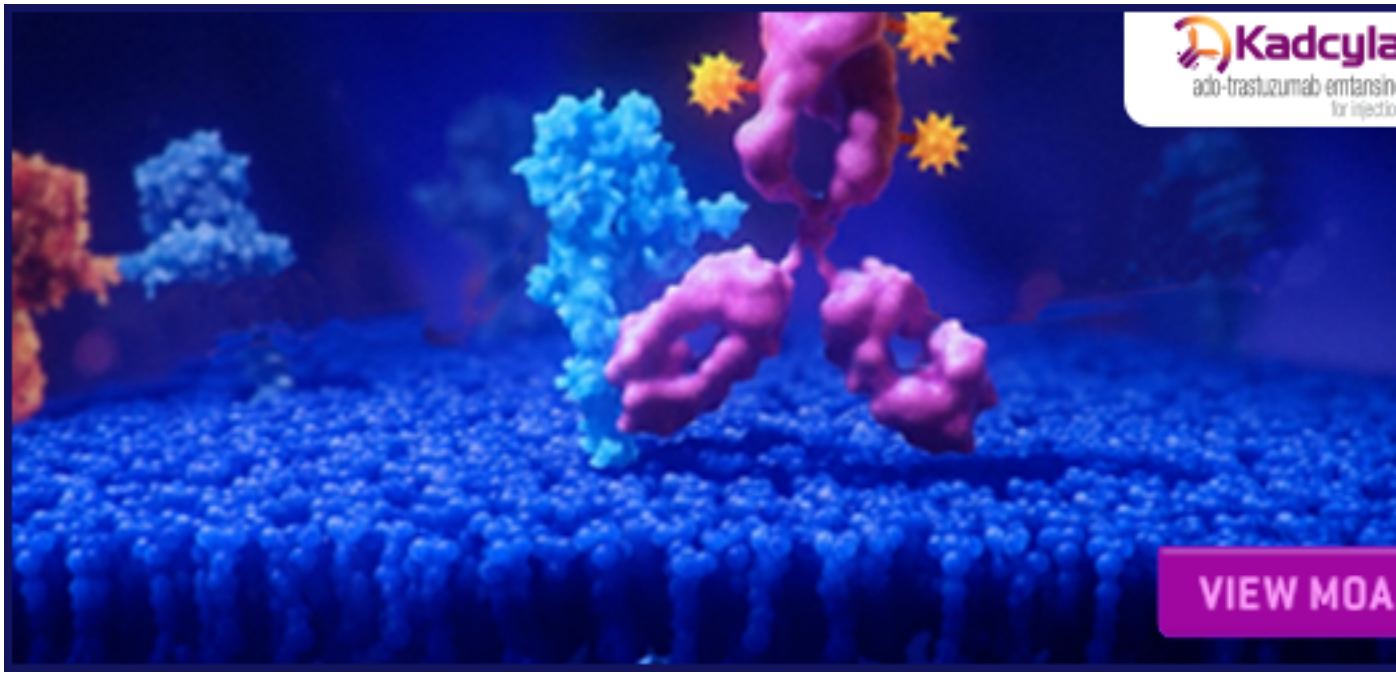
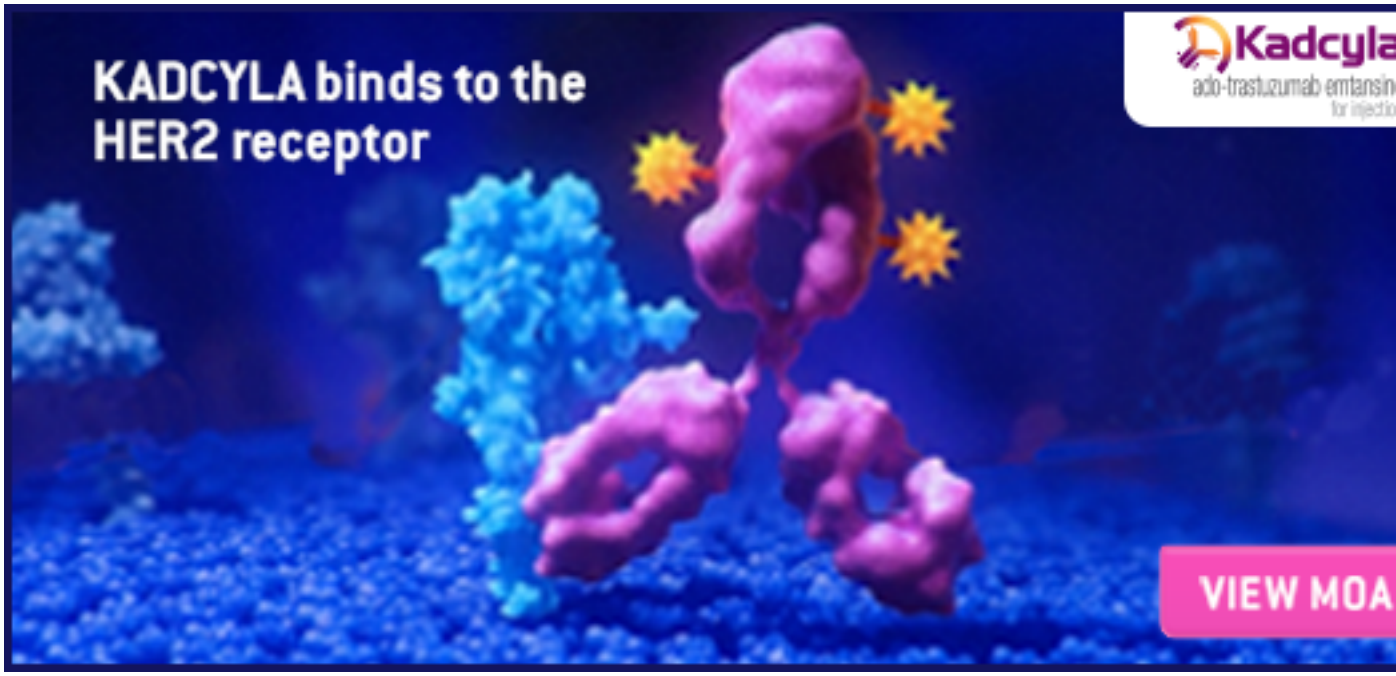
Frame 1



Frame 3



Frame 5

safety for right side of ban

Indication

KADCYLA® (ado-trastuzumab emtansine), as a single agent, is indicated for the treatment of patients with HE metastatic breast cancer (MBC) who previously received trastuzumab and a taxane, separately or in combin either: received prior therapy for metastatic disease, or developed disease recurrence during or within six m 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 t Monitor serum transaminases and bilirubin prior to initiation of KADCYLA treatment and prior to each dose or discontinue KADCYLA as appropriate in cases of increased serum transaminases or total bili**
- **Cardiac Toxicity: KADCYLA administration may lead to reductions in left ventricular ejection fraction (ventricular function in all patients prior to and during treatment with KADCYLA. Withhold treatment for decrease in left ventricular function**
- **Embryo-Fetal Toxicity: Exposure to KADCYLA can result in embryo-fetal death or birth defects. Advis 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 should be permanently discontinued in patients diagnosed with ILD or pneumonitis
- Infusion-related reactions (IRR), Hypersensitivity: KADCYLA treatment should be interrupted in patients wit 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 d appropriate
- Peripheral neuropathy: KADCYLA should be temporarily discontinued in patients experiencing Grade 3 or until resolution to ≤ Grade 2
- Reactions secondary to extravasation: The infusion site should be closely monitored for possible subcutane administration

Additional Important Safety Information:

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