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Eisai Co., Ltd.

HALAVEN™ RECEIVES CHMP POSITIVE OPINION FOR USE IN METASTATIC BREAST CANCER

CHMP Opinion Based on Positive EMBRACE Study Data

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito) announced today that its United Kingdom-based subsidiary Eisai Europe, Ltd. has received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency (EMA), for the company's novel anticancer agent Halaven™ as a monotherapy indicated in the treatment of patients with locally advanced or metastatic breast cancer who have received at least two chemotherapeutic regimens, including an anthracycline and a taxane.

The CHMP submission was supported by results from the global Phase III EMBRACE study (Eisai Metastatic Breast Cancer Study Assessing Treatment of Physician's Choice (TPC) Versus Eribulin E7389) which demonstrated an overall survival (OS) benefit for patients treated with Halaven™ of 2.7 months compared with TPC (13.2 months versus 10.5 months, hazard ratio 0.805, nominal p=0.014). This is the first time that a monotherapy has provided statistically significant OS improvements in metastatic breast cancer patients previously treated with an anthracycline and a taxane in this patient population.

The agent received approval in the United States in November 2010 and applications are currently in progress in Japan, Canada, Singapore and Switzerland. The United Kingdom's National Institute for Health and Clinical Excellence (NICE) recommended that Halaven™ be given a priority review under its Single Technology Appraisal (STA) process.

Eisai believes that the CHMP positive opinion further supports Halaven™'s role in treating locally advanced and metastatic breast cancer and draws the company closer to making this important treatment available to patients. True to its *human health care* philosophy, Eisai remains committed to patients and their families and will continue to work to ensure rapid and sustained patient access to Halaven™ across Europe.

[Please refer to the following notes for further information on the EMBRACE study, Halaven™ and metastatic breast cancer]

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[Notes to editors]

1) About The EMBRACE Study

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) 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.

3) About Metastatic Breast Cancer

Worldwide, more than one million women a year are diagnosed with breast cancer, including 421,000 women in Europe. Approximately 30 percent of women initially diagnosed with earlier stages of breast cancer eventually develop recurrent or metastatic disease, and while around 9 out of 10 of women diagnosed with early stage breast cancer survive beyond five years, this drops to around 1 in 10 among women first diagnosed with MBC. Most MBC patients have a limited survival time of approximately 18–24 months.