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Eisai Co., Ltd.

HALAVEN® RECEIVES APPROVAL IN JAPAN FOR THE TREATMENT OF INOPERABLE AND RECURRENT BREAST CANCER

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that it has received approval to market its novel anticancer Halaven® Injection 1mg (eribulin mesylate) in Japan for the treatment of inoperable and recurrent breast cancer. Discovered and developed by Eisai, Halaven® is now approved in each of the world's three largest pharmaceutical markets, comprising Japan, the United States and the European Union (EU).

The Japan marketing authorization application for Halaven® was submitted in March 2010 and was subsequently granted priority review status by Japan's Ministry of Health, Labour and Welfare in May of the same year. The approval of the agent in Japan was based on results of the global pivotal Phase III EMBRACE (Eisai Metastatic Breast Cancer Study Assessing Physician's Choice Versus E7389) Study as well as a Phase II study (Study 221) conducted in Japan.

A protocol prespecified analysis of the EMBRACE Study demonstrated that patients treated with Halaven® survived a median of 2.5 months longer than patients who received treatment of physician's choice (TPC) (overall survival (OS) of 13.1 months versus 10.6 months, respectively; Hazard Ratio [HR] 0.81; p=0.041). A subsequent updated analysis requested by European and U.S. regulatory authorities found that Halaven®-treated patients actually survived a median of 2.7 months longer than those in the TPC arm (OS of 13.2 months versus 10.5 months, respectively; HR 0.81; p=0.014).

Halaven® is the first single-agent chemotherapy to demonstrate a statistically significant overall survival benefit in patients with pretreated metastatic breast cancer. Against this backdrop, Eisai has strengthened its sales force by having all of its medical representatives (MRs) trained in oncology and will make a concerted effort to provide information to ensure proper usage of the drug in order to further contribute to improving the quality of life of breast cancer patients.

Breast cancer remains one of the leading causes of cancer death among women, with approximately 60,000 patients in Japan being newly diagnosed with the disease each year. Although advances are being made in the treatment of breast cancer in accordance with the development of new anticancer agents, there are still relatively few options available for those patients with inoperable or recurrent disease. This latest approval means that inoperable or recurrent breast cancer patients across Japan will soon have access to treatment with Halaven®, which is expected to provide further benefits to patients and their families.

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 small molecules, biologics, chemotherapies and supportive care agents for cancer across multiple indications. Eisai made its entry into the oncology market in Japan in December 2010 with the launch of its debut anticancer agent Treakisym®. Following the launch of the newly approved Halaven®, the Company also plans to enhance its integrative oncology portfolio with other products such as MORAb-003 (farletuzumab), a monoclonal antibody, and E7080 (lenvatinib).

Through these efforts, Eisai will make further contributions to address the diversified needs of and increase 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 a product outline and further information on the EMBRACE Study, Study 221, Halaven® and breast cancer]

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[Notes to editors]

1. Product Outline

1) Product Name

Halaven® Injection 1mg

2) Generic Name

Eribulin mesylate

3) Indications and Usage

Treatment of inoperable or recurrent breast cancer

4) Administration and Dosage

The recommend adult daily dose of eribulin mesylate is 1.4 mg/m^2 (body surface area). This dose should be administered intravenously over 2 to 5 minutes once a week for two consecutive weeks of a repeated three-week cycle. Dosage may be reduced according to the patients' condition.

2. About the Global Phase III EMBRACE Study

EMBRACE was an open-label, randomized, multi-center, parallel two-arm study designed to compare overall survival (OS) in patients treated with Halaven® versus a Treatment of Physician's Choice (TPC). The study included 762 patients with locally recurrent or 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. Patients were randomized in a 2:1 ratio to receive either Halaven® or TPC. 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 vast majority (97%) of patients in the TPC arm received chemotherapy. A protocol prespecified analysis demonstrated that patients treated with Halaven® survived a median of 2.5 months longer than patients who received TPC (OS of 13.1 months versus 10.6 months, respectively; Hazard Ratio [HR] 0.81; p=0.041).

An updated analysis of overall survival (not protocol prespecified) in the EMBRACE study was performed at the request of European and U.S. regulatory authorities. These results demonstrated a significant increase of 2.7 months in overall survival for Halaven® compared with TPC (OS of 13.2 months versus 10.5 months, respectively; HR 0.81; p=0.014). Data from this analysis was presented at the 33rd Annual San Antonio Breast Cancer Symposium, held in December 2010, and confirmed the overall survival benefits of Halaven® as well as no change in safety profile.

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%).

3. About the Phase II Study (Study 221) Conducted in Japan

Study 221 was a multicenter, open-label trial conducted in advanced or recurrent breast cancer patients 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.

4. About Halaven® (eribulin mesylate)

Halaven®, a non-taxane, microtubule dynamics inhibitor with a novel mechanism of action, 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 sequestering tubulin into nonproductive aggregates.

Synthesizing Halaven® is an extremely difficult and complex process, involving some 62 steps to achieve total synthesis. Halaven® has a molecular weight of 826, including 19 chiral carbons, which means the theoretical number of stereoisomers is 2^{19}, or a possible 524,000, making stereocontrol potentially extremely difficult. However, due to Eisai's advanced technological capabilities, it was possible to stereoselectively control all synthetic reactions and commercially synthesize Halaven®.

Approved in the United States in November 2010, in Singapore in February 2011, and in the European Union the following March, Halaven® is currently under regulatory review in Switzerland and Canada. Eisai is also committed to pursuing the development of Halaven® in numerous other countries such as those in Asia and other emerging regions. The Company 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.

5. About Breast Cancer

Breast cancer is one of the most common types of cancer among women worldwide, and has especially high incidence rates in developed nations in North America and Europe. In recent years, both incidence and mortality rates of breast cancer have been growing in Japan. As the incidence rate starts to rise when women are in their thirties, with a peak incidence among women in their late forties or early fifties, breast cancer poses a more compelling problem than other types of cancer.

Nowadays, the number of patients diagnosed with breast cancer is increasing in accordance with advancements in the healthcare system and screening technology to promote early detection and diagnosis. It is estimated that approximately one million women worldwide are newly diagnosed with breast cancer each year, approximately 40% of which will go on to develop locally advanced or metastatic disease. Studies show that only one in five metastatic breast cancer patients is expected to live more than five years.

In the United States, approximately 200,000 women are newly diagnosed with advanced breast cancer each year, and over 40,000 pass away from the disease. In Europe, breast cancer strikes 110 out of every 100,000 people, with 38 out of every 100,000 losing their lives to the disease. In Japan, these numbers are 33 and 8, respectively. With the number of patients increasing steadily year on year, breast cancer is considered to constitute an area of high unmet medical need.

6. About Inoperable and Recurrent Breast Cancer

Breast cancer is classified into eight stages (stage: 0, I, IIa, IIb, IIIa, IIIb, IIIc, IV) based on breast lump size, whether or not the cancer has spread to the surrounding lymph nodes, and whether or not distant metastases are present. Of these stages, stages IIIb, IIIc, IV are deemed as inoperable forms of breast cancer due to the disease having metastasized or spread extensively throughout the body. Breast cancer that has metastasized to other organs (metastatic breast cancer) or that has recurred near the original site following initial treatment, such as surgical removal of the breast tumor, is referred to as recurrent breast cancer.