KADCYLA contains the active antibody trastuzumab, the cytotoxic agent DM1, and a stable linker

Indication

KADCYLA® (ado-trastuzumab emtansine), as a single agent, is indicated for the treatment of patients with HER2-positive (HER2+), metastatic breast cancer (MBC) 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.

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**

Genentech
A Member of the Roche Group

Additional Important Safety Inform

Left Ventricular Dysfunction (LVD)

- Patients treated with KADCYLA are at increased risk LVD. In EMILIA, LVD occurred in 1.8% of patients in treated group and in 3.3% in the comparator group. F discontinue KADCYLA if LVEF has not improved or has

Pregnancy Registry

- Advise patients to contact their healthcare provider ir they suspect they may be pregnant. Encourage wome be exposed to KADCYLA during pregnancy to enroll ir Pregnancy Registry by contacting 1-800-690-6720

Pulmonary Toxicity

- Cases of interstitial lung disease (ILD), including pneu leading to acute respiratory distress syndrome or fata been reported in clinical trials with KADCYLA. In EMI frequency of pneumonitis was 1.2%
- Treatment with KADCYLA should be permanently dis patients diagnosed with ILD or pneumonitis

Infusion-Related Reactions, Hypersensitivity Rea

- Treatment with KADCYLA has not been studied in pat had trastuzumab permanently discontinued due to inf reactions (IRR) and/or hypersensitivity reactions; treat KADCYLA is not recommended for these patients. In overall frequency of IRRs in patients treated with KAD
- KADCYLA treatment should be interrupted in patients IRR and permanently discontinued in the event of a li IRR. Patients should be closely monitored for IRR reac during the first infusion