# Clinical Cases From Patients With HER2+ Metastatic Breast Cancer

#### **PROGRAM OVERVIEW:**

This program presents hypothetical cases of patients with HER2+ metastatic breast cancer. Each case will discuss eligibility and treatment; the first case will focus on a patient treated with PERJETA, and the second case will focus on a patient treated with KADCYLA.

#### PRESENTED BY

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#### PROGRAM DATE AND LOCATION

Thursday, February 20, 2014 The Stone Terrace 2275 kuser road, Hamilton Square, NJ 08690

### GENENTECH HOSTS

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#### SCHEDULE OF EVENTS

6:00 PM Arrival Time 6:30 PM Presentation Time

#### EVENT CODE

Event Code: PRF42143

# Please note that this is a promotional educational program; CME credit will not be available.

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**Indication:** PERJETA® (pertuzumab) is a HER2/neu receptor antagonist indicated in combination with Herceptin® (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.

#### **Boxed WARNINGS: Cardiomyopathy and Embryo-Fetal Toxicity**

- PERJETA administration can result in subclinical and clinical cardiac failure. Evaluate left ventricular function in all patients prior to and during treatment with PERJETA. Discontinue PERJETA treatment for a confirmed clinically significant decrease in left ventricular function
- 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



**INDICATION: KADCYLA®** (ado-trastuzumab emtansine), as a single agent, is indicated for the treatment of patients with HER2-positive, metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Patients should have either:

- Received prior therapy for metastatic disease, or
- Developed disease recurrence during or within six months of completing adjuvant therapy.

# Boxed WARNINGS: HEPATOTOXICITY, CARDIAC TOXICITY, EMBRYO-FETAL TOXICITY

- Do Not Substitute KADCYLA for or with Trastuzumab
- Hepatotoxicity: Serious hepatotoxicity has been reported, including liver failure and death in patients treated with KADCYLA. Monitor serum transaminases and bilirubin prior to initiation of KADCYLA treatment and prior to each KADCYLA dose. Reduce dose or discontinue KADCYLA as appropriate in cases of increased serum transaminases or total bilirubin
- Cardiac Toxicity: KADCYLA administration may lead to reductions in left ventricular ejection fraction (LVEF). Evaluate left ventricular function in all patients prior to and during treatment with KADCYLA. Withhold treatment for clinically significant decrease in left ventricular function
- Embryo-Fetal Toxicity: Exposure to KADCYLA can result in embryo-fetal death or birth defects. Advise patients of these risks and the need for effective contraception

Please see reverse and accompanying full Prescribing Information for additional Important Safety Information, including Boxed WARNINGS.

## **Safety Information for PERJETA (pertuzumab)**

**Important Safety Information** 

**Boxed WARNINGS: Cardiomyopathy and Embryo-Fetal Toxicity** 

- PERJETA administration can result in subclinical and clinical cardiac failure. Evaluate left ventricular function in all
  patients prior to and during treatment with PERJETA. Discontinue PERJETA treatment for a confirmed clinically significant
  decrease in left ventricular function
- 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

#### **Additional Important Safety Information**

- PERJETA is contraindicated in patients with known hypersensitivity to pertuzumab or to any of its excipients
- PERJETA has been associated with infusion and hypersensitivity reactions/anaphylaxis
- Detection of HER2 protein overexpression is necessary for selection of patients appropriate for PERJETA therapy
- In metastatic breast cancer, the most common adverse reactions (> 30%) seen with PERJETA in combination with Herceptin and docetaxel were diarrhea, alopecia, neutropenia, nausea, fatigue, rash, and peripheral neuropathy

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at (888) 835-2555.

## **Safety Information for KADCYLA (ado-trastuzumab emtansine)**

**Important Safety Information** 

Boxed WARNINGS: HEPATOTOXICITY, CARDIAC TOXICITY, EMBRYO-FETAL TOXICITY

- Do Not Substitute KADCYLA for or with Trastuzumab
- Hepatotoxicity: Serious hepatotoxicity has been reported, including liver failure and death in patients treated with KADCYLA. Monitor serum transaminases and bilirubin prior to initiation of KADCYLA treatment and prior to each KADCYLA dose. Reduce dose or discontinue KADCYLA as appropriate in cases of increased serum transaminases or total bilirubin
- Cardiac Toxicity: KADCYLA administration may lead to reductions in left ventricular ejection fraction (LVEF). Evaluate
  left ventricular function in all patients prior to and during treatment with KADCYLA. Withhold treatment for clinically
  significant decrease in left ventricular function
- Embryo-Fetal Toxicity: Exposure to KADCYLA can result in embryo-fetal death or birth defects. Advise patients of these risks and the need for effective contraception

#### The following additional serious adverse reactions have been reported in clinical trials with KADCYLA:

- Interstitial lung disease (ILD), including pneumonitis, some leading to acute respiratory distress syndrome or fatality: KADCYLA should be permanently discontinued in patients diagnosed with ILD or pneumonitis
- Infusion-related reactions (IRR), hypersensitivity: KADCYLA treatment should be interrupted in patients with severe IRR and permanently discontinued in the event of a life-threatening IRR
- Thrombocytopenia: Monitor platelet counts prior to initiation of KADCYLA and prior to each dose. Institute dose modifications as appropriate
- Peripheral neuropathy: KADCYLA should be temporarily discontinued in patients experiencing grade 3 or 4 peripheral neuropathy until
  resolution to ≤ grade 2
- Reactions secondary to extravasation: The infusion site should be closely monitored for possible subcutaneous infiltration during drug administration

#### **Additional Important Safety Information**

- Detection of HER2 protein overexpression or gene amplification is necessary for selection of patients appropriate for KADCYLA therapy
- Nursing mothers: Discontinue nursing or discontinue KADCYLA taking into consideration the importance of the drug to the mother
- The most common adverse drug reactions (frequency > 25%) across clinical trials with KADCYLA were fatigue, nausea, musculoskeletal pain, thrombocytopenia, headache, increased transaminases, and constipation

You are encouraged to report side effects to Genentech and the FDA. You may contact Genentech by calling 1-888-835-2555. You may contact the FDA by visiting www.fda.gov/medwatch or calling 1-800-FDA-1088.

Please see accompanying full Prescribing Information for additional Important Safety Information, including Boxed WARNINGS.

