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Eisai Co., Ltd.

GERMAN FEDERAL REGULATOR CONFIRMS ADDITIONAL BENEFIT OF ANTICANCER AGENT HALAVEN® FOR METASTATIC OR LOCALLY ADVANCED BREAST CANCER

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that the German Federal Joint Committee (G-BA)[1)], the supreme decision-making body for the self-governing medical system in Germany, considers the use of Halaven® (eribulin mesylate) to have additional benefit versus comparative treatments, defined by the G-BA for women who have already had extensive prior treatment for metastatic or locally advanced breast cancer.

This assessment by the G-BA affirms the additional benefit of Halaven, and differs from the preliminary assessment by Germany's IQWiG (Institute for Quality and Efficiency in Health Care)[2)] published in February in 2012. This assessment is based on the results of the global Phase III EMBRACE (Eisai Metastatic Breast Cancer Study Assessing Treatment of Physician's Choice vs. Eribulin E7389) study. This pivotal study demonstrates that Halaven is the first, single-agent chemotherapy to show a statistically significant overall survival benefit in women with heavily pretreated advanced breast cancer compared to treatment of physician's choice. Halaven has an expected and manageable safety profile which is in line with other single-agent chemotherapy treatments for advanced breast cancer in this setting.

This decision by the G-BA demonstrates support for innovative medicines in the area of oncology, where there are few treatment choices, including breakthrough therapies such as Halaven that prolong the time women with advanced breast cancer can spend with their loved ones,

Eisai remains committed to meaningful progress in oncology research and new drug development, and to making further contributions to address the needs of, and increase the benefits provided to, cancer patients and their families as well as health care professionals, as it seeks to fulfill its mission as a *human health care (hhc)* company.

1) The German Federal Joint Committee (Gemeinsamer Bundesausschuss: G-BA) is the highest decision-making body of the joint self-government of physicians, dentists, hospitals and health insurance funds in Germany. It issues directives for the benefit catalogue of statutory health insurance funds (GKV) and thus specifies which drugs and medical services are reimbursed by the GKV.

2) IQWiG (Institute for Quality and Efficiency in Health Care) is an independent scientific research institute contracted by the German Federal Joint Committee (G-BA) to carry out economic assessments of medical interventions, including drugs, in order to ensure greater quality and cost-efficiency of health services.

[Please refer to the following notes for further information on the EMBRACE study, Halaven and breast cancer in Europe]

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[Notes to editors]

1. About the Global Phase III EMBRACE Study

EMBRACE was an open-label, randomized, multi-center, parallel two-arm study designed to compare overall survival (OS) in patients treated with Halaven versus a Treatment of Physician's Choice (TPC). The study included 762 patients with locally recurrent or metastatic breast cancer who previously had been treated with at least two and a maximum of five prior chemotherapies, including an anthracycline and a taxane. Patients were randomized in a 2:1 ratio to receive either Halaven or TPC. TPC was defined as any single-agent chemotherapy, hormonal treatment or biologic therapy approved for the treatment of cancer; or palliative treatment or radiotherapy administered according to local practice. The vast majority (97%) of patients in the TPC arm received chemotherapy. A protocol prespecified analysis demonstrated that patients treated with Halaven survived a median of 2.5 months longer than patients who received TPC (OS of 13.1 months versus 10.6 months, respectively; Hazard Ratio [HR] 0.81; p=0.041).

An updated analysis of overall survival (not protocol prespecified) in the EMBRACE study was performed at the request of European and U.S. regulatory authorities. These results demonstrated a significant increase of 2.7 months in overall survival for Halaven compared with TPC (OS of 13.2 months versus 10.5 months, respectively; HR 0.81; p=0.014). Data from this analysis was presented at the 33rd Annual San Antonio Breast Cancer Symposium, held in December 2010, and confirmed the overall survival benefits of Halaven as well as no change in safety profile.

The most common adverse reactions (incidence greater than or equal to 25%) among patients treated with Halaven were asthenia (fatigue), neutropenia, anemia, alopecia (hair loss), peripheral neuropathy (numbness and tingling in arms, legs and 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%).

2. About Halaven® (eribulin mesylate) Injection

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. Halaven is approved for the treatment of patients with locally advanced or metastatic breast cancer who have been previously treated with at least two chemotherapeutic regimens, including an anthracycline and a taxane.

As part of efforts to expand the range of approved indications, Eisai is currently conducting late stage clinical trials investigating the potential of Halaven 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, sarcoma, and prostate cancer.

3. Breast Cancer in Europe

Worldwide, more than one million women are diagnosed with breast cancer each year, including 421,000 women in Europe. The incidence of breast cancer is continuing to rise.