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Targeted therapy for acute myeloid leukemia

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Singapore - The steady march of progress in new treatments for patients with acute myeloid leukemia (AML), one of the deadliest blood cancers which takes more than 10,000 lives in the U.S. each year, continues with the U.S. Food & Drug Administration approval of gemtuzumab ozogamicin (Mylotarg).

After four decades of little progress for this lethal disease, FDA's approval of Mylotarg, manufactured by Pfizer, marks the fourth approval of a therapy for AML patients in just the past three months. The Leukemia & Lymphoma Society (LLS) has played a role in the advancement of each of these therapies at some point along their development.

The FDA approved Mylotarg for treatment of adults with newly diagnosed AML both in combination with chemotherapy and on its own, and for the treatment of patients aged 2 years and older who have experienced a relapse or who have not responded to initial treatment.

Mylotarg is approved for patients whose AML cells express a specific protein, CD33, commonly found on the surface of the cancer cells. The drug consists of an antibody that binds to the CD33 protein and a toxin that kills the cancer cells.

More than 21,000 people in the United States are diagnosed with AML each year.

Mylotarg had originally been FDA approved in 2000 under the agency's accelerated approval process, but was voluntarily removed from the market in 2010 because a post-marketing trial failed to show improvement in multiple patient outcome measurements. It also was found to result in a high rate of fatalities due to toxicity.

On July 11, an FDA review panel recommended its return to market, citing a new clinical trial where a lower dose of Mylotarg was used. In this study, there was improvement in the patients' response to treatment. Today's FDA decision was also based on two studies testing the drug as a stand-alone treatment.

"FDA's approval is another important step in addressing the critical unmet medical need for AML patients," said Louis J. DeGennaro, LLS President and CEO. "After so many years of limited options we are finally building a treatment armamentarium to give AML patients more choices and a chance for better outcomes."