European Group for Blood and Marrow Transplantation

www.ebmt.org

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August 2011

Subject: Non-interventional study on the off-label transplant use of plerixafor

Dear Colleague,

The EMA license for plerixafor requires Genzyme to perform the outcome monitoring of patients transplanted with plerixafor-mobilized cells, compared to equivalent patients transplanted without the use of plerixafor. The EMA has acceded the collaboration of Genzyme 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).
As a post-marketing commitment to the EMA, Genzyme will additionally monitor the **off-label transplant use of plerixafor** using data in the EBMT registry.

> ***In case this invitation does not apply to your department, could you please forward these documents to the appropriate department? We hope that you will help us and make the study generally known in your centre.***

The use of plerixafor in off-label settings will be collected from data entries over a 5-year period after the date of marketing authorization, namely data entered

between **31 July 2009** and **31 July 2014**.

It concerns patients treated with plerixafor, who meet one or more of the following conditions:

- Background disease other than lymphoma or MM
- Younger than 18 years of age
- Received transplant using ex-vivo plerixafor-mobilised cells
- Received treatment with plerixafor alone
- Contraindication for G-CSF
- Transplants using plerixafor-mobilised cells from allogeneic donor
- Received transplant using plerixafor-mobilised BM cells
- Routes of administration other than subcutaneous
- Patients whose cells do not mobilise poorly
- Other

EBMT Registered Office: P.O. Box 3151, 6202 ND Maastricht, The Netherlands **Registration Number**: 41166105 **VAT Number**: NL8042.17.257.B01

Data request

Centres should include all consecutive eligible patients. The patient registration form collects only the off-label transplant use indication and patient identification items. EBMT expects your data forms to be registered at day 100 after transplant as usual.

For the patients transplanted and registered prospectively with the EBMT, in general no ethical approval is necessary. However, regulations on approval may differ per centre. Please contact you EC in case of any doubts. It is sufficient to collect the general patient consent forms for data submission to the EBMT registry.

The invitation letter, study protocol, summary of the protocol, information for the Ethics Committee, patient registration form/MED C (without the flowchart) and leaflet can be downloaded from the website:

http://www.ebmt.org/5WorkingParties/CLWP/clwp11.html.

To participate in this EBMT study, please complete the patient registration form(s) and return these to the EBMT Data Office in Leiden, The Netherlands,
via fax at +49 711 4900 8723, or e-mail at plerolebmt@lumc.nl.

Thank you again for your cooperation.

Sincerely,

Annelies Kleijne	Curly Morris	Anna Sureda
Study Coordinator	*Myeloma subctte*	*Lymphoma WP*
Anja van Biezen	Theo de Witte	Peter Dreger
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