

The next era of treatment

KADCYLA: The first antibody-drug conjugate for HER2- positive metastatic breast cancer



[View Proposed Mechanism of Action](#)

[View Clinical Information](#)

Indication

KADCYLA® (ado-trastuzumab emtansine), as a single agent, is indicated for the treatment of patients with HER2-positive 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

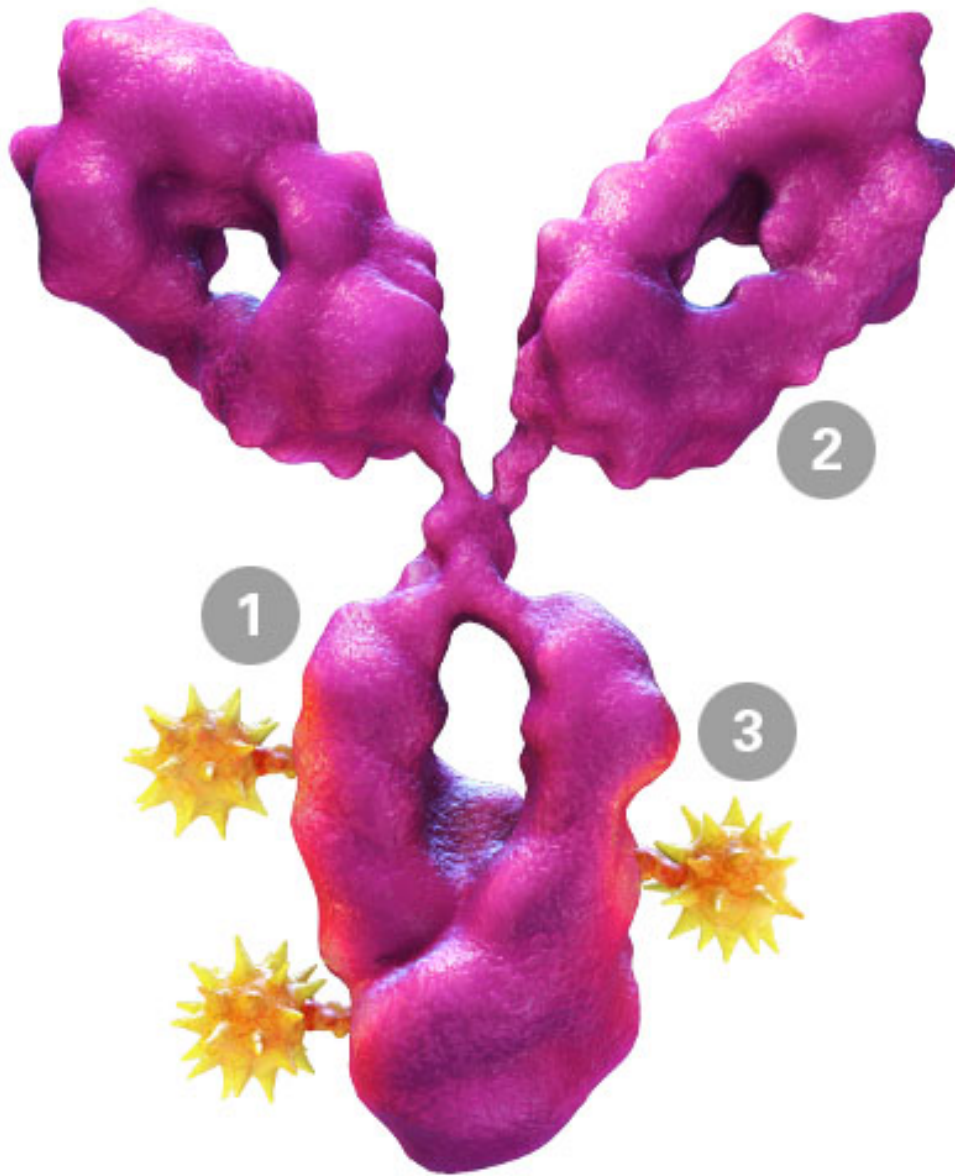
Important Safety Information

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 treatment. 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) and left ventricular function in all patients prior to and during treatment with KADCYLA. Withhold treatment for clinical signs and symptoms of heart failure or a decrease in left ventricular function.
- Embryo-Fetal Toxicity: Exposure to KADCYLA can result in embryo-fetal death or birth defects. Advise patients of the potential risks and the need for effective contraception.

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Please see accompanying full [Prescribing Information](#) for additional [Important Safety Information](#), including [Boxed WARNINGS](#).



