CALM

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 marketing approval on 31st July 2009 for use in combination with granulocyte-colony stimulating factor (G-CSF) to enhance mobilisation of haematopoietic stem cells to the peripheral blood for collection and subsuquent transplantation in adult patients with lymphoma and MM whose cells mobilise poorly.

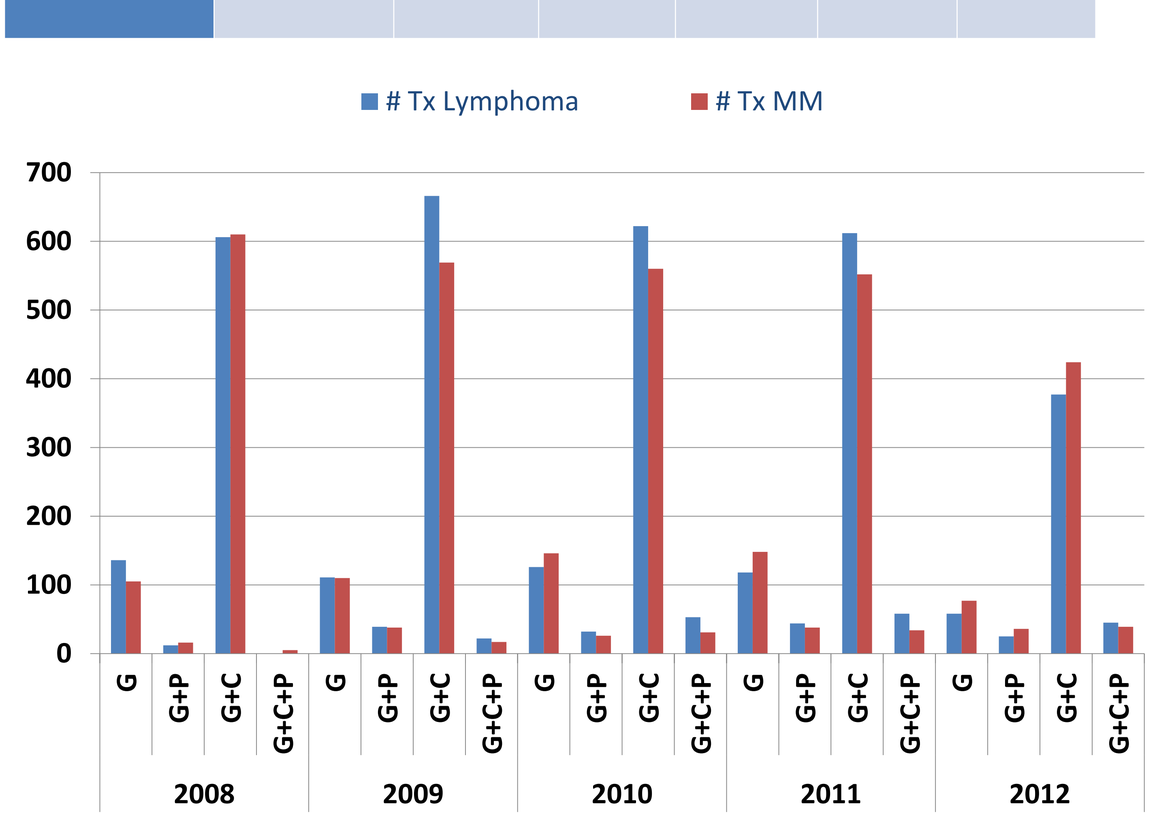
In common with all mobilisation regimens there is a theoretical risk of tumour cell mobilisation and subsequent contamination of apheresis product. The clinical relevance of tumour cell mobilisation and tumour cell contamination in the apheresis product is not clear.

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. The CALM Study is sponsored by SANOFI.

Current status

- Baseline database lock July 2015
- Baseline Transplants MED A , MED B and MED C Total collected: **8185** Tx

	1st auto Tx Lymphoma	1st auto Tx MM	2nd auto Tx (MM)	3rd auto Tx (MM)	4th auto Tx (MM)	Total Tx
Plerixafor	330	280	41	3	0	654
No Plerixafor	3488	3347	644	44	6	7529
Total	3818	3627	685	47	8	**8185**



G = G-CSF alone G+P = Plerixafor + G-CSF G+C = G-CSF + chemotherapy
G+C+P = Plerixafor + G-CSF + chemotherapy

- Currently collecting Annual follow up
- Follow up (FU) for patients enrolled in
  - 2008 and 2009 until the end of 2014
  - 2010 to 2012 until the end of 2015

CALM Question & Answer session

Question and Answer session
Monday April 4th , 2016, from 17:00-17:30
at ROOM 3B

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

Data collection

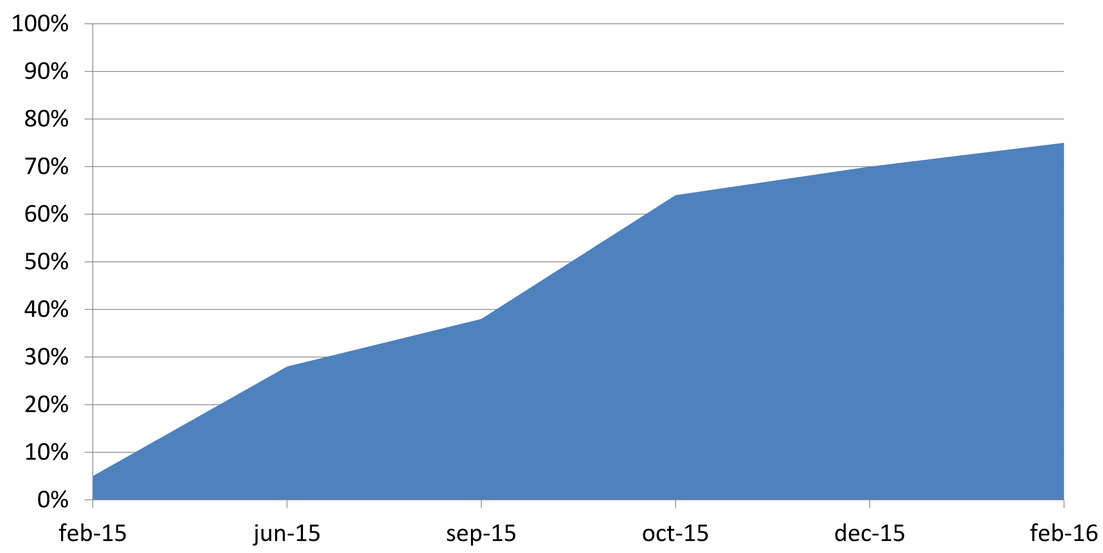
*** Please send your Annual Follow up data to the EBMT Data Office Leiden***

Data Quality Control:

All participating centers have received missing data files for the (Annual) Follow Up data. Please complete them and send them to the CALM study team.

If the patient is not complete it could effect your reimbursement

Percentage Follow Up complete



Deadline data submission

April 2016

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Data cleaning

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Final database transfer to Sanofi

June 2016

CALM Contacts

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

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