FDA Expands Use of Approved Breast Cancer Drug

February 1, 2010

Washington D.C. (RPRN) 02/01/10 — Provides oral regime for hormone positive and HER2-positive advanced breast cancer

The U.S. Food and Drug Administration today approved Tykerb (lapatinib) in combination with Femara (letrozole) to treat hormone positive and HER2-positive advanced breast cancer in postmenopausal women for whom hormonal therapy is indicated.

HER2 is a protein involved in normal cell growth. It is found on some types of cancer cells, including breast cancer cells. In hormone positive breast cancer, the presence of certain hormones contributes to breast cancer growth. In HER2-positive breast cancer, stimulation of the HER2 receptor contributes to cancer cell growth. Breast cancer is the second leading cause of death among women. More than 192,000 women will be diagnosed with breast cancer this year.

“This drug combination of Tykerb plus Femara provides women being treated for advanced breast cancer with an important treatment option. This entirely oral treatment regimen works by targeting both HER2 and the hormone receptors, thereby slowing the cancer cells’ ability to grow or spread,” said Richard Pazdur, M.D., director of the Office of Oncology Drug Products, in the FDA’s Center for Drug Evaluation and Research.

Women with HER2-positive disease receiving the Tykerb plus Femara combination more than doubled the time they lived without the cancer progressing compared with those receiving Femara alone (35 weeks vs. 13

weeks). Women in the company sponsored study were randomized to receive Tykerb plus Femara or Femara alone. It is too early to determine whether an improvement in overall survival will be observed in the clinical trial.

Tykerb works by depriving tumor cells of signals needed to grow. Tykerb enters the cell and blocks the function of the HER2 protein.

Tykerb was initially approved in combination with a chemotherapy drug, Xeloda (capecitabine) in 2007. This combination was used to treat women with advanced breast cancer tumors with the HER2 protein who had received prior treatment with chemotherapy drugs, including an anthracycline and a taxane, and Herceptin (trastuzumab), an anti-cancer antibody used to treat HER2-positive advanced breast cancer.

Safety information from this study was consistent with previous Tykerb clinical studies in advanced breast cancer. The most commonly reported side effects of the combination were diarrhea, rash, nausea and fatigue. Treatment with Tykerb also has been associated with decreases in heart function, liver damage, and lung tissue inflammation. Fetal harm may occur if used to treat advanced breast cancer in pregnant women. Patients should talk to their health care provider about the potential side effects, drug interactions, and other medical conditions.

Tykerb is marketed by Collegeville, Pa.-based GlaxoSmithKline.
Femara is marketed by Lebanon, Pa.-based Novartis AG.

For more information:

FDA Office of Oncology Drug Products
http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm091745.htm

National Cancer Institute – Breast Cancer
http://www.cancer.gov/cancertopics/types/breast

RSS Feed for FDA News Releases [what is RSS?]

About the author:

FDA is an agency within the Department of Health and Human Services and consists of seven centers and offices

---

Filed Under: FDA- Pharmaceutical news, Health and Fitness, Food-Nutrition, Lifestyle, PRESS RELEASE

RUSH PR NEWS newswire and press release services at rushprnews.com / Anne Howard annehowardpublicist.com