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Eisai Co., Ltd.

## **EISAI' S INVESTIGATIONAL ANTICANCER AGENT ERIBULIN MESYLATE (E7389) RECEIVES PRIORITY REVIEW STATUS IN THE UNITED STATES**

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced that the U.S. Food and Drug Administration (FDA) accepted for review and granted priority review status to the New Drug Application (NDA) on May 28, 2010 (US Eastern Time) submitted by the U.S. subsidiary Eisai Inc. for eribulin mesylate ("eribulin", also known as E7389) for the treatment of locally advanced and metastatic breast cancer. Eribulin is an investigational anticancer agent discovered and developed by Eisai.

FDA priority review status is granted to those drugs that if approved, have the potential to provide, in the treatment, prevention, or diagnosis of a disease, one of the following: (1) safe and effective therapy where no satisfactory alternative therapy exists; or (2) a significant improvement compared to marketed products. The goal for completing a review of an NDA with priority review status is September 30, 2010.

Eisai submitted simultaneous regulatory applications for approval to the health authorities in Japan, the United States and Europe on March 30, 2010. In Japan, Ministry of Health, Labour and Welfare accepted it immediately and in Europe, European Medicine Agency accepted it on May 25, 2010. The Company has also submitted regulatory applications to health authorities in Switzerland and Singapore.

The applications submitted in March were based primarily on data from a pivotal, global Phase III study known as EMBRACE (**Eisai Metastatic Breast Cancer Study Assessing Physician's Choice Versus E7389**). EMBRACE was an open-label randomized, parallel two-arm, multi-center study involving 762 women with locally recurrent or metastatic breast cancer previously treated with at least two prior chemotherapy regimens, including an anthracycline and a taxane. Patients in the study were treated with either eribulin (administered intravenously over two to five minutes on days 1 and 8 of a 21 day treatment cycle) or treatment of physician's choice. Treatment of physician's choice was defined as any single agent chemotherapy, hormonal treatment or biological therapy approved for the treatment of cancer; or palliative treatment or radiotherapy administered according to local practice.

The EMBRACE Study met its primary endpoint of demonstrating a statistically significant improvement in overall survival in eribulin-treated patients compared to treatment of physician's choice. The most frequent adverse events reported by patients treated with eribulin included asthenia, neutropenia, alopecia, nausea and peripheral neuropathy. Grade 3 or Grade 4 peripheral neuropathy, which is said to significantly affect patients' quality of life, was reported in less than 10% of eribulin patients. The study also showed that eribulin has a favorable tolerability profile.

Eisai defines oncology as a therapeutic area of focus and is committed to the development of novel anticancer agents and treatments for supportive care. Through these efforts, Eisai will make further contributions to addressing the diversified needs of patients and their families as well as healthcare professionals.

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