FDA Approves New Breast Cancer Treatment

The US Food and Drug Administration (FDA) has approved Nerlynx (neratinib), made by Puma Biotechnology for the extended adjuvant treatment of early-stage, HER2-positive breast cancer, aggressive tumors that can spread to other parts of the body.

For patients with this type of cancer, Nerlynx, a kinase inhibitor that works by blocking several enzymes that promote cell growth, is the first extended adjuvant therapy, a form of therapy taken after an initial treatment to further lower the risk of the cancer returning. The drug is indicated for adult patients who have been previously treated with a regimen that includes the drug trastuzumab.

Safety and efficacy of Nerlynx were studied in a randomized trial of 2,840 patients with early-stage HER2-positive breast cancer who had 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 return or for death to occur from any cause. After two years, 94.2% of patients treated with Nerlynx had not experienced cancer recurrence or death compared with 91.9% of patients receiving a placebo, reports in medical journals said.

The treatment comes with a number of side effects, many of them not life-threatening but is not recommended for women who are pregnant or breastfeeding.

According to the US National Cancer Institute, NCI, around 15% of patients with breast cancer have tumors that are HER2-positive.

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