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**KADCYLA™ (ado-trastuzumab emtansine)
for the Treatment of HER2-Positive
Metastatic Breast Cancer in Patients
Previously Treated With Trastuzumab and
a Taxane**

This program is presented on behalf of Genentech, and the information presented is consistent with FDA guidelines. The speaker has been compensated by Genentech to serve as faculty for this program (if applicable to the speaker).

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Kadcyla™
ado-trastuzumab emtansine

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**KADCYLA™ (ado-trastuzumab emtansine) for the Treatment of HER2-Positive
Metastatic Breast Cancer in Patients Previously Treated With Trastuzumab and a
Taxane**

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KADCYLA: Indication

- KADCYLA™ (ado-trastuzumab emtansine), injection for intravenous use, 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.

Please see slides 3-5, 36-43 and KADCYLA full Prescribing Information for additional Important Safety Information.

Abbreviation: HER2, human epidermal growth factor receptor 2.

Reference: KADCYLA [package insert]. South San Francisco, CA: Genentech USA, Inc; February 2013.

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KADCYLA: Indication

- Review as stated

Reference

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KADCYLA: 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.

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KADCYLA: Boxed WARNINGS

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Important Safety Information

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 \leq Grade 2.
- Reactions secondary to **extravasation**: The infusion site should be closely monitored for possible subcutaneous infiltration during drug administration.

Please see slides 3-5, 36-43 and KADCYLA full Prescribing Information for additional Important Safety Information.

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KADCYLA: Important Safety Information

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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 slides 3-5, 36-43 and KADCYLA full Prescribing Information for additional Important Safety Information.

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KADCYLA: Additional Important Safety Information

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