframe:

Day 4, Day 5

Notes:

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

Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

End point values	G-CSF Alone	G-CSF + Plerixafor		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9	8		
Units: cells/mcgl				
arithmetic mean (standard deviation)	0 (± 0)	0 (± 0)		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Myeloma Tumor Cells (*10⁵ Cells/Kg) in the Apheresis Product

End point title	Number of Myeloma Tumor Cells (*10 ⁵ Cells/Kg) in the Apheresis Product ^[6]
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End point description:

The overall number of myeloma tumor cells was calculated as: sum of total myeloma tumor cells in apheresis product from Day 5 up to Day 8. Analysis was performed on ITT population.

End point type	Primary
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End point timeframe:

Day 5 up to Day 8

Notes:

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

Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

End point values	G-CSF Alone	G-CSF + Plerixafor		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: cells (*10 ⁵ cells/Kg)				
arithmetic mean (standard deviation)	1.32 (± 3.42)	0.62 (± 1.33)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Mobilizing At least 4.5*10⁵ Myeloma Tumor cells/kg Body Weight in Apheresis Product

End point title	Percentage of Subjects Mobilizing At least 4.5*10 ⁵ Myeloma Tumor cells/kg Body Weight in Apheresis Product ^[7]
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End point description:

The percentage of subjects mobilizing at least 4.5*10⁵ myeloma tumor cells/kg body weight in the apheresis product from Day 5 up to Day 8 were reported. Overall data was calculated as subjects with the sum of total myeloma tumor cells with $\geq 4.5 \times 10^5$ myeloma tumor cells/kg in apheresis product from Day 5 up to Day 8. Analysis was performed on ITT population.

End point type	Primary
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End point timeframe:

Day 5 up to Day 8

Notes:

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

Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

End point values	G-CSF Alone	G-CSF + Plerixafor		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: percentage of subjects				
number (not applicable)	10	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Total CD34+ (*10⁶ cells/kg) Stem Cell Yield

End point title	Total CD34+ (*10 ⁶ cells/kg) Stem Cell Yield
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End point description:

Total CD34+ (*10⁶ cells/kg) stem cell yield from apheresis 1 up to apheresis 4 (up to Day 8) were reported. Analysis was performed on ITT population.

End point type	Secondary
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End point timeframe:

Day 5 up to Day 8

End point values	G-CSF Alone	G-CSF + Plerixafor		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: cells (*10 ⁶ cells/kg)				
arithmetic mean (standard deviation)	6.81 (± 2.92)	8.5 (± 3.26)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Reaching the Minimal Target of $\geq 2 \times 10^6$ CD34+ cells/kg

End point title	Percentage of Subjects Reaching the Minimal Target of $\geq 2 \times 10^6$ CD34+ cells/kg
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End point description:

Percentage of subjects reaching the minimal target of $\geq 2 \times 10^6$ CD34+ cells/kg from Day 5 up to Day 8 were reported. Analysis was performed on ITT population.

End point type	Secondary
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End point timeframe:

Day 5 up to Day 8

End point values	G-CSF Alone	G-CSF + Plerixafor		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: percentage of subjects				
number (not applicable)	100	100		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Reaching the Optimal Target of $\geq 6 \times 10^6$ CD34+ cells/kg

End point title	Percentage of Subjects Reaching the Optimal Target of $\geq 6 \times 10^6$ CD34+ cells/kg
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End point description:

Percentage of subjects reaching the optimal target of $\geq 6 \times 10^6$ CD34+ cells/kg from Day 5 up to Day 8 were reported. Analysis was performed on ITT population.

End point type	Secondary
End point timeframe:	
Day 5 up to Day 8	

End point values	G-CSF Alone	G-CSF + Plerixafor		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: percentage of subjects				
number (not applicable)	40	70		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects That Proceeded to Transplantations

End point title	Percentage of Subjects That Proceeded to Transplantations
End point description:	
Transplantation of the collected apheresis product was performed within 2 months of last apheresis according to the standard procedures at the site. Analysis was performed on ITT population.	
End point type	Secondary
End point timeframe:	
Up to two months after last apheresis (last apheresis = up to Day 8)	

End point values	G-CSF Alone	G-CSF + Plerixafor		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: percentage of subjects				
number (not applicable)	90	90		

Statistical analyses

No statistical analyses for this end point

Secondary: Overall survival

End point title	Overall survival
End point description:	
Overall survival was defined as the time interval between the date of randomization and the date of death from any cause. In the absence of death before the cut-off date for the final analysis, overall survival time was censored at the earlier between the last date subject was known to be alive and the cut-off date. Estimation was performed by Kaplan-Meier method. Analysis was performed on ITT population. 99999 represented that data was not estimable due to the low number of subjects who died.	

