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Eisai Co., Ltd.

EISAI ANNOUNCES LAUNCH OF ANTICANCER AGENT HALAVEN® IN INDIA

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that its Indian subsidiary Eisai Pharmaceuticals India Pvt. Ltd. (Mumbai, "Eisai India") has launched the anticancer agent Halaven® (eribulin mesylate).

Halaven is a novel anticancer agent discovered and developed in-house by Eisai and is currently approved in more than 50 countries, including Japan, the United States and in Europe. Halaven was approved in India in April 2013 for the treatment of locally advanced or metastatic breast cancer previously treated with at least two chemotherapy regimens including an anthracycline and a taxane.

Approximately 115,000 women in India are newly diagnosed with breast cancer each year[*1], with this type of cancer estimated to overtake cervical cancer by 2020 as the most common cancer type among Indian women[*2]. Furthermore, due to late diagnosis and treatment, discontinuation of treatment and similar factors, the mortality rate among patients with breast cancer in India is higher than that in European countries and the United States.[*1] In addition to a lack of understanding about the disease and poor access to treatment, economic reasons are also among the contributing causes.

To coincide with the launch, Eisai India will also introduce a tiered-pricing model in which the cost burden to patients is differentiated according to income level, with costs to range from full payment by the patient to total reimbursement by Eisai. As a global pharmaceutical company, Eisai believes that improving access to medicines is an important mission and, since launching its anti-Alzheimer's agent Aricept® (brand name in India: Aricep®) and proton pump inhibitor Pariet® (brand name in India: Parit™) in India in 2005, has been providing both drugs to patients at affordable prices that take into account India's economic and medical conditions to ensure that patients are able to cover the cost of purchasing these medicines.

Eisai will continue to adopt proactive measures aimed at increasing access to its innovative pharmaceutical products in emerging countries and the developing world in order to contribute to an increase in the benefits provided to local patients and their families.

*1 *International Agency for Research on Cancer (http://globocan.iarc.fr/)*

*2 *Shetty P. India faces growing breast cancer epidemic. The Lancet 2012; 379: 992-3*

[Please refer to the following notes for further information on Halaven.]

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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) of Halaven versus treatment of physician's choice (TPC) in 762 patients with advanced or recurrent breast cancer previously treated with an anthracycline and a taxane, Halaven indicated an 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 TPC. 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%). Halaven was first approved as a treatment for breast cancer in the United States in November 2010, and is approved in 50 countries worldwide, including European Union member states, Japan, Singapore and Switzerland. Furthermore, with the aim of maximizing value of the drug, Eisai has filed an application to the European Medicines Agency (EMA) for Halaven as a therapy in the treatment of breast cancer with fewer prior treatments, and continues to work on further development of the drug as treatment of soft-tissue sarcoma and non-small cell lung cancer.