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U.S. Department of Health & Human Services

U.S. Food and Drug Administration

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FDA NEWS RELEASE

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FDA: Pfizer Voluntarily Withdraws Cancer Treatment Mylotarg from U.S. Market

Pfizer Inc. today announced the voluntary withdrawal from the U.S. market of the drug Mylotarg (gemtuzumab ozogamicin) for patients with acute myeloid leukemia (AML), a bone marrow cancer. The company took the action at the request of the U.S. Food and Drug Administration after results from a recent clinical trial raised new concerns about the product's safety and the drug failed to demonstrate clinical benefit to patients enrolled in trials.

Mylotarg was approved in May 2000 under the FDA's accelerated approval program. This program allows the agency to approve a drug to treat serious diseases with an unmet medical need based on a surrogate endpoint – a laboratory measurement or a physical sign used as a substitute for a clinically meaningful endpoint that directly measures how a patient feels, functions, or survives.

Under accelerated approval, the company is required to conduct additional clinical trials after approval to confirm the drug's benefit. If those trials fail to confirm clinical benefit to patients, or if the company does not pursue the required confirmatory trials with due diligence, the FDA can withdraw the drug from the market using expedited procedures.

Mylotarg was approved to treat patients ages 60 years and older with recurrent AML who were not considered candidates for other chemotherapy. The initial approval was based on the surrogate endpoint of response rate (i.e., the percentage of patients whose leukemia decreased or disappeared in laboratory tests), observed in 142 patients with AML across three clinical trials.

A confirmatory, post approval clinical trial was begun by Wyeth (now Pfizer) in 2004. The trial was designed to determine whether adding Mylotarg to standard chemotherapy demonstrated an improvement in clinical benefit (survival time) to AML patients. The trial was stopped early when no improvement in clinical benefit was observed, and after a greater number of deaths occurred in the group of patients who received Mylotarg compared with those receiving chemotherapy alone.

At initial approval, Mylotarg was associated with a serious liver condition called veno-occlusive disease, which can be fatal. This rate has increased in the postmarket setting.

"Mylotarg was granted an accelerated approval to allow patient access to what was believed to be a promising new treatment for a devastating form of cancer," said Richard Pazdur, M.D., director, Office of Oncology Drug Products, part of FDA's Center for Drug Evaluation and Research. "However, a confirmatory clinical trial and years of postmarketing experience with the product have not shown evidence of clinical benefit in patients with AML."

As a result of the withdrawal, Mylotarg will not be commercially available to new patients. Patients who are currently receiving the drug may complete their therapy following consultation with their health care professional. Health care professionals should inform all patients receiving Mylotarg of the product's potential safety risks.

Following the withdrawal, any future use of Mylotarg in the United States will require submission of an investigational new drug application to FDA.

Mylotarg is manufactured by New York City-based Pfizer.

For more information:

- Pfizer: Mylotarg Withdrawal[1]
- FDA: Access to Investigational Drugs[2]
- FDA: Office of Oncology Drug Products[3]

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