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May 2011

## Subject: Collaboration to collect Autologous transplant outcomes in Lymphoma and Myeloma (CALM).

Dear Colleague,

The EMA license for plerixafor requires Genzyme to undertake monitoring of the outcome of patients transplanted with plerixafor mobilized cells and compare these to equivalent patients transplanted without the use of plerixafor. The EMA agreed that Genzyme collaborate with EBMT to collect the required data by using the EBMT registry.

For this purpose Genzyme and the EBMT have developed the **CALM** study (Collaboration to collect Autologous transplant outcomes in Lymphoma and Myeloma).

The study is an analysis of a prospectively defined cohort of patients with data reported retrospectively to the EBMT covering the **autologous PBSC transplants in adults for Myeloma and Lymphoma from 01/01/2008 to 31/12/2011** with a further follow up to the end of 2014. Patients will be eligible when they are  $\geq 18$  years old and received their first autologous PBSC transplant using cells with one of the following mobilization regimens:

- plerixafor (label indication) + G-CSF
- plerixafor (label indication) + G-CSF + chemotherapy
- G-CSF + chemotherapy
- G-CSF alone.

For the patients transplanted in 2011 and registered prospectively with the EBMT, in general no approval by the Ethics Committee is needed. Please see the EC letter attached to the invitation e-mail, as this could differ per centre.

Centres should include all consecutive eligible patients. The data request has been kept to an absolute minimum. In addition to submitting the mandatory data for this study (MED B + autograft form + follow up), only a 4-page Med C form needs to be filled out.

For your convenience, after you have registered your centre for participation you will receive two documents from the EBMT Data Office Leiden on which all of your MM and Lymphoma patients transplanted from 01/01/2008 onwards and already registered in PromISE will be listed.

For participating centres, there will be a **financial compensation of 250 Euros per fully completed MED B/C** for the effort put into this study. Based on the



number of patients your centre expects to be able to include, there are multiple options for payment of this compensation. For example, to give centres the opportunity to appoint a data manager to the study, it will be possible to receive a prepayment. Upon registration, you will receive a financial agreement form on which you can indicate your preference.

We aim to collect data of 5000-7000 patients. This means that this study is not only important for the treatment of Lymphoma and Myeloma patients but is also a great opportunity for updating and completing the EBMT data base, thus increasing the research capacity of the SCT community.

To participate in this unique EBMT study, please complete the centre registration form and return it to the EBMT Data Office in Leiden, The Netherlands via fax at +49 711 4900 8723 or via e-mail at [calmebmt@lumc.nl](mailto:calmebmt@lumc.nl).

Thank you again for your cooperation.  
Sincerely,

Marcha Suits  
Jennifer Hoek  
Study Coordinators

Curly Morris  
Myeloma subctte

Theo de Witte  
Chair CLWP

Anna Sureda  
Lymphoma WP

Peter Dreger  
Chair LWP

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