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*Eisai is a Human Health Care Corporation striving for innovative solutions in prevention, cure and care for the health and well-being of people worldwide. We combine our talents to understand and meet the needs of patients and their families to enhance the quality of life.*

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## **FOR IMMEDIATE RELEASE**

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### **Eisai Submits Regulatory Applications for Investigational Anticancer Agent Eribulin Mesylate (E7389) in Japan, the United States and Europe**

Eisai Co., Ltd. (Headquarters: Tokyo, President and CEO: Haruo Naito) announced today that it has submitted regulatory applications for approval of eribulin mesylate (“eribulin”) for the treatment of locally advanced or metastatic breast cancer to health authorities in Japan (Ministry of Health, Labour and Welfare), the United States (U.S. Food and Drug Administration) and Europe (European Medicines Agency). Eribulin is a potential anticancer agent discovered and developed by Eisai.

The submissions are 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-centre 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. In this study, the patients were treated with either eribulin (administered intravenously over two to five minutes on days 1 and 8 every 21 days) or with 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.

Study results demonstrated a statistically significant improvement in overall survival, the primary endpoint in this study, for eribulin-treated patients when compared with patients who received treatment of physician’s choice. The most frequently reported adverse events included asthenia, neutropenia, alopecia, nausea and peripheral neuropathy. Incidence of Grade 3 or Grade 4 peripheral neuropathy, which are often said to affect patients’ quality of life significantly, was reported in less than 10% of patients with eribulin. The study showed that eribulin also has a favourable tolerability profile.

In a Phase II study conducted in Japan in patients with advanced or relapsed breast cancer previously treated with an anthracycline and a taxane, eribulin also demonstrated a high objective response rate and favourable tolerability profile in patients treated with eribulin.

Eribulin is a new chemical compound discovered and developed by Eisai. It is a synthetic analogue of halichondrin B, a naturally-derived compound that was first isolated from a marine sponge. While taxanes inhibit cell division by stabilising microtubules, eribulin is a microtubule dynamics inhibitor with a new mechanism that arrests the cell cycle through inhibition of the growth of microtubules without interfering with microtubule shortening.

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 locally advanced or metastatic 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.

Eisai defines oncology as a therapeutic area of focus and is committed to developing novel anti-cancer 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 to patients and families affected by cancer as well as healthcare professionals.

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