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Kadcyla™
ado-trastuzumab emtansine

KADCYLA is the first FDA-approved antibody-drug conjugate (ADC) for HER2-positive metastatic breast cancer.

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.[1]

FDA approval of KADCYLA is based on the EMILIA trial, a multicenter, open-label, randomized Phase III study conducted with 991 patients with locally advanced or metastatic HER2-positive mBC.[1]

The pivotal EMILIA trial demonstrated significant improvements in overall and progression-free survival in HER2-positive mBC patients previously treated with trastuzumab and a taxane.[1]

- KADCYLA extended median OS by 5.8 months, from 25.1 months observed in the lapatinib + capecitabine arm to 30.9 months in the KADCYLA arm (HR = 0.682 [95% CI: 0.548-0.849], $P = 0.0006$).
- KADCYLA extended median PFS* by 3.2 months, from 6.4 months observed in the lapatinib + capecitabine arm to 9.6 months in the KADCYLA arm (HR = 0.650 [95% CI: 0.549-0.771], $P < 0.0001$).

*As assessed by an independent review committee (IRC)

To learn more, please visit http://www.KADCYLA.com.

Select codes for your reference[1-9]	
NDC	**50242-088-01** – 100 mg single-use vial **50242-087-01** – 160 mg single-use vial
ICD-9 Codes	**174.0–174.9** – Malignant neoplasm of female breast **175.0, 175.9** – Malignant neoplasm of male breast
CPT Codes	**96413** – Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug **96415** – Chemotherapy administration, intravenous infusion technique, each additional hour
HCPCS Codes	**J3490** – Unclassified drugs **J3590** – Unclassified biologics **J9999** – Not otherwise classified, antineoplastic drugs **C9399** – Unclassified drugs or biologics

- KADCYLA is available through authorized specialty distributors and wholesalers via the KADCYLA distribution model. Please visit http://www.KADCYLA.com for more information on the network.
- Customers can also acquire KADCYLA through authorized specialty pharmacies and freestanding infusion centers if a patient is covered by a commercial healthcare plan.
- For information on distribution and patient access support, please contact KADCYLA Access Solutions by calling 1-888-249-4918 or by visiting http://www.Genentech-Access.com/KADCYLA.

For more information, please contact your Account Manager or submit your inquiry at http://www.gene.com/contact-us/email-us.

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**

Please see reverse for additional important safety information and accompanying full Prescribing Information, including Boxed WARNINGS.

Demonstrating the Value of Innovation

Additional Important Safety Information

Pulmonary Toxicity

- Cases of interstitial lung disease (ILD), including pneumonitis, some leading to acute respiratory distress syndrome or fatal outcome have been reported in clinical trials with KADCYLA. In EMILIA the overall frequency of pneumonitis was 1.2%
- Treatment with KADCYLA should be permanently discontinued in patients diagnosed with ILD or pneumonitis

Infusion-Related Reactions, Hypersensitivity Reactions

- Treatment with KADCYLA has not been studied in patients who had trastuzumab permanently discontinued due to infusion-related reactions (IRR) and/or hypersensitivity reactions; treatment with KADCYLA is not recommended for these patients. In EMILIA, the overall frequency of IRRs in patients treated with KADCYLA was 1.4%
- KADCYLA treatment should be interrupted in patients with severe IRR and permanently discontinued in the event of a life-threatening IRR

Thrombocytopenia

- In EMILIA, the incidence of ≥ Grade 3 thrombocytopenia was 14.5% in the KADCYLA-treated group and 0.4% in the comparator group
- Monitor platelet counts prior to initiation of KADCYLA and prior to each KADCYLA dose. Institute dose modifications as appropriate

Neurotoxicity

- In EMILIA, the incidence of ≥ Grade 3 peripheral neuropathy was 2.2% in the KADCYLA-treated group and 0.2% in the comparator group
- Monitor for signs or symptoms of neurotoxicity. KADCYLA should be temporarily discontinued in patients experiencing Grade 3 or 4 peripheral neuropathy until resolution to ≤ Grade 2

HER2 Testing

- Detection of HER2 protein overexpression or gene amplification is necessary for selection of patients appropriate for KADCYLA. Perform using FDA approved tests by laboratories with demonstrated proficiency

Extravasation

- In KADCYLA clinical studies, reactions secondary to extravasation have been observed and were generally mild. The infusion site should be closely monitored for possible subcutaneous infiltration during drug administration

Nursing Mothers

- Discontinue nursing or discontinue KADCYLA taking into consideration the importance of the drug to the mother

Pregnancy Registry

- Encourage women who may be exposed to KADCYLA during pregnancy to enroll in the MotHER Pregnancy Registry by contacting 1-800-690-6720

Adverse Reactions

- The most common ADRs seen with KADCYLA in EMILIA (frequency > 25%) were nausea, fatigue, musculoskeletal pain, thrombocytopenia, increased transaminases, headache, and constipation. The most common NCI-CTCAE (version 3) ≥ Grade 3 ADRs (frequency >2%) were thrombocytopenia, increased transaminases, anemia, hypokalemia, peripheral neuropathy and fatigue

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 accompanying full Prescribing Information for additional important safety information, including Boxed WARNINGS.

References: 1. KADCYLA™ (ado-trastuzumab emtansine) full prescribing information. Genentech, Inc., February 2013. **2.** ICD9Data. Malignant neoplasm of the female breast. http://www.icd9data.com/2013/Volume1/140-239/170-176/174/default.htm. Accessed January 29, 2013. **3.** ICD9Data. Malignant neoplasm of the male breast. http://www.icd9data.com/2013/Volume1/140-239/170-176/175/default.htm. Accessed January 29, 2013. **4.** American Medical Association. CodeManager. https://ocm.ama-assn.org/OCM/CPTRelativeValueSearchResults.do?locality=7&keyword=96413. Accessed January 29, 2013. **5.** American Medical Association. CodeManager. https://ocm.ama-assn.org/OCM/CPTRelativeValueSearchResults.do? locality=7.keyword=96415. Accessed January 29, 2013. **6.** ICD9Data. 2013 HCPCS J3490. http://www.icd9data.com/ HCPCS/2012/J/J3490.htm. Accessed January 29, 2013. **7.** ICD9Data. 2013 HCPCS J3590. http://www.icd9data.com/HCPCS/2013/J/J3590.htm. Accessed January 29, 2013. **8.** ICD9Data. 2013 HCPCS J9999. http://www.icd9data.com/HCPCS/2013/J/J9999.htm. Accessed January 29, 2013. **9.** ICD9Data. 2013 HCPCS C9399. http://www.icd9data.com/HCPCS/2013/C/C9399.htm. Accessed January 29, 2013.

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