



Pfizer Inc
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Dear Healthcare Professional Letter

Pfizer Prepares for Voluntary Withdrawal of U.S. New Drug Application and for Discontinuation of Commercial Availability of Mylotarg for Relapsed Acute Myeloid Leukemia

IMPORTANT PRESCRIBING INFORMATION

June 21, 2010

Dear Healthcare Professional,

Re: Mylotarg[®] (gemtuzumab ozogamicin for Injection) for patients with CD33+ acute myeloid leukemia (AML) in first relapse who are 60 years of age or older and who are not considered candidates for other cytotoxic chemotherapy.

Pfizer would like to inform you of an important outcome for Mylotarg in the U.S. resulting from the failure of a required post-approval study to confirm the drug's clinical benefit. This study was stopped early based on interim results from the study showing no evidence of improved efficacy for patients treated with Mylotarg in addition to chemotherapy for previously untreated Acute Myeloid Leukemia (AML) (Southwest Oncology Group Web site. <https://swog.org/Visitors/Spring10GpMtg/ROS1004.asp>. Accessed June 17, 2010). The study also showed, in patients evaluable for induction toxicity, the fatal induction toxicity rate was significantly higher in the study arm containing Mylotarg combined with induction chemotherapy than the arm using chemotherapy alone (i.e. without Mylotarg).

After discussions with the U.S. Food and Drug Administration (FDA), Pfizer will be discontinuing commercial availability of Mylotarg and will be voluntarily withdrawing the New Drug Application (NDA) for Mylotarg in the United States effective October 15, 2010.

Patients who are currently taking Mylotarg and those patients who have been prescribed Mylotarg may continue their course of therapy, in consultation with their physicians. However, Pfizer recommends that no new patients in the U.S. be prescribed Mylotarg. Future use of Mylotarg for new patients in the U.S. will require physician submission of an Investigational New Drug (IND) application to the FDA.

Discussions are continuing with FDA to manage the orderly discontinuation of Mylotarg from commercial availability while ensuring continued access to the drug for your patients currently receiving the drug under the US labeled indication or through participation in approved clinical trials during this transition period up to October 15, 2010.

Data Summary:

Mylotarg[®] (gemtuzumab ozogamicin for Injection) was approved in the U.S. as a single agent treatment for patients with CD33 positive acute myeloid leukemia (AML) in first relapse who are 60 years of age or older and who are not considered candidates for other cytotoxic chemotherapy.

The approval of single agent Mylotarg in the U.S. was granted under FDA's accelerated approval regulations (Subpart H) based on overall response rate in three non-comparative studies. Accelerated approval is subject to the requirement to submit additional data to confirm clinical benefit. The required post approval study (SWOG Study S0106) combining Mylotarg with chemotherapeutic agents, daunorubicin and cytosine arabinoside, versus the same chemotherapy agent combination without Mylotarg in first-line AML patients under the age of 61 was conducted to confirm clinical benefit for Mylotarg. A total of 627 patients were enrolled in this study.

The decision to voluntarily withdraw the NDA is based on data from SWOG Study S0106 which failed to confirm clinical benefit. This study was stopped early based on interim results from the study showing no evidence of improved efficacy for patients treated with Mylotarg in addition to chemotherapy for previously untreated AML. Additionally, the fatal induction toxicity rate was significantly higher in the daunorubicin and cytosine arabinoside + Mylotarg arm (16/283=5.7% vs. 4/281=1.4%, P=0.01) (SWOG Update, April 15, 2010).

A second Phase 3 study (AML 15) enrolled over 1100 patients and evaluated the addition of Mylotarg to induction and/or consolidation chemotherapy in the first-line treatment of patients of ages 0-70 with AML. This study also failed to show improvement in relapse-free survival or overall survival in the intent to treat population with the addition of Mylotarg. Of note, the addition of Mylotarg to the induction chemotherapy treatment regimen did not add significant additional toxicity (Burnett et al., 2010, N. Engl. J. Med. submitted).

Although these studies did not confirm clinical benefit, it is Pfizer's view that the results do not directly impact the risk/benefit profile of Mylotarg in its approved indication as a single agent. While Pfizer is disappointed by the recent first line combination Phase 3 study results, we remain committed to provide Mylotarg in the near future to U.S. patients currently receiving the drug as agreed upon with the FDA.

For more information about Mylotarg, please contact Pfizer Medical Information at **1-800-438-1985** or **www.pfizer.com**. We hope you find this information helpful in understanding this subject so you can continue to appropriately treat your patients.

Sincerely,



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