FDA News Release

FDA approves new treatment to reduce the risk of breast cancer returning

For Immediate Release

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Release

The U.S. Food and Drug Administration today approved Nerlynx (neratinib) for the extended adjuvant treatment of early-stage, HER2-positive breast cancer. For patients with this type of cancer, Nerlynx is the first extended adjuvant therapy, a form of therapy that is taken after an initial treatment to further lower the risk of the cancer coming back. Nerlynx is indicated for adult patients who have been previously treated with a regimen that includes the drug trastuzumab.

“HER2-positive breast cancers are aggressive tumors and can spread to other parts of the body, making adjuvant therapy an important part of the treatment plan,” said Richard Pazdur, M.D., director of the FDA’s Oncology Center of Excellence and acting director of the Office of Hematology and Oncology Products in the FDA’s Center for Drug Evaluation and Research. “Now, these patients have an option after initial treatment that may help keep the cancer from coming back.”

Breast cancer is the most common form of cancer in the United States. The National Cancer Institute (NCI) estimates approximately 252,710 women will be diagnosed with breast cancer this year, and 40,610 will die of the disease. According to the NCI, approximately 15 percent of patients with breast cancer have tumors that are HER2-positive.

Nerlynx is a kinase inhibitor that works by blocking several enzymes that promote cell growth.

The safety and efficacy of Nerlynx were studied in a randomized trial of 2,840 patients with early-stage, HER2-positive breast cancer who completed treatment with trastuzumab within the previous two years. The study measured the amount of time after the start of the trial that it took for the cancer to come back or for death to occur from any cause (invasive, disease-free survival). After two years, 94.2 percent of patients treated with Nerlynx had not experienced cancer recurrence or death compared with 91.9 percent of patients receiving placebo.

Common side effects of Nerlynx include diarrhea, nausea, abdominal pain, fatigue, vomiting, rash, swollen and sore mouth (stomatitis), decreased appetite, muscle spasms, indigestion (dyspepsia), liver damage (AST or ALT enzyme increase), nail disorder, dry skin, abdominal swelling (distention), weight loss and urinary tract infection.

Patients should be given loperamide for the first 56 days of treatment with Nerlynx and as needed thereafter to help manage diarrhea. Additional antidiarrheals, fluids and electrolytes should also be given as clinically indicated to help manage diarrhea. Patients who experience severe side effects, including diarrhea or liver damage (hepatoxicity), should stop taking Nerlynx. Women who are pregnant or breastfeeding should not take Nerlynx because it may cause harm to a developing fetus or a newborn baby.

The FDA granted the approval of Nerlynx to Puma Biotechnology Inc.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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