PERJETA™ (pertuzumab) is a HER2/neu receptor antagonist that is NOW APPROVED in combination with trastuzumab 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. 

FDA approval of PERJETA is based on CLEOPATRA, a randomized, multicenter, double-blind, placebo-controlled, Phase III clinical trial conducted in 808 patients with HER2-positive metastatic breast cancer. 

Pivotal CLEOPATRA trial demonstrated a significant efficacy benefit in HER2-positive mBC. 

- PERJETA in combination with trastuzumab and docetaxel extended median progression-free survival (PFS) to 18.5 months compared to 12.4 months in the trastuzumab + docetaxel arm.
- The most common adverse reactions (>30%) seen with PERJETA in combination with trastuzumab and docetaxel were diarrhea, alopecia, neutropenia, nausea, fatigue, rash, and peripheral neuropathy.

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In the randomized trial, the overall frequency of infusion reactions/anaphylaxis was 10.8% in the PERJETA-treated group compared to 9.1% in the placebo-treated group when all drugs were administered on the same day. The most common infusion reactions in the PERJETA-treated group (≥1.0%) were fatigue, dysgeusia, hypersensitivity, myalgia, and vomiting.

If a significant infusion reaction occurs, slow or interrupt the infusion and administer appropriate medical therapies.

When all drugs were administered on the same day, the most common infusion reactions in the PERJETA-treated group and the placebo-treated group were fatigue, dysgeusia, hypersensitivity, myalgia, and vomiting.

In the randomized trial, the overall frequency of hypersensitivity reactions/anaphylaxis was 10.8% in the PERJETA-treated group and 3.1% in the placebo-treated group.

If a significant infusion reaction occurs, slow or interrupt the infusion and administer appropriate medical therapies. Monitor patients carefully until complete resolution of signs and symptoms. Consider permanent discontinuation in patients with severe infusion reactions.

PERJETA has been associated with infusion and hypersensitivity reactions 

When all drugs were administered on the same day, the most common infusion reactions in the PERJETA-treated group (1-9%) were fatigue, dysgeusia, hypersensitivity, myalgia, and vomiting.

Left Ventricular Dysfunction

- Left ventricular dysfunction, which includes symptomatic left ventricular systolic dysfunction (LVSD) (congestive heart failure) and decreases in left ventricular ejection fraction (LVEF), occurred in 4.4% of patients in the PERJETA-treated group and 8.3% of patients in the placebo-treated group.
- Assess LVEF prior to initiation of PERJETA and at regular intervals (eg, every 3 months) during treatment to ensure that LVEF is within your institution's normal limits.
- Withhold PERJETA and trastuzumab and repeat LVEF assessment within 3 weeks in patients with significant decrease in LVEF. Discontinue PERJETA and trastuzumab if the LVEF has not improved or has declined further.

Infusion-Associated Reactions, Hypersensitivity Reactions / Anaphylaxis

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- Please see PERJETA full Prescribing Information including Boxed WARNING for additional Important Safety Information.

Important Safety Information

Boxed WARNING: Embryo-Fetal Toxicity

- Exposure to PERJETA can result in embryo-fetal death and birth defects. Studies in animals have resulted in oligohydramnios, delayed renal development, and death. Advise patients of these risks and the need for effective contraception.
- Verify pregnancy status prior to the initiation of PERJETA. Advise patients of the risks of embryo-fetal death and birth defects and the need for contraception during and after treatment. Advise patients to contact their healthcare provider immediately if they suspect they may be pregnant.
- Encourage women who may be exposed to PERJETA during pregnancy to enroll in the MotHER Pregnancy Registry by contacting 1-800-690-8720.
- Monitor patients who become pregnant during PERJETA therapy for oligohydramnios.

Additional Important Safety Information

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