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Eisai Co., Ltd.

EISAI RECEIVES APPROVAL FOR ANTICANCER AGENT HALAVEN® IN SOUTH KOREA

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that its South Korean sales subsidiary Eisai Korea Inc. ("Eisai Korea") has received approval from the regulatory authorities in South Korea to market the anticancer agent Halaven® (eribulin mesylate) for the treatment of locally advanced or metastatic breast cancer patients who previously have been treated with at least two prior chemotherapies, including an anthracycline and a taxane.

Halaven is the 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 South Korea, Halaven is currently approved in 38 countries worldwide.

Breast cancer is the second most commonly diagnosed type of cancer in the world, with an estimated 15,000 people being newly diagnosed with the disease in South Korea each year. This latest approval of Halaven will now enable late-stage metastatic breast cancer patients with significant unmet medical needs across South Korea to access this innovative therapeutic agent.

South Korea is the third largest market in Asia after Japan and China, and constitutes the 12th largest pharmaceutical market in the world. Eisai Korea has already established a presence in the area of integrative oncology with the launch of the anticancer agent Symbenda® (bendamustine hydrochloride) in October 2011 for the treatment of chronic lymphocytic leukemia and multiple myeloma. Going forward, the company will continue to step up its efforts in the field of oncology with the addition of Halaven to its integrative oncology product portfolio as it seeks to make further contributions to address the diversified needs of, and increase the benefits provided to, cancer patients and their families.

[Please refer to the following notes for a product outline and information on clinical studies and breast cancer]

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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 38 countries worldwide, including European Union member states, Japan, Singapore and Switzerland. 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.

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 breast cancer incidence rate has been growing in both Japan and Korea. Breast cancer poses a compelling problem 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.

Nowadays, the number of patients diagnosed with breast cancer is increasing in accordance with 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. In Japan, these numbers are 33 and 8, respectively. With the number of patients increasing steadily year after year, breast cancer is considered to constitute an area of high unmet medical need.