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Eisai Co., Ltd.

EISAI RECEIVES APPROVAL TO MARKET ANTICANCER AGENT HALAVEN® IN AUSTRALIA

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that its Australian pharmaceutical sales subsidiary Eisai Australia Pty. Ltd. has received approval from the Australian Department of Health and Aging to market the anticancer agent Halaven® (eribulin mesylate) 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 unless patients were not suitable for these treatments.

Halaven is the first anticancer agent to be discovered and developed by Eisai in-house, and is the only single-agent chemotherapy to demonstrate a statistically significant overall survival (OS) benefit in Phase III studies (EMBRACE study) conducted in pretreated advanced and metastatic breast cancer patients. Including Australia, Halaven is currently approved in 39 countries worldwide.

Breast cancer is the second most commonly diagnosed type of cancer in the world. In Australia, breast cancer affects an estimated 150,000 people[1)], with approximately 15,000 new cases[2)] of the disease being diagnosed each year. This latest approval of Halaven will now enable late-stage metastatic breast cancer patients with significant unmet medical needs across Australia to access this innovative therapeutic agent.

Under its great globalization strategy outlined in its mid-term strategic plan "HAYABUSA," Eisai seeks to enter the world top 20 largest pharmaceuticals markets by fiscal 2015 and make contributions to over 500 million patients worldwide. Eisai will establish a presence in Australia, the largest country in Oceania and 13th largest pharmaceuticals market in the world, with the launch of Halaven, and going forward, will enhance its product lineup and marketing framework as it seeks to increase the benefits it provides to patients and families across Australia.

1) Australian Institute of Health and Welfare & National Breast and Ovarian Cancer Centre 2009. Breast cancer in Australia: an overview, 2009. Cancer series no. 50. Cat. no. CAN 46. Canberra: AIHW.
2) Australian Institute of Health and Welfare & Australasian Association of Cancer Registries 2010. Cancer in Australia: an overview, 2010. Cancer series no. 60. Cat. no. CAN 56. Canberra: AIHW.

[Please refer to the following notes for a product outline and information on the Halaven Global Phase III Study (EMBRACE Study), breast cancer and Eisai Australia Pty. Ltd.]

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[Notes to editors]

1. 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.

Halaven was first approved as a treatment for breast cancer in the United States in November 2010, and is now approved in 39 countries worldwide, including European Union member states, Japan, Singapore, Switzerland, South Korea, and Australia. Eisai is currently conducting late stage clinical trials investigating the potential of Halaven as a monotherapy in the treatment of other types of cancer such as breast cancer with fewer prior treatments, soft-tissue sarcoma and non-small cell lung cancer. Furthermore, the company is also preparing to commence clinical trials of a liposome formulation that it hopes will more effectively deliver Halaven to target cancer cells.

2. Global Phase III Study (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 at 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).

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 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, Europe and other regions. In recent years, the number of patients diagnosed with breast cancer has been increasing in accordance with a rise in the number of women undergoing breast check-ups and advances in healthcare systems 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 are 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. With the number of patients increasing steadily year after year, breast cancer is considered to constitute an area with high unmet medical needs.

4. About Eisai Australia Pty. Ltd.

Eisai Australia Pty. Ltd. was established as a pharmaceutical sales subsidiary of Eisai Co., Ltd. in January 2006.