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Eisai Co., Ltd.

EISAI ANNOUNCES CANADIAN APPROVAL OF ITS ANTICANCER AGENT HALAVEN™

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that its Canadian pharmaceutical sales subsidiary Eisai Limited ("Eisai Canada") has received approval from Health Canada for Halaven™ (eribulin mesylate), a novel anticancer agent discovered and developed by Eisai, for the treatment of patients with metastatic breast cancer who have previously received at least two chemotherapeutic regimens for the treatment of metastatic disease. Prior therapy should have included an anthracycline and a taxane administered in either the adjuvant or metastatic setting. Eisai Canada will move forward with preparations for the launch of Halaven™ with a view to commencing sales of the product during the fiscal year ending March 31, 2012.

Halaven™ is the first single-agent chemotherapy to demonstrate a statistically significant overall survival (OS) benefit in previously treated metastatic breast cancer patients. Eisai simultaneously submitted marketing authorization applications seeking approval of Halaven™ to the regulatory authorities in Japan, the European Union (EU) and the United States in March 2010. As of December 2011, the agent is approved in 35 countries worldwide including Canada, the most recent approval, the United States, EU member countries, Japan, Switzerland and Singapore.

In Canada, like many European countries and the United States, breast cancer is one of the most frequently diagnosed cancers among women, with over 23,000 new cases expected annually. An estimated 5,000 Canadians die each year as a result of breast cancer.

Eisai Canada was established in April 2010 as Eisai's first pharmaceutical sales base in the Canadian market. Having commenced fully-fledged operations earlier this year, the company has already launched the antiepileptic agent Banzel™ as well as the chemotherapeutic implant Gliadel® Wafer for the treatment of certain malignant brain tumors. From next year onwards, Eisai Canada also plans to submit New Drug Submissions (NDSs) for the AMPA receptor antagonist perampanel (generic name) and a range of other additional new products in the fields of oncology and neurology, Eisai's defined areas of global therapeutic focus, thereby expanding its Canadian product portfolio.

With the approval of Halaven™ in Canada, Eisai will strive to make the product available in Canada as soon as possible and make further contributions to increase the benefits provided to patients and their families as it seeks to fulfill its mission as a *human health care (hhc)* company.

**[Please refer to the following notes for further information on Halaven™ and
Eisai's Commitment to Women's Oncology]**

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[Notes to editors]

1. About Halaven™

Halaven (eribulin mesylate), 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.

Synthesizing Halaven is an extremely difficult and complex process, involving some 62 steps to achieve total synthesis. Halaven has a molecular weight of 826, including 19 chiral carbons, which means the theoretical number of stereoisomers is 2^{19} , or a possible 524,000, making stereocontrol potentially extremely difficult. However, due to Eisai's advanced technological capabilities, it was possible to stereoselectively control all synthetic reactions and commercially synthesize Halaven.

Halaven was approved in the United States, Singapore, European Union (EU), and Japan in November 2010, February 2011, March 2011 and April 2011, respectively, and is approved in 35 countries worldwide including Canada. Eisai is currently pursuing the development of Halaven in numerous other countries such as those in Asia and emerging regions, and is conducting late stage clinical trials investigating the potential of the drug as a single-agent therapy in the treatment of other types of cancer such as breast cancer with fewer prior treatments, non-small cell lung cancer and sarcoma.

2. Eisai's Commitment to Women's Oncology

The number of women dying from cancer is increasing year by year, and according to the World Health Organization (WHO), approximately three million women worldwide lose their lives to the disease each year. Eisai considers it extremely meaningful to support women living with cancer and improve their quality of life.

By committing itself to "Women's Oncology," an area of oncology that places emphasis on the perspectives of women, Eisai will stand alongside women facing cancer, while at the same time bringing them hope and making contributions to improve their quality of life.

Eisai believes that its mission is to deliver innovative new therapies to patients fighting cancer as soon as possible by further contributing to breast cancer patients through indication expansion and the development of additional formulations of Halaven, and developing other therapeutic agents such as farletuzumab, a monoclonal antibody targeting ovarian cancer, and lenvatinib, a potential treatment for thyroid and endometrial cancer. Furthermore, Eisai is committed to implementing access programs to ensure that its products reach individual patients around the world as well as the overall improvement of healthcare systems.

3. About the Canadian Pharmaceutical Market

With a population of approximately 34 million people, Canada is highly stable nation with a real GDP growth rate of 3.3%. Canada comprises the world's ninth largest, and North America's second largest, pharmaceuticals market, boasting sales of 21.6 billion U.S. dollars (approximately 1.64 trillion yen) in 2010 and a growth rate of 3%.

In Canada, like many European countries and the United States, breast cancer is one of the most frequently diagnosed cancers among women, with over 23,000 new cases expected annually. An estimated 5,000 Canadians die each year as a result of breast cancer.