1 DM1* (cytotoxic maytansinoid)
 Inhibits tubulin polymerization
 cell-cycle arrest
 cell death

2 Trastuzumab (monoclonal antibody)
 Binds to HER2 subdomain IV
 anti-HER2 activity

3 MCC* (stable maytansinoid)
 Covalently linked to trastuzumab

Based on preclinical models

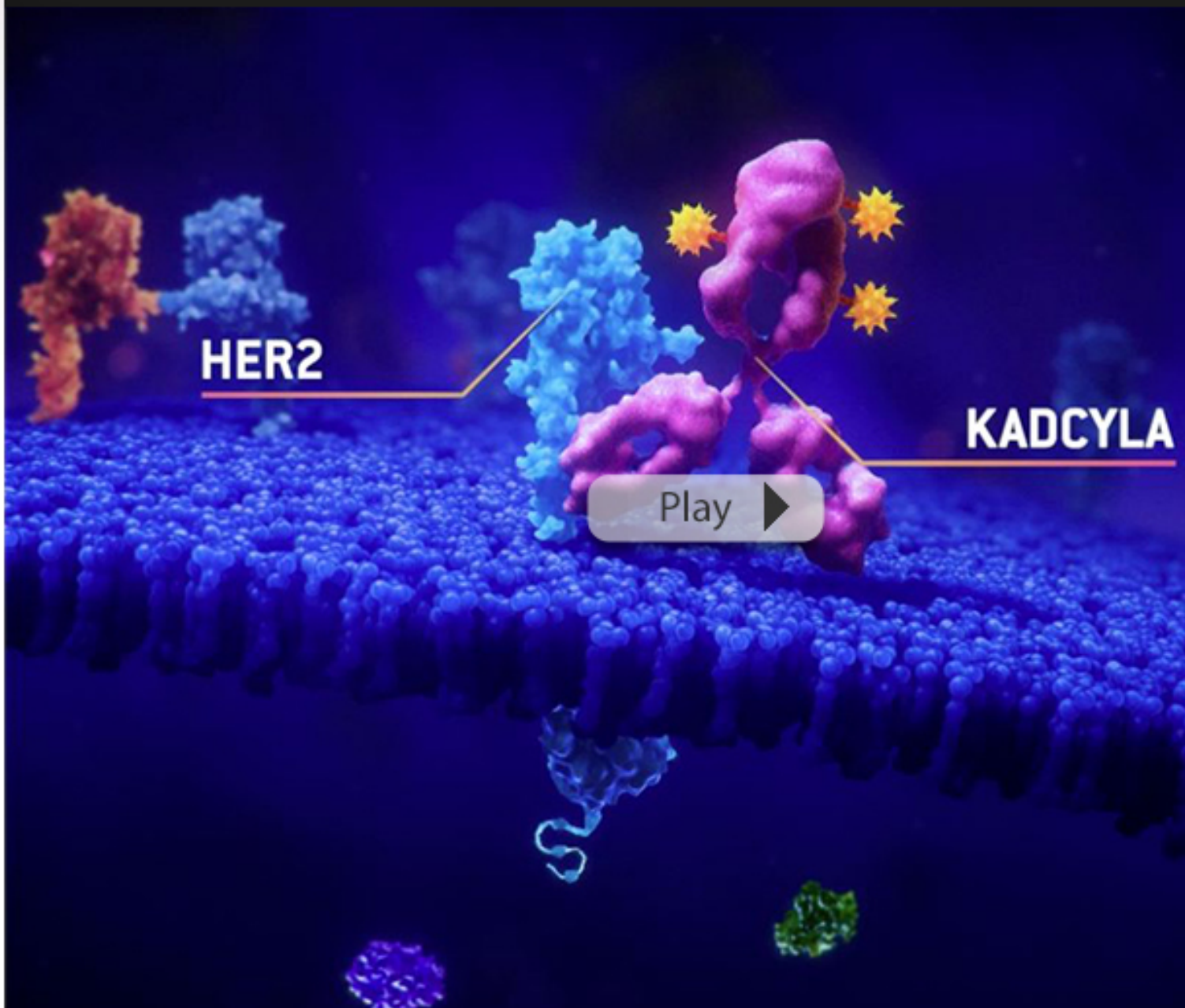
*Emtansine is the combination of DM1, a cytotoxic maytansinoid, and the stable MCC linker.

Reference: 1. KADCYLA Prescribing Information. Genentech, Inc. May 2013.

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KADCYLA selectively binds to HER2 receptor at subdomain IV



PREVIOUS
IMPORTANT SAFETY
INFORMATION

NEXT
TRASTUZUMAB ACTIVITIES

ADCC=antibody-dependent cell-mediated cytotoxicity.

*Cytotoxic DM1-containing catabolites (primarily lysine-bound emtansine).

