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Eisai Co., Ltd.

EISAI ANNOUNCES JAPAN LAUNCH OF ANTICANCER AGENT HALAVEN®

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") today announced the launch of its novel anticancer agent Halaven® in Japan for the treatment of inoperable or recurrent breast cancer. Halaven® is the first novel anticancer agent to be discovered and developed by the Eisai. Having simultaneously submitted marketing authorization applications to the regulatory authorities in Japan, the United States and the European Union (EU) in March 2010, the company first launched Halaven® in the United States in November of the same year, and began marketing the agent in the United Kingdom, Germany and other European countries in April 2011.

Halaven® is the first single-agent chemotherapy to demonstrate a statistically significant overall survival (OS) benefit in pretreated metastatic breast cancer patients. In a Phase III study (EMBRACE study) conducted overseas in pretreated patients with advanced or recurrent breast cancer, Halaven® extended overall survival by 2.7 months compared to Treatment of Physician's Choice (TPC) (OS: 13.2 months vs. 10.5 months; Hazard Ratio[HR] 0.81; p=0.014). Additionally, a Phase II study (Study 221) conducted in Japan in patients with advanced or recurrent breast cancer patients previously treated with an anthracycline and a taxane showed that Halaven® monotherapy demonstrated an excellent antitumor effect as well as a favorable tolerability profile.

Breast cancer remains one of the leading causes of cancer death among women, with approximately 60,000 patients in Japan being affected by 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. The launch of Halaven® in Japan means that it will now be possible for inoperable or recurrent breast cancer patients across country to have access to the agent.

Going forward, Eisai seeks to expand the value of Halaven® for breast cancer patients globally through the development of additional indications for refractory recurrent or metastatic breast cancer with fewer prior treatments and post-operative adjuvant therapy, as well as a new liposomal formulation. It also plans to develop Halaven® as a treatment for other types of cancer such as non-small cell lung cancer, sarcoma, and prostate cancer, which along with the development of its existing pipeline products including MORAb-003 (farletuzumab), a monoclonal antibody targeting ovarian cancer, and E7080 (lenvatinib), a potential treatment for thyroid or endometrial cancer, will enhance the company's portfolio of Women's Oncology products.

In line with its *human health care mission (hhc),* Eisai's entire force of medical representatives (MRs) will work together to strengthen the company's activities in the Japanese oncology market, thereby contributing to fulfilling the needs of women and families throughout the country living with breast cancer and improving the quality of life.

[Please refer to the following notes for a product outline and further information on clinical studies, Halaven®, breast cancer, and Eisai's Commitment to Women's Oncology]

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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 recommended 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.

5) Listed Price

Halaven® Injection 1 mg 64,070 yen (per 2 ml vial)

6) Packaging

Halaven® Injection 1mg: 1 vial

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 an 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 Canada and is being developed in numerous other countries such as those in Asia and other emerging regions. 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.

5. About Breast Cancer

Breast cancer is the leading cause of cancer death among women, with approximately 60,000 patients in Japan being newly diagnosed with the disease each year. 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 compelling problem and constitutes and area with high unmet medical needs.

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.

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.

6. Eisai’s Commitment to Women’s Oncology

The number of women dying from cancer is increasing year by year, and according to the World Health Organization (WHO), approximately three million women worldwide lose their lives to the disease each year. With women taking on an increasingly more important role in society nowadays, Eisai considers it extremely meaningful to support women living with cancer and improve their quality of life.

By committing itself to “Women’s Oncology,” an area of oncology that places emphasis on the perspectives of women, Eisai will stand alongside women facing cancer, while at the same time bringing them hope and making contributions to improving their quality of life.

Eisai believes that its mission is to deliver innovative new therapies to patients fighting cancer as soon as possible, by making further contributions to breast cancer patients through indication expansion and the development of additional formulations of Halaven®, and developing other therapeutic agents, such as farletuzumab, a monoclonal

antibody targeting ovarian cancer, and lenvatinab, a potential treatment for thyroid and endometrial cancer. Furthermore, Eisai is committed to implementing access programs to ensure that its products reach patients around the world and the overall improvement of healthcare systems.

Eisai also strives to conduct activities that address the specific needs of female cancer patients and seek out collaborations with medical institutions to provide training programs for oncology care management specialists. By helping to build community care networks that provide a seamless range of services from point of diagnosis through treatment, including home care, palliative care and end-of-life care, the company aims to further its commitment to improving the quality of life of cancer patients and their families and creating communities that are supportive of people living with the disease.