Perjeta® (pertuzumab) – Expanded indication

- On December 20, 2017, Genentech announced the FDA approval of Perjeta (pertuzumab) for use in combination with Herceptin® (trastuzumab) and chemotherapy for the adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence.

- The FDA has also converted the previously granted accelerated approval of the Perjeta-based regimen to full approval for neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer for use in combination with Herceptin and chemotherapy.

    — Previously, Perjeta was approved for use in combination with Herceptin and docetaxel for the neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer as part of a complete treatment regimen for early breast cancer.
    — Perjeta is also approved for use in combination with Herceptin and docetaxel for the treatment of patients with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.

- The expanded indication of Perjeta is based on results of the APHINITY study. APHINITY involved 4,804 patients randomized to Perjeta or placebo in combination with adjuvant Herceptin and chemotherapy. The major efficacy outcome was invasive-disease free survival (IDFS).

    — After a median follow-up of 45.4 months, a statistically significant improvement in IDFS was demonstrated in patients randomized to Perjeta vs. placebo (HR = 0.82; 95% CI 0.67, 1.00, p = 0.047).
    — There was no difference in overall survival between the Perjeta and placebo groups (3.3% vs. 3.7%, respectively; HR = 0.89; 95% CI: 0.66, 1.21).

- The most common adverse reactions (> 30%) with Perjeta use in combination with Herceptin and chemotherapy were diarrhea, nausea, alopecia, fatigue, peripheral neuropathy and vomiting.

- Refer to the Perjeta drug label for dosing information for all indications.