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Eisai Co., Ltd.

EISAI ANNOUNCES LAUNCH OF ANTICANCER AGENT HALAVEN® AS COMPANY'S FIRST PRODUCT IN BRAZIL

LAUNCH MARKS THE COMMENCEMENT OF BUSINESS IN LATIN AMERICA

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that its Brazil subsidiary Eisai Laboratórios Ltda. (Location: San Paulo, "Eisai Brazil") has launched the anticancer agent Halaven® (eribulin mesylate) in the country. This marks the Eisai Group's first product to be marketed by Eisai in Latin America.

Halaven is an anticancer agent discovered and developed by Eisai. It is currently approved in more than 50 countries worldwide including Japan, the United States, and in Europe. In Brazil, Halaven was approved for the treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least two chemotherapy regimens for advanced disease. Prior therapy should have included an anthracycline and a taxane. Eisai Brazil has been preparing for the launch of Halaven since receiving approval in May 2013. In Brazil, approximately 67,000 women are newly diagnosed with breast cancer each year, and this type of cancer is the cause of death for approximately 16,000 patients a year.[1]

In 2013, the Brazilian pharmaceutical market was worth US$30.7 billion (approximately 3.0 trillion yen) and growing at a rate of 16% on a local currency basis, constitutes the 6th largest market in the world.[2] It is expected to continue to achieve double digit growth going forward, and is predicted to be the 4th largest pharmaceutical market in the world after the United States, Japan and China in 2018.[3] Eisai established Eisai Brazil in April 2011 as its first pharmaceutical sales company in Latin America and has since been working on submitting products for marketing authorization. In addition to Halaven being launched, the company currently has submitted the anticancer agent Gliadel®, the antiepileptic agents Fycompa® and Inovelon® as well as the antiobesity agent BELVIQ® for review.

With the launch of Halaven, Eisai is committed to delivering innovative new treatments to patients in Brazil while enhancing its product lineup and marketing framework as it seeks to further increase the benefits it provides to patients and their families in the region.

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[Notes to editors]

1. About the Brazilian Healthcare System

The Brazilian constitution defines health care as a right for all citizens and in principle, all citizens can receive public health care for free through the publicly funded Sistema Único de Saúde (SUS) which was introduced in 1990. As the medicines and medical services provided through SUS are limited due to its financial difficulties, around a quarter of the population pays for private health insurance which covers approximately 60% of all medical expenses.

2. About Business Expansion in Latin America

Eisai has positioned the six countries/regions of Russia, Brazil, Mexico, Canada, Australia and the Middle East as strategic markets, and is working on establishing business infrastructure and expansion in these locations. Among these strategic markets, Eisai positions Brazil and Mexico, which are the core drivers of the expected future growth in Latin America, as the most important. In addition to the commencement of business in Brazil, a pharmaceutical sales subsidiary was established in Mexico in August 2011, and with seven products including Halaven and Fycompa currently undergoing regulatory review, is aiming to commence business during fiscal 2014.

3. About Halaven

Halaven, the first in the halichondrin class of microtubule dynamics inhibitors 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 more than 55 countries worldwide, including European Union member states, Japan and other Asian countries. In June 2014, Eisai received approval from the European Commission of the indication expansion of Halaven to contribute earlier treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting, unless patients were not suitable for these treatments. Furthermore, the clinical development of Halaven as the treatment of other types of cancer such as soft-tissue sarcoma is also ongoing.

The approval of Halaven in Brazil was based on the results of the pivotal Phase III EMBRACE study, an open-label, randomized, multi-center, parallel two-arm study designed to compare overall survival (OS) in women treated with Halaven versus a Treatment of Physician's Choice (TPC). In the study, which included 762 participants with metastatic breast cancer who previously had been 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, 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 effect reported in patients receiving Halaven was neutropenia. The most common adverse reaction resulting in discontinuation of treatment with Halaven was peripheral neuropathy (5%).

[1] http://globocan.iarc.fr/Pages/DataSource_and_methods.aspx

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