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Eisai Co., Ltd.

EISAI LAUNCHES ANTICANCER AGENT HALAVEN® IN AUSTRALIA

FIRST EXCLUSIVELY MARKETED PRODUCT TO MARK COMMENCEMENT OF FULL-SCALE OPERATIONS

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that its Australian pharmaceutical sales subsidiary Eisai Australia Pty. Ltd. (Eisai Australia) has launched Halaven® (eribulin mesylate) in the country. The product is the first to be marketed exclusively by Eisai in Australia.

Halaven is an anticancer agent discovered and developed by Eisai. It is currently approved in more than 55 countries worldwide including Japan, the United States, and in Europe. In Australia, Halaven has received approval from the Australian Department of Health and Aging 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.

Breast cancer is the second most commonly diagnosed type of cancer in the world. In Australia, breast cancer affects an estimated 150,000 people[1], with approximately 15,000 new cases[2] of the disease being diagnosed each year. In addition, global studies have reported that approximately 40% of the patients diagnosed with early stages of breast cancer will go on to develop locally advanced or metastatic disease.

In January 2006, Eisai established Eisai Australia to commence operation in Australia, the largest country in Oceania and 14th largest pharmaceutical market in the world.[3]

With the launch of Halaven, Eisai is committed to delivering a new treatment option to as many patients with advanced breast cancer as possible, while enhancing its product lineup and marketing framework as it seeks to increase the benefits it provides to patients and their families across Australia.

1. Australian Institute of Health and Welfare & National Breast and Ovarian Cancer Centre 2009. Breast cancer in Australia: an overview, 2009. Cancer series no. 50. Cat. no. CAN 46. Canberra: AIHW.
2. Australian Institute of Health and Welfare & Australasian Association of Cancer Registries 2010. Cancer in Australia: an overview, 2010. Cancer series no. 60. Cat. no. CAN 56. Canberra: AIHW.
3. 2014 IMS Health World Review

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[Notes to editors]

1. About Halaven® (eribulin mesylate)

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 Australia 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 adverse reaction resulting in discontinuation of treatment with Halaven was peripheral neuropathy (5%).

2. Outline of Eisai Australia Pty. Ltd.

1) Company Name: Eisai Australia Pty. Ltd.
2) Location: Melbourne, Australia
3) Representative: Jaime McCoy
4) Scope of Business: Pharmaceutical sales
5) Capital: 4 million Australian Dollars
6) Shareholder: Eisai Co., Ltd.