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Mary Anne Bergman  
National Comprehensive Cancer Network  
275 Commerce Dr, Suite 300  
Fort Washington, PA 19034

**RE: FDA approval of HALAVEN™ (eribulin mesylate) for metastatic breast cancer  
NCCN Guidelines Panel: Breast Cancer**

Dear Ms. Bergman:

On behalf of Eisai, Inc., I respectfully request for the NCCN Breast Cancer Guidelines Panel to consider review of data enclosed for HALAVEN™ (eribulin mesylate), a non-taxane microtubule inhibitor, for the treatment of metastatic breast cancer.

Specific Changes: Request to update to the NCCN Clinical Practice Guidelines in Oncology—Breast Cancer and the NCCCN Drugs & Biologics Compendium, to reflect this FDA approval.

FDA status: On 11/15/2010, the Food and Drug Administration (FDA) approved HALAVEN™ (eribulin mesylate) for the treatment of patients with metastatic breast cancer who have previously received at least two chemotherapy regimens for metastatic disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting.

Rationale: Eribulin mesylate met the primary endpoint of overall survival in the Phase III EMBRACE study, documenting that patients who received eribulin mesylate (N=508) survived a median of 2.5 months longer than patients randomized to single-agent treatment of physician's choice ("TPC"; N=254), including chemotherapy and hormonal therapies (13.1 months versus 10.6 months, respectively; p=0.041).

Enclosed citations:

1. FDA NDA approval letter for HALAVEN™ (eribulin mesylate), Effective Date: 11/2010.
2. HALAVEN™ (eribulin mesylate) prescribing information. Eisai, Inc., 11/2010.

We look forward to the timely addition of this new product information to the NCCN Guidelines and Compendium.

Should you have any questions regarding the content of this letter and supporting documents, please contact me. Thank you for your prompt attention to this matter.

Sincerely,

David Cox, PhD  
Medical Director, Oncology  
US Medical Affairs  
Eisai, Inc.