December 14, 2015

Joan McClure, MS
National Comprehensive Cancer Network
500 Old York Road, Suite 250
Jenkintown, PA 19046

Dear Ms. McClure,

On behalf of Sanofi U.S., I respectfully request the NCCN Myeloid Growth Factors panel review the enclosed data regarding the use of plerixafor for peripheral mobilization of autologous stem cells in patients with non-Hodgkins lymphoma (NHL) and multiple myeloma.

The enclosed submission contains a copy of the referenced data and the Mozobil prescribing information for your review.

I appreciate the opportunity to provide this information for consideration by the NCCN. If you have any questions or require additional information, please do not hesitate to contact us at (800) 633-1610, option 1 or via e-mail at MED.INFO@sanofi.com. Thank you for your time and consideration.

Sincerely,

Julia Petses, PharmD
Director, Oncology Medical Information Services
Sanofi U.S.

Enclosures: Submission with copy of referenced primary literature

MOZ-12654

Name: Julia Petses
Company/Organization: Sanofi U.S.
Address: 55 Corporate Drive, Bridgewater, NJ 08807
Phone: (800) 633-1610, option 1
Email: MED.INFO@sanofi.com
Date of request: December 14, 2015
NCCN Guidelines Panel: Myeloid Growth Factors

Specific Changes: For section MGF-F, "Myeloid Growth Factors in Mobilization and Post-Stem Cell Transplant"

- Reference plerixafor registration trials (references #1 and #2 below by DiPersio et al.) for statement: "Combination of filgrastim/filgrastim-sndz* with plerixafor (for selected patients with non-Hodgkin's lymphoma or multiple myeloma)"
- Change dosing statement to "Plerixafor dose: 0.24 mg/kg/day for patients weighing >83 kg; 20 mg/day fixed dose or 0.24 mg/kg/day for patients weighing ≤83 kg; maximum 4 doses (if creatinine clearance >50 mL/min, maximum dose 40 mg/d)"
- Change "Plerixafor is indicated for:" statement to "NCCN recommends plerixafor for:"

FDA Status: Plerixafor is indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells (HSCs) to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma (NHL) and multiple myeloma.

Rationale: The plerixafor phase III registration trials included patients undergoing peripheral blood collection for subsequent autologous transplantation in NHL and multiple myeloma patients, and were not limited to patients at "high risk" for poor mobilization (i.e., heavily pre-treated, prior treatment with >10 cycles cytotoxic chemotherapy, etc). Additionally, recommended dosing should be consistent with approved prescribing information.

References:

1. DiPersio JF, Micallef IN, Stiff PJ, et al. Phase III prospective randomized double-blind placebo-controlled trial of plerixafor plus granulocyte colony-stimulating factor compared with placebo plus granulocyte colony-stimulating factor for autologous stem-cell mobilization and transplantation for patients with non-Hodgkin's lymphoma. *J Clin Oncol*. 2009; 27(28):4767-4773.

2. DiPersio JF, Stadtmauer EA, Nademanee A, et al. Plerixafor and G-CSF versus placebo and G-CSF to mobilize hematopoietic stem cells for autologous stem cell transplantation in patients with multiple myeloma. *Blood*. 2009; 113(23):5720-5726.

3. Mozobil [package insert]. Cambridge, MA: Genzyme; 2015.

Sincerely,

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Sanofi U.S.

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