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Eisai Co., Ltd.

EISAI FILES FOR INDICATION EXPANSION OF ANTICANCER AGENT HALAVEN® WITH EUROPEAN MEDICINES AGENCY

SEEKS EARLIER-LINE USE IN TREATMENT OF METASTATIC BREAST CANCER

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that its U.K. subsidiary, Eisai Europe Ltd., has filed an application with the European Medicines Agency (EMA) for anticancer agent Halaven® (eribulin mesylate, "eribulin"), requesting an indication expansion of eribulin to contribute to earlier-line treatment of patients with metastatic breast cancer.

Among the clinical evidence submitted with the application were results of a multicenter, randomized, open-label, Phase III clinical study (Study 301) that compared eribulin versus capecitabine in 1,102 patients with locally advanced or metastatic breast cancer previously treated with an anthracycline and a taxane. The majority of the patients received zero or one previous chemotherapeutic regimens for metastatic disease.

Also provided as clinical evidence was the outcome of a Phase III clinical study (Study 305: EMBRACE) of eribulin versus treatment of physician's choice (TPC) in patients with locally advanced or metastatic breast cancer who had previously received two to five chemotherapeutic regimens. The study results demonstrate eribulin to be the first and only single-agent chemotherapy in the world to statistically, significantly extend overall survival compared to TPCs. Eribulin is currently indicated in Europe for the treatment of patients with locally advanced and metastatic breast cancer who have progressed after at least two chemotherapeutic regimens that included an anthracycline and a taxane for advanced disease. This latest application aims for an expansion of the current indication, which is limited to patients who have previously received at least two chemotherapeutic regimens, to include patients with metastatic breast cancer with less prior treatment.

Although advances are being made in the treatment of breast cancer each year with the development of new diagnostic technologies and anticancer agents, the unmet medical needs of patients with metastatic breast cancer continue to remain high. Eisai remains committed to providing scientific evidence aimed at maximizing the value of Halaven as it seeks to make further contributions to address the diversified needs of, and increase the benefits provided to, patients with cancer and their families as well as healthcare providers.

[Please refer to the following notes for further information on Halaven® and a Study 301 summary.]

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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.

In a Phase III clinical study (EMBRACE) conducted overseas of Halaven versus treatment of physician's choice (TPC) in 762 patients with locally advanced or metastatic breast cancer previously treated with an anthracycline and a taxane, Halaven indicated extended overall survival (OS) of 2.5 months (OS of 13.1 months versus 10.6 months, respectively; Hazard Ratio (HR) 0.81; p=0.041) when compared to selected, major existing therapies. An updated analysis of OS (not protocol-specified) in the EMBRACE study was also performed at the request of European and U.S. regulatory authorities. These results demonstrated an increase of 2.7 months in OS 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 (events with an incidence rate of at least 25%) among patients treated with Halaven were asthenia (fatigue), neutropenia, anemia, alopecia (hair loss), peripheral neuropathy (numbness and tingling in arms, legs and/or 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%). Furthermore, in a Phase II clinical study conducted in Japan, Halaven was found to possess excellent anticancer effects and tolerability in patients with advanced or recurrent breast cancer who had previously undergone treatment.

Halaven was first approved as a treatment for breast cancer in the United States in November 2010, and is currently approved in more than 40 countries worldwide, including European Union member states, Japan, Singapore and Switzerland. In Japan, the drug has been approved to treat inoperable or recurrent breast cancer and was launched in the country in July 2011. Furthermore, with the aim of maximizing value of the drug, Eisai is currently conducting late-stage clinical developments investigating the potential of Halaven as a therapy in the treatment of breast cancer with fewer prior treatments as well as soft-tissue sarcoma and non-small cell lung cancer.

2. Study 301 Design Summary

Study 301 was an open-label, randomized, two-parallel-arm, multicenter study designed to evaluate Halaven versus capecitabine in 1,102 women with locally advanced or metastatic breast cancer who had up to three prior chemotherapy regimens, and no more than two prior regimens for advanced and/or metastatic disease. The regimens must have included an anthracycline and a taxane, either in the (neo)adjuvant setting, or for locally advanced or metastatic disease. Patients must have had documented evidence of progression during or after their most recent anticancer therapy. Patients were also randomized according to their human epidermal growth factor receptor 2 (HER2) status (positive, negative or unknown) and geographical region (Eastern Europe, North America, Latin America, Western Europe, South Africa, and Asia) at a ratio of 1:1 to receive treatment with either Halaven 1.4 mg/m^2/day (administered intravenously on days 1 and 8, every 21 days) or capecitabine 2.5 g/m^2/day (administered orally on days 1 to 14, every 21 days). The primary endpoints of the study were overall survival and progression-free survival.

The results of the study were presented at the 2012 CTRC-AACR San Antonio Breast Cancer Symposium (SABCS), which was held in December 2012. (For more information, please see the Eisai press release published on December 7, 2012 via the following link: http://www.eisai.com/news/news201281.html.)