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Eisai Co., Ltd.

SINGAPORE HSA APPROVES EISAI'S HALAVEN[®] (ERIBULIN MESYLATE) INJECTION FOR TREATMENT OF METASTATIC BREAST CANCER

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito) announced today that the Singapore Health Sciences Authority (HSA) approved the company's novel anticancer agent HALAVEN[®] (generic name: eribulin mesylate) injection on February 9 (Singapore local time) for the treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least two chemotherapeutic regimens for advanced disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting. Discovered and developed by Eisai, HALAVEN[®] is a non-taxane, microtubule dynamics inhibitor and a synthetic analog of halichondrin B, a natural product isolated from the marine sponge *Halichondria okadai*. Following approval in the United States, Singapore is the second country in the world in which HALAVEN[®] has been approved. Regulatory applications seeking approval are also under review in Japan, the EU, Switzerland and Canada.

The HALAVEN[®] new drug application submitted in Singapore was accepted in July 2009. The global pivotal Phase III clinical study EMBRACE (Eisai Metastatic Breast Cancer Study Assessing Physician's Choice Versus Eribulin) showed that patients treated with Halaven[®] survived a median of 2.7 months longer than patients who received treatment of physician's choice (overall survival of 13.2 months versus 10.5 months, respectively, $p=0.014$). HALAVEN[®] is the first and only single-agent therapy to demonstrate a significant overall survival benefit in patients with late-stage metastatic breast cancer.

Singapore has the highest breast cancer incidence in Asia, with the disease accounting for 29.7% of all female cancers. Furthermore, about 1,100 new cases of breast cancer are diagnosed annually and approximately 270 women die in Singapore each year from breast cancer.¹⁾

Eisai's commitment to meaningful progress in oncology research, built on scientific expertise, is supported by a global capability to conduct discovery and preclinical research, and develop low molecular weight organic compounds, therapeutic vaccines, monoclonal antibody-based therapies, biologics, and supportive care agents for cancer across multiple indications. 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 as it seeks to fulfill its *human health care (hhc)* mission.

1) Breast cancer in Singapore: some perspectives; Breast cancer, 17, 23 (2010)

[Please refer to the following notes for Halaven[®] (eribulin mesylate) and the Global Phase III Clinical Study]

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[Notes to editors]

1. Halaven® (eribulin mesylate)

Halaven® is a non-taxane, microtubule dynamics inhibitor indicated for the treatment of patients with breast cancer who have previously received at least two chemotherapeutic regimens for metastatic disease and whose prior therapy should have included an anthracycline and a taxane. Halaven® belongs to a class of antineoplastic agents, the halichondrins, which are natural products isolated from the marine sponge *Halichondria okadae*. It is believed to work by inhibiting the growth phase of microtubule dynamics without affecting the shortening phase and sequestering tubulin into nonproductive aggregates.

Eisai is currently conducting late stage clinical trials investigating the potential of Halaven® as a single-agent therapy in the treatment of other types of cancer such as breast cancer with fewer prior treatments, non-small cell lung cancer, sarcoma, and prostate cancer with the aim of expanding the range of indications for which the agent can be used to treat.

2. Global Phase III Clinical Study (EMBRACE)

EMBRACE was an open-label, randomized, global, multi-center, parallel two-arm study designed to compare overall survival in patients treated with Halaven® versus a Treatment of Physician's Choice (TPC arm). TPC was defined as any single-agent chemotherapy, hormonal treatment or biologic therapy approved for the treatment of cancer; or palliative treatment or radiotherapy administered according to local practice. The study included 762 patients with metastatic breast cancer who previously had been treated with at least two and a maximum of five prior chemotherapies, including an anthracycline and a taxane. The vast majority (97%) of patients in the TPC arm received chemotherapy.

The most common adverse reactions (incidence greater than or equal to 25%) among patients treated with Halaven® were asthenia (fatigue), neutropenia, anemia, alopecia (hair loss), peripheral neuropathy (numbness and tingling in arms, legs and other parts of the body), nausea and constipation. The most common serious side effects reported in patients receiving Halaven® were neutropenia with or without fever (4% and 2%, respectively). The most common adverse reaction resulting in discontinuation of treatment with Halaven® was peripheral neuropathy (5%).