Nerlynx® (neratinib) – New indication

- On February 26, 2020, Puma Biotechnology announced the FDA approval of Nerlynx (neratinib), in combination with capecitabine for the treatment of adult patients with advanced or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer who have received two or more prior anti-HER2 based regimens in the metastatic setting.

- Nerlynx is also approved as a single agent for the extended adjuvant treatment of adult patients with early-stage HER2-positive breast cancer, to follow adjuvant trastuzumab based therapy.

- HER2-positive breast cancer is often more aggressive than other types of breast cancer, increasing the risk of disease progression and death. Approximately 20% to 25% of breast cancer tumors over-express the HER2 protein.

- The approval of Nerlynx for the new indication was based on NALA, a randomized, open-label study in 621 patients with metastatic HER2 positive breast cancer who had received 2 or more prior anti-HER2 based regimens in the metastatic setting. Patients were randomized to receive Nerlynx in combination with capecitabine or Tykerb® (lapatinib) in combination with capecitabine. The main efficacy outcome measures were progression-free survival (PFS) and overall survival (OS).

    - Median PFS was 5.6 months (95% CI: 4.9, 6.9) for Nerlynx + capecitabine vs. 5.5 months (95% CI: 4.3, 5.6) for Tykerb + capecitabine (hazard ratio [HR] 0.76; 95% CI: 0.63, 0.93; p = 0.0059).
    - Median OS was 21.0 months (95% CI: 17.7, 23.8) for Nerlynx + capecitabine vs. 18.7 months (95% CI: 15.5, 21.2) for Tykerb + capecitabine (HR 0.88; 95% CI: 0.72, 1.07; p = 0.2086).
    - The objective response rate was 32.8% (95% CI: 27.1, 38.9) for Nerlynx + capecitabine vs. 26.7% (95% CI: 21.5, 32.4) for Tykerb + capecitabine.
    - The median duration of response was 8.5 months (95% CI: 5.6, 11.2) for Nerlynx + capecitabine vs. 5.6 months (95% CI: 4.2, 6.4) for Tykerb + capecitabine.

- The most common adverse reactions (≥ 5%) with Nerlynx use in combination with capecitabine were diarrhea, nausea, vomiting, decreased appetite, constipation, fatigue/asthenia, weight decreased, dizziness, back pain, arthralgia, urinary tract infection, upper respiratory tract infection, abdominal distention, renal impairment, and muscle spasms.

- The recommended dose of Nerlynx in the advanced or metastatic breast cancer setting is 240 mg (six tablets) given orally once daily with food on days 1 to 21 of a 21-day cycle plus capecitabine (750 mg/m^2 given orally twice daily) on days 1 to 14 of a 21-day cycle until disease progression or unacceptable toxicities.

    - Antidiarrheal prophylaxis should be administered during the first 2 cycles of treatment and initiated with the first dose of Nerlynx. If diarrhea occurs despite prophylaxis, treat with additional antidiarrheals, fluids and electrolytes as clinically indicated. Nerlynx dose interruptions and dose reductions may also be required to manage diarrhea.

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— Refer to the Nerlynx drug label for dosing as an extended adjuvant treatment of early stage breast cancer.

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