FDA approves neratinib for metastatic HER2+ breast cancer

April 2020—The FDA approved neratinib (Nerlynx, Puma Biotechnology) in combination with capecitabine for adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2–based regimens in the metastatic setting.

Efficacy of neratinib with capecitabine was investigated in NALA, a randomized, multicenter, open-label clinical trial of 621 patients with metastatic HER2-positive breast cancer who received two or more prior anti-HER2–based regimens in the metastatic setting. Median progression-free survival was 5.6 months (95 percent CI: 4.9, 6.9) for patients who received neratinib with capecitabine and 5.5 months (95 percent CI: 4.3, 5.6) for those receiving lapatinib with capecitabine (hazard ratio, 0.76; 95 percent CI: 0.63, 0.93; $P = 0.0059$). The PFS rate at 12 months was 29 percent (95 percent CI: 23, 35) versus 15 percent (95 percent CI: 10, 20), respectively. Median overall survival was 21 months (95 percent CI: 17.7, 23.8) for patients receiving neratinib with capecitabine compared with 18.7 months (95 percent CI: 15.5, 21.2) for those receiving lapatinib plus capecitabine (HR, 0.88; 95 percent CI: 0.72, 1.07; $P = 0.2086$).

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