Indication

KADCYLA® (ado-trastuzumab emtansine), as a single agent, is indica
HER2-positive (HER2+), metastatic breast cancer (MBC) who previous
separately or in combination. Patients should have either:

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

Important Safety Information

Boxed WARNINGS: HEPATOTOXICITY, CARDIAC
EMBRYO-FETAL TOXICITY

- **Do Not Substitute KADCYLA for or with Trastuzumab**
- **Hepatotoxicity: Serious hepatotoxicity has been reported, i treated with KADCYLA. Monitor serum transaminases and b treatment and prior to each KADCYLA dose. Reduce dose or cases of increased serum transaminases or total bilirubin**
- **Cardiac Toxicity: KADCYLA administration may lead to redu (LVEF). Evaluate left ventricular function in all patients prior Withhold treatment for clinically significant decrease in lef**
- **Embryo-Fetal Toxicity: Exposure to KADCYLA can result in e patients of these risks and the need for effective contracept**

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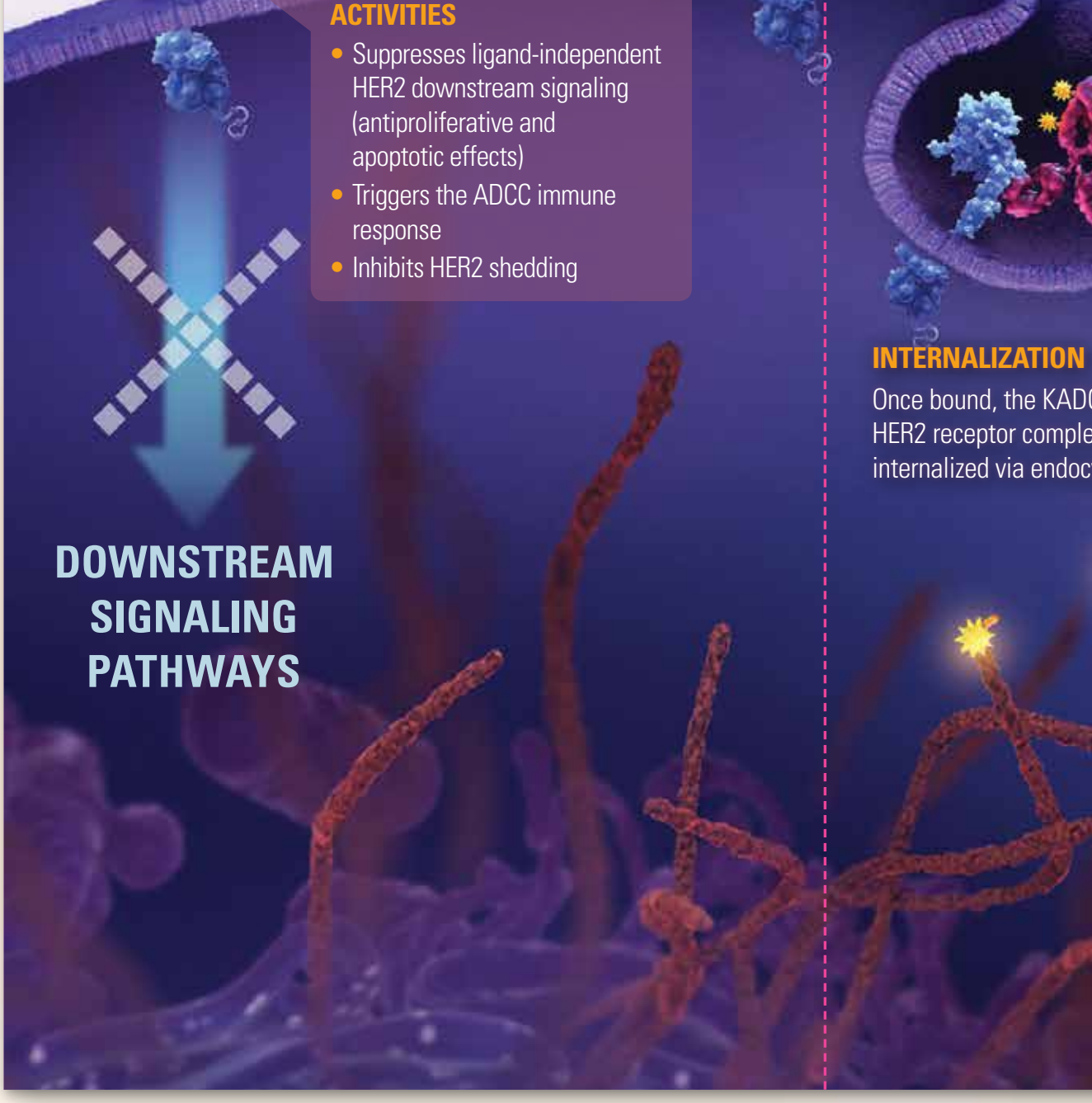

