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FDA NEWS RELEASE

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FDA approves new treatment for late-stage breast cancer

En Español (/NewsEvents/Newsroom/ComunicadosdePrensa/ucm341213.htm)

The U.S. Food and Drug Administration today approved Kadcyla (ado-trastuzumab emtansine), a new therapy for patients with HER2-positive, late-stage (metastatic) breast cancer.

HER2 is a protein involved in normal cell growth. It is found in increased amounts on some types of cancer cells (HER2-positive), including some breast cancers. In these HER2-positive breast cancers, the increased amount of the HER2 protein contributes to cancer cell growth and survival.

Kadcyla is intended for patients who were previously treated with trastuzumab, another anti-HER2 therapy, and taxanes, a class of chemotherapy drugs commonly used for the treatment of breast cancer.

“Kadcyla is trastuzumab connected to a drug called DM1 that interferes with cancer cell growth,” said Richard Pazdur, M.D., director of the Office of Hematology and Oncology Products in the FDA’s Center for Drug Evaluation and Research. “Kadcyla delivers the drug to the cancer site to shrink the tumor, slow disease progression and prolong survival. It is the fourth approved drug that targets the HER2 protein.”

Referred to as T-DM1 during clinical research, Kadcyla was reviewed under the FDA’s priority review program, which provides for an expedited six-month review of drugs that may provide safe and effective therapy when no satisfactory alternative therapy exists, or offer significant improvement compared to marketed products. Other FDA-approved drugs used to treat HER2-positive breast cancer include trastuzumab (1998), lapatinib (2007) and pertuzumab (2012).

The safety and effectiveness of Kadcyla were evaluated in a clinical study of 991 patients randomly assigned to receive Kadcyla or lapatinib plus capecitabine, another chemotherapy drug. Patients received treatment until either the cancer progressed or the side effects became intolerable. The study

was designed to measure progression-free survival, the length of time patients lived without the cancer progressing, and overall survival, the length of time patients lived before death.

Results showed that patients treated with Kadcyla had a median progression-free survival of 9.6 months compared to 6.4 months in patients treated with lapatinib plus capecitabine. The median overall survival was 30.9 months in the Kadcyla group and 25.1 months in the lapatinib plus capecitabine group.

Kadcyla is being approved with a Boxed Warning alerting patients and health care professionals that the drug can cause liver toxicity, heart toxicity and death. The drug can also cause severe life-threatening birth defects, and pregnancy status should be verified prior to starting Kadcyla treatment.

The most common side effects reported in patients treated with Kadcyla were nausea, fatigue, pain in the muscles or joints, low levels of platelets in the blood (thrombocytopenia), increased levels of liver enzymes, headache, and constipation.

Breast cancer (http://www.cancer.gov/cancertopics/types/breast) is the second leading cause of cancer-related death among women. An estimated 232,340 women will be diagnosed with breast cancer, and 39,620 will die from the disease in 2013, according to the National Cancer Institute. Almost 20 percent of breast cancers have increased amounts of the HER2 protein.

Kadcyla, trastuzumab and pertuzumab are marketed by South San Francisco, Calif.-based Genentech, a member of the Roche Group. Lapatinib is marketed by GlaxoSmithKline, based in Research Triangle Park, N.C.

For more information:

FDA: Office of Hematology and Oncology Products (/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm091745.htm)

FDA: Approved Drugs: Questions and Answers (/Drugs/ResourcesForYou/Consumers/ucm054420.htm)

FDA: Drug Innovation (http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/default.htm)

NCI: Breast Cancer (http://www.cancer.gov/cancertopics/types/breast)

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