Plerixafor (Mozobil®) received EU approval on 31 July 2009. As a post-approval commitment, EMA have asked Genzyme to examine progression free survival, overall survival and relapse rate of patients with lymphoma or multiple myeloma who have received autologous transplants of stem cells mobilized with or without plerixafor. 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.

**Study objectives** Monitoring the off-label transplant use of plerixafor, using data entries in the EBMT registry over a 5-year period after the date of marketing authorization. The patient registration form collects only the off-label transplant use indication and patient identification items.

**Inclusion period** Transplants between 31 July 2009 and 31 July 2014

**Inclusion Criteria**

After data collection, while completing the data set, a number of registrations showed to be not eligible for the Plerixafor Off-label study: patients appeared to be eligible for the CALM study, they had a transplant before the inclusion date, they died before transplant, or they did not yet have the transplant.

Received registrations on 28 February 2015 N=159; eligible registrations N=113

**159 registrations**

- Plerixafor given to patients / allogeneic donors
- Patient not eligible (label use: CALM study): 27
- HSCT before plerixafor introduction: 11 July 2009: 8
- Patient died before HSCT: 2
- Patient did not yet have HSCT: 2
- Eligible registrations: 106

**Participation per centre**

A Non-Interventional Study

31 July 2009 - 31 July 2014

Contact

Plerixafor Off-label study coordinator Annelies Kleijne
EBMT Data Office Leiden
+31 71 526 4746, a.kleijne@lumc.nl
Plerixafor Off-label Study Code 42286645

#EBMT15

www.ebmt.org