February 22, 2013

Submission Request
c/o Joan McClure
National Comprehensive Cancer Network (NCCN)
275 Commerce Dr, Suite 300
Fort Washington, PA  19034

Dear Ms. McClure:

Enclosed are copies of the Kadcyla™ (ado-trastuzumab emtansine) prescribing information and the corresponding pivotal trial publication in *New England Journal of Medicine* for your product information updating needs. Genentech, Inc. received approval for Kadcyla on February 22, 2013.

Kadcyla is a HER2-targeted antibody and microtubule inhibitor conjugate indicated, as a single agent, 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

Kadcyla was approved based on results of a randomized, international, multicenter, 2-arm, open-label, Phase III study (EMILIA), which evaluated the safety and efficacy of Kadcyla compared with lapatinib plus capecitabine in locally advanced breast cancer (LABC) and MBC HER2-positive patients. Kadcyla demonstrated a statistically significant improvement in both primary endpoints of progression free survival (PFS) and overall survival (OS). Data on patient-reported outcomes from the EMILA study were also presented at a recent congress meeting. The most common adverse drug reactions (frequency >25%) with Kadcyla were fatigue, nausea, musculoskeletal pain, thrombocytopenia, headache, increased transaminases, and constipation.

Please be aware of a potential name confusion between ado-trastuzumab emtansine (Kadcyla) and trastuzumab (Herceptin®). Kadcyla should not be substituted for or with trastuzumab.

Additional Phase II data is available for previously treated and previously untreated patients with HER2-positive MBC.

Refer to the enclosed full prescribing information for complete product indication and safety information.

I hope this information is helpful to you in updating your drug information publications. If you have any questions or need additional assistance, please contact me directly at (650) 225-8084 or by email at costerison.emily@gene.com.

Sincerely,

Emily Costerison, PharmD, Scientist
Medical Communications, Medical Affairs
Genentech, Inc.

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Enclosures


Kadcyla Prescribing Information

References:


2. Verma S, Miles D, Gianni L, et al. Updated overall survival results from EMILIA, a Phase 3 study of trastuzumab emtansine (T-DM1) vs capecitabine and lapatinib in HER2-positive locally advanced or metastatic breast cancer. Presented at the European Society for Medical Oncology in Vienna, Austria; September 28 - October 2, 2012. ESMO Oral Presentation #LBA12


4. Kadcyla Prescribing Information

