

No.12-44

July 10, 2012
Eisai Co., Ltd.

EISAI ANNOUNCES PRELIMINARY RESULTS OF PHASE III STUDY (STUDY 301) OF ANTICANCER AGENT HALAVEN® VERSUS CAPECITABINE IN LOCALLY ADVANCED OR METASTATIC BREAST CANCER

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") today announced preliminary results from a Phase III study (Study 301) of its in-house discovered and developed anticancer agent Halaven® (eribulin mesylate) versus capecitabine in women with locally advanced or metastatic breast cancer for whom prior treatment with both an anthracycline and taxane has failed. The study was conducted with a view to expanding the current indication to allow such patients to receive benefits from Halaven from an even earlier stage in the treatment of their disease.

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 previously treated with anthracyclines and taxanes. Patients were randomized at a ratio of 1:1 to receive treatment with either Halaven or capecitabine in accordance with their HER2 (Human Epidermal Growth Factor Receptor Type2) status and geographic region which were pre-specified in the study protocol.

Preliminary results showed that the trial did not meet the pre-specified criteria for either of the co-primary endpoints of overall survival (OS) and progression-free survival (PFS). The study did show, however, a trend toward improved OS for patients who received Halaven compared with capecitabine, but the improvement was not statistically significant. No difference was seen in PFS. Furthermore, data showed that the safety profile of Halaven was consistent with that reported in previous clinical studies.

Eisai is conducting detailed analyses of clinical trial data including the secondary endpoints and subgroup analyses pre-specified in the study protocol, and will work closely with the health authorities towards potential regulatory filing.

Although advances are being made in the treatment of breast cancer each year in line with the development of new anticancer agents, the unmet medical needs of locally advanced or metastatic breast cancer patients continue to remain high. Halaven is currently approved for the treatment of breast cancer in 37 countries worldwide, including Japan, the United States, European Union (EU) member states and Singapore. Phase III clinical trials evaluating the agent for the additional indications of soft-tissue sarcoma and non-small cell lung cancer are currently underway, and depending upon the outcome of those studies, Eisai will be able to submit regulatory applications simultaneously in Japan, the United States and the EU during fiscal 2014 (fiscal year ending March 31, 2015). Eisai remains committed to generating 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, cancer patients and their families as well as healthcare providers.

**[Please refer to the following notes for further information on Halaven, Study 301,
breast cancer and Eisai's Commitment to Oncology]**

Media Inquiries:
Public Relations Department,
Eisai Co., Ltd.
+81-(0)3-3817-5120

[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 37 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, as represented by Study 301, 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. About Study 301 Design Outline

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. In cases where it was known that a tumor overexpressed HER2 (Human Epidermal Growth Factor Receptor type2), patients may have been treated with trastuzumab, and estrogen and/or progesterone receptor-expressing tumors may have been treated with hormonal therapy. Patients were randomized in accordance with their 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 1.4mg/m²/day (administered intravenously on days 1 and 8, every 21 days) or capecitabine 2.5g/m²/day (administered orally on days 1 to 14, every 21 days).

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, both incidence and mortality rates of breast cancer have been growing in Japan. 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.

4. Eisai's Commitment to Oncology

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. Having already successfully launched the anticancer agents, Treakisym[®] and Halaven, Eisai plans to enhance its portfolio of products in the field of oncology with other agents such as the monoclonal antibody MORAb-003 (farletuzumab) and the VEGF receptor tyrosine kinase inhibitor/multi-kinase inhibitor E7080 (lenvatinib).