European Society for Blood and Marrow Transplantation

SANOFI ONCOLOGY

CALM

A Non-Interventional Study

Collaboration to Collect Autologous transplant outcomes in Lymphoma and Myeloma patients

Background and Objectives

To compare progression-free survival(PFS), overall survival (OS)and relapse rate (RR) of patients with lymphoma or multiple myeloma (MM) who have received autologous transplants of stem cells using cells mobilised with Plerixafor plus G-CSF to other mobilisation methods.

Plerixafor (Mozobil®), a CXCR4 antagonist, received EU approval on 31st July 2009

In common with all mobilisation regimens there is a theoretical risk of tumour cell mobilisation and subsequent contamination of apheresis product. The clinical relevance of tumour cell mobilisation and tumour cell contamination in the apheresis product is not clear.

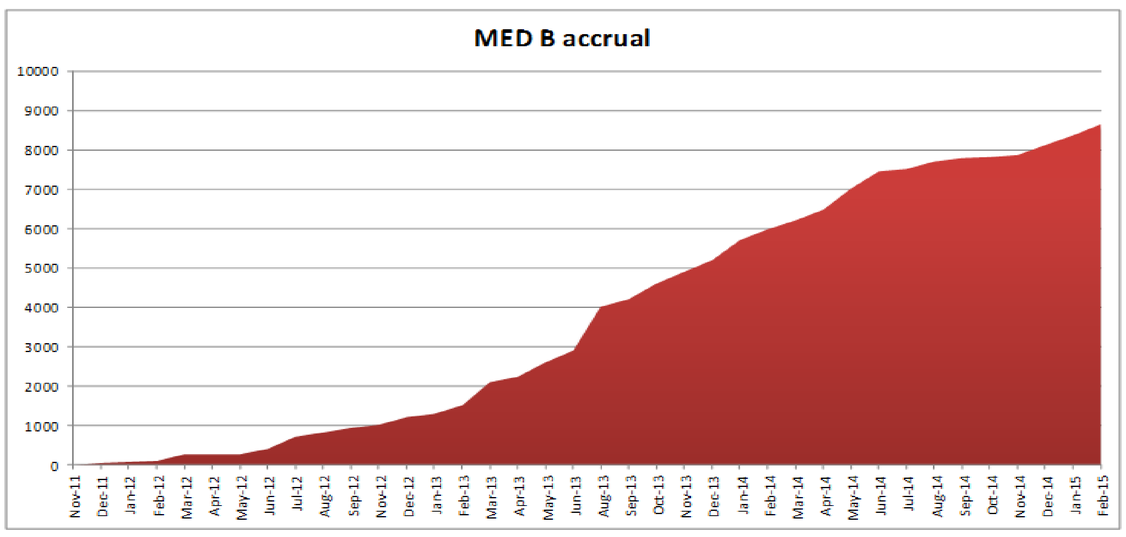
As a post-approval commitment, EMA have asked Genzyme to examine PFS, OS and RR in patients with MM and Lymphoma who received an autograft mobilised with or without Plerixafor

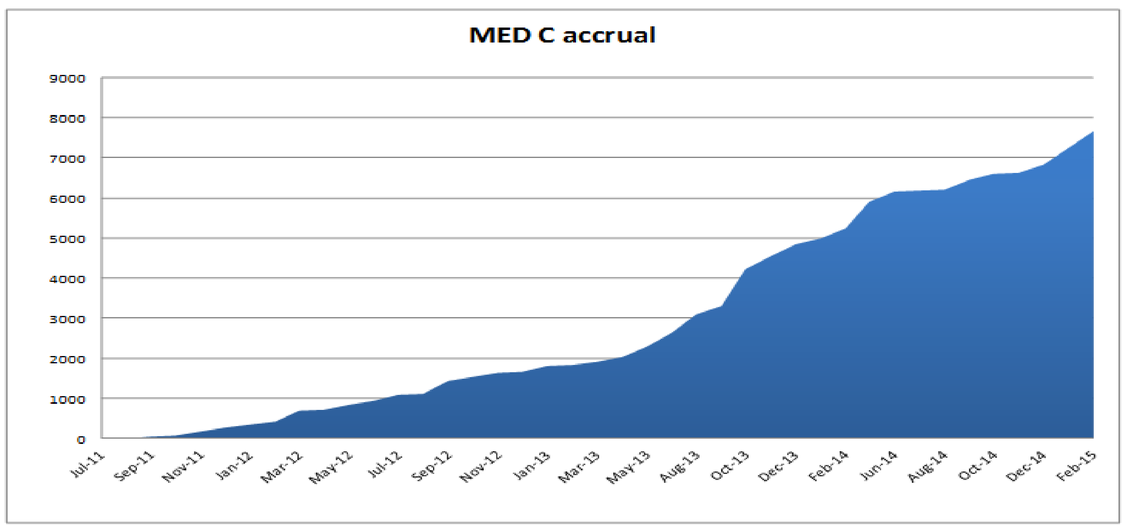
Current status

Centre registration has been closed

- **Inclusion period:** 2008 – 2012 with a further follow-up (FUP) for the patients enrolled in 2008 and 2009 until the end of 2014, while those enrolled from 2010 to 2012 will be followed up until the end of 2015 inclusive.
- **Data request**: full completion of MED B (+ autograft form + FUP) and a 4-page MED C form

Expecting to collect **9000** MED B + MED C





CALM lunch

Thank you!

All CALM participants are invited for a lunch and drinks on Tuesday March 24, 2015 from 13:00-14:00 **at ROOM 3B/10 at B3 level**

Question & Answer Session:

Tuesday March 24, 2015, after/during the CALM lunch from 13:00 till 15:00 at **ROOM 3B/10 at B3 level**

Inclusion Criteria

Inclusion criteria:

Lymphoma or Multiple Myeloma

Autologous PBSCT

First transplant between 01/01/2008 and 31/12/2012

Age ≥ 18 years

One of these 4 mobilisation regimens used:

Plerixafor + G-CSF

Plerixafor + G-CSF + chemotherapy

G-CSF alone
G-CSF + chemotherapy

Baseline data collection

Please send your MED B, MED C and Follow Up data
AS SOON AS POSSIBLE

If you are not performing your own data entry, send the MED-B data for the transplantations not yet registered in ProMISe to the EBMT Data Office in London.

The MED-B data for the transplantations already registered in ProMISe as well as the MED-C data for all transplantations should be sent to the EBMT Data Office in Leiden.

If you are performing your own data entry, please be reminded to create a working party record in ProMISe and enter the CALM study code **42206644**.

For each transplant we need a MED B and a MED C form otherwise the transplant will *not* be reimbursed

Baseline database lock April 2015

CALM Follow Up and Quality Control

Follow Up:

- Expecting to collect 25.000 Follow Up moments for the inclusion period.
- Duration Follow Up period 2009 - 2015
- 52 % of the participating centers have already sent their Follow Up
- Annual follow up for years 2008-2011 Deadline **2nd quarter 2015**
- Annual follow up for years 2012-2014 Deadline **3rd quarter 2015**
- Annual follow up for year 2015 **1st quarter 2016**

*** Please send in your Follow up data ***

Data Quality Control:

All participating centers have received data quality requests files for the baseline and follow up data. Please complete them and send them to the CALM study team.

CALM Contact:

For questions contact the CALM study coordinators at the EBMT Leiden data office

Paul Bosman 00 31 6 10397433
Steffie van der Werf

calmebmt@lumc.nl