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Pfizer to Withdraw Cancer Drug Mylotarg

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The Food and Drug Administration said Monday Pfizer Inc. is withdrawing its cancer drug Mylotarg from the U.S. market after a clinical study showed the drug wasn't effective and had more safety problems. The Wall Street Journal detailed this story well. Here are excerpts:

Mylotarg, marketed by Wyeth until Pfizer bought the company last year, was approved in 2000 as part of FDA's accelerated-approval program. The drug was approved for patients age 60 and older with a type of acute myeloid leukemia, a bone-marrow cancer. About 2,500 patients in the U.S. are treated with the product annually. Pfizer said it would voluntarily withdraw the new-drug application for Mylotarg effective Oct. 15, 2010, which will allow patients currently being treated with the product to stay on treatment if necessary. The FDA said Mylotarg shouldn't be offered to new patients.

In Mylotarg's case, studies conducted at the time of approval showed up to 30% of patients responded to the drug, which means the number of leukemia cells were reduced or eliminated. The FDA required Wyeth to conduct a follow-up study involving Mylotarg to see if the product allowed patients to live longer.

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The study, which involved 627 patients, started in 2004 and was stopped early in 2009 after an interim analysis showed patients being treated with Mylotarg didn't appear to receive any additional clinical benefit and had a higher death rate. All patients in the study were given standard chemotherapy drugs while some patients were also treated with Mylotarg.

The FDA also said at the time of its approval that Mylotarg was associated with a serious liver condition called veno-occlusive disease, the rate of which has increased in the postmarket setting.

Pfizer said a measure known as the fatal induction toxicity rate, or the death rate during initial treatment, showed it was significantly higher among patients receiving Mylotarg plus standard chemotherapy. Specifically, 16 patients out of 283 patients, or 5.7%, treated with Mylotarg plus chemotherapy died compared to four patients out of 281 patients, or 1.4%, who received only chemotherapy.

AML affects about 12,300 new patients annually in the U.S., according to the American Cancer Society.