ADCC=antibody-dependent cell-mediated cytotoxicity.
†Cytotoxic DM1-containing catabolites (primarily lysine-bound emtansine).[1]

References: 1. KADCYLA Prescribing Information. Genentech, Inc. May 2013. **2.** Junttila TT, Li G, Parsons mechanisms of action of trastuzumab and efficiently inhibits growth of lapatinib insensitive breast cancer. et al; EMILIA Study Group. Trastuzumab emtansine for HER2-positive advanced breast cancer [published c 367:1783-1791 and Supplementary Appendix. **4.** Scheuer W, Friess T, Burtscher H, Bossenmaier B, Endl J, pertuzumab combination treatment on HER2-positive human xenograft tumor models. *Cancer Res*. 2009;69

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- Most patients (>88%) had received one or mor metastatic setting[1]
- More than half of the trial population (55%) had
- 12% of patients received only neoadjuvant or a disease relapse during or within 6 months of co

Select Important Safety Information:

Pulmonary Toxicity

- Cases of interstitial lung disease (ILD), including pneu respiratory distress syndrome or fatal outcome, have KADCYLA. Treatment with KADCYLA should be perm diagnosed with ILD or pneumonitis

Thrombocytopenia

- Thrombocytopenia was reported in clinical trials of KA was higher in Asian patients. Independent of race, the hemorrhagic events was low. Monitor platelet counts prior to each dose. Institute dose modifications as app

ER=estrogen receptor; PR=progesterone receptor.

References: 1. KADCYLA Prescribing Information. Genentech, Inc. May 2013. **2.** Verma S, Miles D, Gianni advanced breast cancer [published correction appears in *N Engl J Med.* 2013;368:2442]. *N Engl J Med.* 201

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Key secondary endpoints[1]

- Objective response rate (CR + PR): 43.6% vs 30
  (12.7% difference; 95% CI: 6.0, 19.4)
- Duration of response: median 12.6 months (95%
  (95% CI: 5.5, 7.2) with lapatinib + capecitabine

Select Important Safety Information:

Infusion Related/Hypersensitivity Reactions

- Treatment with KADCYLA has not been studied in pa
  discontinued due to infusion-related reactions (IRR) a
  treatment with KADCYLA is not recommended for th
  should be interrupted in patients with severe IRR and
  of a life-threatening IRR

CI=confidence interval; CR=complete response; PR=partial response.

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

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Hypokalemia	10.2	9.4
Neutropenia	6.7	9.0
PPES	1.4	59.0

- The most common NCI-CTCAE (version 3) ARs
were thrombocytopenia, increased transaminase
peripheral neuropathy, and fatigue[1]

PPES=palmar-plantar erythrodysesthesia syndrome.
*Most common ARs (>25% [all grades] or >2% [Grades ≥3] in either study arm) are included. ARs categoriz

References: 1. KADCYLA Prescribing Information. Genentech, Inc. May 2013. **2.** Data on file. Genentech, I

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