Beat: News

FDA approves new late-stage breast cancer treatment

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USPA News - The U.S. Food and Drug Administration (FDA) on Friday approved Kadcyla, a new therapy for patients with late-stage breast cancer. Richard Pazdur, M.D., director of the Office of Hematology and Oncology Products in the FDA`s Center for Drug Evaluation and Research, explained that Kadcyla delivers the drug to the cancer site to shrink the tumor, slow disease progression and prolong survival. Kadclya(ado-trastuzumab emtansine) is directed for patients whoe are HER2-positive.

HER2 is a protein involved in normal cell growth, but 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. The treatment, which is the FDA`s fourth approved drug that targets the HER2 protein, is trastuzumab connected to a drug called DM1 that interferes with cancer cell growth, added Pazdur. 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. The FDA said 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. 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. However, the FDA is labeling the drug 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. Breast cancer 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. Other FDA-approved drugs used to treat HER2-positive breast cancer include trastuzumab (1998), lapatinib (2007) and pertuzumab (2012).

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