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Eisai Co., Ltd.

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

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that the Japanese Ministry of Health, Labour and Welfare (MHLW) granted priority review status on May 18, 2010 to the Marketing Authorization Application submitted by the Company for eribulin mesylate ("eribulin," also known as E7389) for the treatment of inoperable or recurrent breast cancer. Eribulin is an investigational anticancer agent discovered and developed by Eisai.

Eisai submitted simultaneous regulatory applications for approval of eribulin to the health authorities in Japan, the United States and the European Union (EU) on March 30, 2010. The Company also submitted regulatory applications to the health authorities in Switzerland and Singapore in July 2009. On May 28, 2010 (U.S. Eastern Standard Time), eribulin was granted priority review status in the United States by the U.S. Food and Drug Administration (FDA).

The application submitted in Japan was 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)**, as well as a Phase II study (Study 221) conducted in Japan.

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. Results showed that the study met its primary endpoint of overall survival, demonstrating that patients who received eribulin survived a median of 2.5 months longer than patients who received treatment of physician's choice (13.12 months versus 10.65 months, respectively,  $p=0.04$ ). The study also showed that eribulin has a favorable tolerability profile.

Study 221 was an open-label, multi-center study conducted in women with advanced or relapsed breast cancer previously treated with an anthracycline and a taxane. The study demonstrated a high response rate of 21.3% (response observed in 17 out of 80 evaluable patients), and showed that eribulin has a favorable tolerability profile.

Breast cancer remains one of the leading causes of cancer mortality in women. Although advances are being made every year in the treatment of breast cancer thanks to the development of new anti-cancer drugs, there are still only limited treatment options available to women with inoperable or recurrent breast cancer. Eisai has been pursuing the development of eribulin with the aim of addressing the unmet medical needs of breast cancer patients as well as healthcare professionals.

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

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