Reference: 1. KADCYLA Prescribing Information. Genentech, Inc. May 2013.

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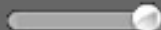
DOCKET
ALARM

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KADCYLA selectively binds to HER2 receptor at subdomain IV



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INFORMATION

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TRASTUZUMAB ACTIVITIES

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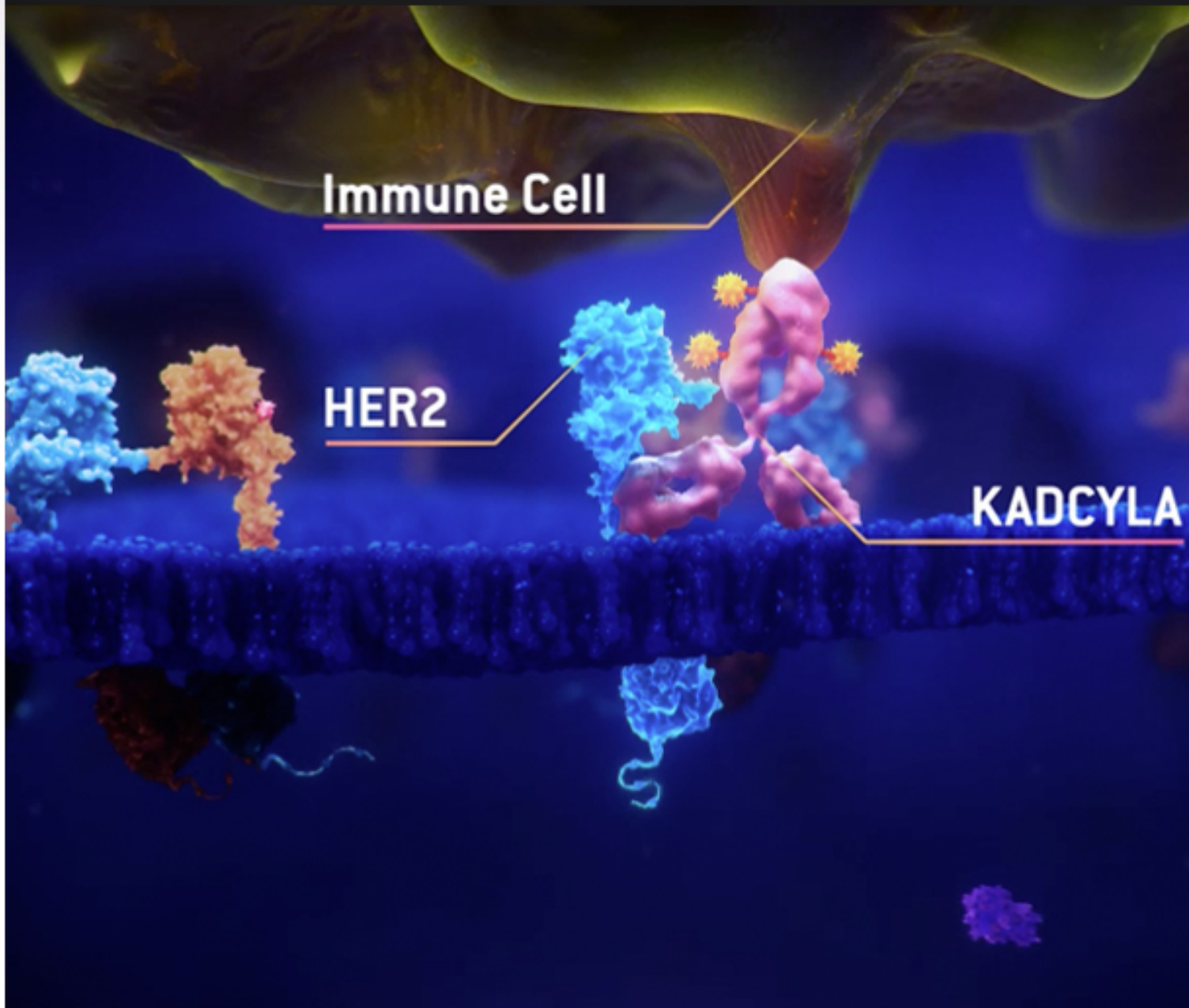
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• Inhibits HER2 receptor signaling • Triggers the ADCC immune response • Inhibits HER2



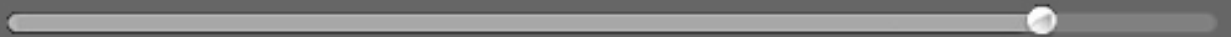
Immune Cell

HER2

KADCYLA



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PREVIOUS
HER2 BINDING

NEXT
INTERNALIZATION

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