Mylotarg (gemtuzumab ozogamicin): Market Withdrawal

U.S. Food & Drug Administration

ISSUE: FDA notified healthcare professionals that results from a recent clinical trial raised new concerns about the productÃ¢??s safety, and the drug failed to demonstrate clinical benefit to patients enrolled in trials.

BACKGROUND: Mylotarg (gemtuzumab ozogamicin), indicated for treatment of acute myeloid leukemia (AML), a bone marrow cancer, was approved in May 2000 under the FDAÃ¢??s accelerated approval program. 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.

RECOMMENDATION: 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 productÃ¢??s potential safety risks. Any future use of Mylotarg in the United States will require submission of an investigational new drug application to the FDA.

[06/21/2010 - News Release [1] - FDA]

SOURCE [2]

Links:
[1] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm216448.htm
[2] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm216458.htm