End point type	Secondary
End point timeframe:	
Baseline until death or study cut-off (up to 2 years follow up)	

End point values	G-CSF Alone	G-CSF + Plerixafor		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: months				
median (full range (min-max))	99999 (20.44 to 99999)	24.4 (24.38 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Best Overall Response (BOR)

End point title	Best Overall Response (BOR)
End point description:	
BOR was assessed using International Myeloma Working Group Uniform Response Criteria. Complete Response(CR):Negative immunofixation on serum & urine & disappearance of any soft tissue plasmacytomas & <5% plasma cells in bone marrow.Stringent CR(sCR):CR + normal free light chain(FLC)ratio & absence of clonal cells in bone marrow by immunohistochemistry/immunofluorescence.Very good partial response(VGPR):Serum & urine M-protein detectable by immunofixation but not on electrophoresis or >=90% reduction in serum M-component + urine M-component level <100 mg/24 hr.Partial Response(PR):>=50% reduction of serum M-protein and reduction in 24 hrs urinary M-protein by >=90% or to <200 mg/24Hr.Stable disease: Not meeting criteria for CR,VGPR,PR/Progressive Disease (PD).PD:Increase of >25% from lowest response value in any one or more of the following: •Serum M-component and/or (absolute increase must be >=0.5 g/dL)•Urine M-component and/or(absolute increase must be >=200mg/24 hr).ITT population.	
End point type	Secondary
End point timeframe:	
From randomization until disease progression (DP) or the end of the 2 years follow-up	

End point values	G-CSF Alone	G-CSF + Plerixafor		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: percentage of subjects				
number (not applicable)				
Complete response (CR)	0	20		
Stringent CR (sCR)	0	10		
Very Good Partial Response (VGPR)	60	40		
Partial Response (PR)	20	20		
Stable Disease	0	0		
Progressive Disease	10	10		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All Adverse Events (AEs) were collected from signature of the informed consent form up to the final visit (up to follow up visit of 2 year) regardless of seriousness or relationship to investigational product.

Adverse event reporting additional description:

Reported AEs and deaths are treatment-emergent adverse events that is AEs that developed/worsened during the 'on treatment period' (any AEs occurring from the first G-CSF administration up to end of the 2-year follow-up period).

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups

Reporting group title	G-CSF Alone
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Reporting group description:

G-CSF (non-pegylated only) 10 mcg/kg once daily (qd) in the morning for 5 consecutive days. Morning doses of G-CSF was followed by apheresis and continued for up to a maximum of 4 apheresis or until $\geq 6 \times 10^6$ CD34+ cells/kg were collected.

Reporting group title	G-CSF + Plerixafor
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Reporting group description:

G-CSF (non-pegylated only) 10 mcg/kg/day qd in the morning for 4 consecutive days, Plerixafor 240 mcg/kg in the evening of Day 4, and G-CSF (non-pegylated only) 10 mcg/kg in the morning on Day 5. Evening doses of plerixafor and morning doses of G-CSF was followed by apheresis and continued for up to a maximum of 4 apheresis or until $\geq 6 \times 10^6$ CD34+ cells/kg were collected.

Serious adverse events	G-CSF Alone	G-CSF + Plerixafor	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
number of deaths (all causes)	2	3	
number of deaths resulting from adverse events	0	0	
Respiratory, thoracic and mediastinal disorders			
Pleural Effusion			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	G-CSF Alone	G-CSF + Plerixafor	
Total subjects affected by non-serious adverse events subjects affected / exposed	3 / 10 (30.00%)	6 / 10 (60.00%)	
Nervous system disorders			
Headache subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
Hypoaesthesia subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Abdominal Pain subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Constipation subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Diarrhoea subjects affected / exposed	0 / 10 (0.00%)	2 / 10 (20.00%)	
occurrences (all)	0	2	
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Back Pain subjects affected / exposed	3 / 10 (30.00%)	3 / 10 (30.00%)	
occurrences (all)	3	3	
Bone Pain subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Musculoskeletal Chest Pain subjects affected / exposed	2 / 10 (20.00%)	0 / 10 (0.00%)	
occurrences (all)	2	0	
Myalgia subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported