MedicalXpress

Nerlynx approved to help prevent breast cancer's return

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(HealthDay)—Nerlynx (neratinib) has been approved by the U.S. Food and Drug Administration to help prevent HER2-positive breast cancer from returning.

It's the first drug designed to prevent return of HER2-positive breast cancer, a genetic form of the disease that's particularly aggressive and can spread to other parts of the body, the agency said in a news release.

The drug is meant for what's known as extended adjuvant therapy—given after initial treatment, to further reduce the risk that cancer will return.

Breast cancer is the most common form of cancer in the United States, the FDA said. The disease is projected to be diagnosed in more than 250,000 women this year, and more than 46,000 are likely to die of the disease, according to the U.S. National Cancer Institute.

Nerlynx, among a class of drugs designed to block enzymes that fuel cancer-cell growth, was evaluated in clinical studies involving more than 2,800 people with early-stage HER2-positive breast cancer who had completed treatment with the chemotherapy drug trastuzumab. After two years, 94.2 percent of users hadn't had their cancer recur, compared with 91.9 percent of those treated with an inactive placebo.

The most common side effects of Nerlynx included diarrhea, nausea, abdominal pain, fatigue, vomiting, rash and mouth swelling. People who

take the drug should be given the anti-diarrhea medication loperamide for the first 50 days of use, the FDA advised.

Women who are pregnant shouldn't take Nerlynx because it can harm a developing fetus, the agency added.

Approval for Nerlynx was granted to Puma Biotechnology, based in Los Angeles.

More information: Visit the FDA to learn more.