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Eisai Co., Ltd.

U.S. FDA APPROVES EISAI'S HALAVEN™ (ERIBULIN MESYLATE) INJECTION FOR TREATMENT OF METASTATIC BREAST CANCER

New Treatment Synthetically Derived From a Sea Sponge (Halichondria okadai) Demonstrated a Statistically Significant Improvement in Overall Survival in Late-Stage Metastatic Breast Cancer

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito) announced today that the United States Food and Drug Administration (FDA) approved the company's novel anticancer agent Halaven™ (generic name: eribulin mesylate) injection on November 15 (United States local time) for the treatment of patients with metastatic breast cancer who have previously received at least two chemotherapeutic regimens for the treatment of metastatic disease. Prior therapy should have included two common chemotherapy treatments, an anthracycline and a taxane, for early or advanced breast cancer. 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*.

The FDA approval of Halaven™ is based on results from the global pivotal Phase III clinical study EMBRACE (Eisai Metastatic Breast Cancer Study Assessing Physician's Choice Versus Eribulin), which showed that patients treated with Halaven™ survived a median of 2.5 months longer than patients who received treatment of physician's choice (overall survival of 13.12 months versus 10.65 months, respectively, p=0.041). Halaven™ is the first and only single-agent therapy to demonstrate a significant overall survival benefit in patients with late-stage metastatic breast cancer.

Many women with metastatic breast cancer see their disease progress after receiving multiple therapies. With the approval of Halaven™, Eisai can now offer a new option that has been shown to improve survival in women with metastatic disease.

A New Drug Application (NDA) for Halaven™ was submitted in the United States in March 2010 and was granted product priority review status by the FDA. Regulatory applications seeking approval of eribulin mesylate as a treatment for metastatic breast cancer are also currently under review in Japan, the European Union (EU), Switzerland and Singapore. As with the United States, the application submitted in Japan was also granted priority review status. Eisai is also planning the subsequent submission of regulatory applications in Asia and other regions in addition to the regions in which it has already filed for approval.

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.

[Please refer to the following notes for information on the global Phase III clinical study (EMBRACE), metastatic breast cancer, and Halaven™ (eribulin mesylate) Injection]

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[Notes to editors]

1. About the 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 percent) 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 (four percent and two percent, respectively). The most common adverse reaction resulting in discontinuation of treatment with Halaven™ was peripheral neuropathy (5%).

2. About Metastatic Breast Cancer

Metastatic breast cancer is an advanced stage of the disease that occurs when cancer spreads beyond the breast to other parts of the body.

In 2010, an estimated 207,000 women will be diagnosed with breast cancer in the United States and 40,000 women will die from the disease. Approximately 10 percent of women with breast cancer will have metastatic disease at the time of diagnosis and others with local and regional disease may eventually develop metastatic disease. An estimated one in five women with metastatic breast cancer is expected to survive five years.

3. Halaven™（eribulin mesylate）Injection

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 okadai*. It is believed to work by inhibiting the growth phase of microtubule dynamics without affecting the shortening phase and sequesters 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 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.