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FDA Approves Tykerb for Advanced Breast Cancer Patients

The Food and Drug Administration (FDA) today approved Tykerb (lapatinib), a new targeted anti-cancer treatment, to be used in combination with capectabine (Xeloda), another cancer drug, for patients with advanced, metastatic breast cancer that is HER2 positive (tumors that exhibit HER2 protein). The combination treatment is indicated for women who have received prior therapy with other cancer drugs, including an anthracycline, a taxane, and trastuzumab (Herceptin). According to the American Cancer Society, about 180,000 new cases of breast cancer are diagnosed each year. Approximately 8,000 to 10,000 women die from metastatic HER2 positive breast cancer each year.

Tykerb, a new molecular entity (NME), is a kinase inhibitor working through multiple pathways (targets) to deprive tumor cells of signals needed to grow. Unlike, for example, trastuzumab — a monoclonal antibody, which is a large protein molecule that targets the part of the HER2 protein on the outside of the cell — Tykerb is a small molecule that enters the cell and blocks the function of this and other proteins. Because of this difference in mechanism of action, Tykerb works in some HER2 positive breast cancers that have been treated with trastuzumab and are no longer benefiting.

"Today's approval is a step forward in making new treatments available for patients who have progression o their breast cancer after treatment with some of the most effective breast cancer therapies available," saic Steven Galson, MD, M.P.H., Director of FDA's Center for Drug Evaluation and Research. "New targeted therapies such as Tykerb are helping expand options for patients."

The approval of Tykerb was based on a randomized clinical trial in about 400 women with advanced or metastatic breast cancer that was also HER2 positive. In the trial, half the patients received Tykerb with capecitabine and half received capecitabine alone. Compared to patients receiving capecitabine alone, the group of patients receiving Tykerb with capecitabine had a statistically significant improvement in the time to tumor progression. In addition, the tumor response rate was higher in the group of patients receiving Tykerb with capecitabine (24 percent vs. 14 percent). The survival data are not yet mature.

The most commonly reported Tykerb-related side effects included diarrhea, nausea, vomiting, rash and hand-foot syndrome which may include numbness, tingling, redness, swelling and discomfort of hands and feet. Generally reversible decreases in heart function (that can lead to shortness of breath) have also beer reported in a small percentage of patients. Patients should talk to their doctor about potential side effects, potential drug interactions, and other medical conditions including heart and liver problems. Tykerb is available in tablets of 250 mg. An undivided dose of 1,250 mg should be taken orally once daily for 21 days and in combination with capecitabine on days 1-14 of a 21 day cycle.

Tykerb will be distributed by GlaxoSmithKline, of Research Triangle Park, North Carolina.

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