European Group for Blood and Marrow Transplantation

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August 2011

Subject: Information Ethics Committee non-interventional study on the off-label transplant use of plerixafor

Dear Colleague,

We greatly appreciate your participation in the non-interventional plerixafor off-label study, conducted by the European Group for Blood and Marrow Transplantation (EBMT).

Non-interventional prospective studies are prospective studies, set up to investigate events that will take place after the study has been initiated. The main and very important difference between a clinical trial and a NIS is that the data collection or patient-participation in the NIS does not interfere with the choice of treatment, sample collection, procedures, and the treatment itself, which entirely follow standard hospital practices.

Following the standard procedures for all EBMT studies, the collected data will be filed non-identifiably. Only authorized and qualified collaborators of the government bodies and of the hospital have been allowed access to the data of this study. A unique code number will protect all medical data collected during the study; patient or donor full names will never be used. No personal data will be used in any study documentation, in reports or publications.

As the patients in this NIS will receive the same treatment and diagnostic procedures as they would have received if they were not included in this study, ethical approval might not be needed. A non-interventional study is always strictly observational. However, regulations may differ per centre. Please contact your Ethics Committee in case of any doubts.

A patient consent form should be collected as standard procedure of your transplant management. Please collect these consent forms on every consecutive eligible patient you will include in this study and file them at your centre.

Thank you again for your cooperation.
Sincerely,

Annelies Kleijne	Curly Morris	Anna Sureda
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