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Eisai Co., Ltd.

## **EISAI ANNOUNCES LAUNCH OF ANTICANCER AGENT HALAVEN<sup>®</sup> AS COMPANY'S FIRST PRODUCT IN RUSSIA**

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that Halaven<sup>®</sup> (eribulin mesylate), an anticancer agent, has now been launched in Russia, making it the first product to be marketed in Russia by the company.

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. In Russia, Halaven was approved in July 2012 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 50,000 women in Russia are newly diagnosed with breast cancer each year, with this type of cancer being the leading cause of death in women aged 45 to 55 years.

The Russian pharmaceutical market constitutes the 11th largest in the world and is expected to continue to achieve double-digit growth going forward. Eisai established Limited Liability Company Eisai ("Eisai Russia") as a pharmaceutical sales company in Moscow in April 2013 and has also received local marketing approval for the antiepileptic agents Zonegran<sup>®</sup> (zonasamide) and Exalief<sup>®</sup> (eslicarbazepine acetate; brand name in the EU: Zebinix<sup>®</sup>). Through Eisai Russia, Eisai plans to follow up the launch of Halaven in Russia with launches for both products in the country by the end of this fiscal year. Moreover, Eisai has also filed for regulatory approval in Russia for Fycompa<sup>®</sup> (perampanel), an AMPA receptor antagonist, and Inovelon<sup>®</sup> (rufinamide), a treatment for seizures associated with Lennox-Gastaut syndrome.

As part of Eisai's globalization strategy as defined in its midterm strategic plan, "HAYABUSA," the company aims to expand its operations into each of the world's top 20 largest pharmaceutical markets in order to contribute to more than 500 million patients worldwide. By delivering its innovative medicines to patients in Russia, Eisai seeks to increase the benefits provided to patients and their families in this region.

**[Please refer to the following notes for further information on Halaven, Eisai's globalization strategy as outlined under its midterm strategic plan, "HAYABUSA," and the company's business operations in Russia.]**

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## [Notes to editors]

### 1. About Halaven<sup>®</sup> (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.

### 2. Eisai's Globalization Strategy as Outlined Under Its Midterm Strategic Plan, "HAYABUSA"

Eisai has set the goal of entering the world's top 20 largest pharmaceutical markets as part of the company's globalization strategy outlined in its midterm strategic plan, "HAYABUSA." Of the eight countries (Russia, Canada, Brazil, Australia, Turkey, Poland, Mexico, and Venezuela) that Eisai announced it would enter as part of that strategy when the "HAYABUSA" plan was launched in March 2011, the company has already established pharmaceutical sales subsidiaries in Australia (January 2006), Canada (April 2010), Brazil (April 2011), and Mexico (August 2011) in addition to Russia. Eisai seeks to improve access to medicines through its provision of comprehensive disease solutions, engagement in public-private partnerships and other initiatives, and the implementation of its affordable pricing policy, among other activities. Furthermore, the company aims to dramatically expand the total number of patients it serves from the just over 200 million it recorded for the period from fiscal 2006 through fiscal 2010, to its current target of more than 500 million patients for the five-year period between fiscal 2011 and fiscal 2015. In doing so, Eisai believes it will be able to better contribute to increasing the benefits provided to as many patients and their families as possible worldwide.

### 3. Eisai's Business Operations in Russia

In April 2013, Eisai established the pharmaceutical sales company Limited Liability Company Eisai in Moscow, Russia, and began full-scale business operations in the country. To coincide with its launch of the anticancer agent Halaven<sup>®</sup>, Eisai is deploying sales representatives to major cities such as Moscow and Saint Petersburg and building sales infrastructure. Furthermore, with the aim of also launching four products from its epilepsy franchise (Zonegran<sup>®</sup>, Exalief<sup>®</sup> [brand name in the EU: Zebinix<sup>®</sup>], Fycompa<sup>®</sup> and Inovelon<sup>®</sup>), Eisai plans to further expand its local sales infrastructure as early as fiscal 2014. With business operations in the country focused on its oncology and epilepsy units, the company seeks to establish its presence and effectively realize contributions to patients in Russia.