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Eisai is a Human Health Care Corporation striving for innovative solutions in prevention, cure and care for the health and well-being of people worldwide. We combine our talents to understand and meet the needs of patients and their families to enhance the quality of life.

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Eisai Co., Ltd.

Eisai Files Submission to Health Authorities in Switzerland for E7389, Novel Anti-cancer Agent, for the Treatment of Metastatic and Locally Advanced Breast Cancer

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that its Swiss subsidiary, Eisai Pharma AG (Location: Zurich, Switzerland, Director: Folker Kindl), has submitted to the health authorities (Swissmedic) marketing authorisation applications for eribulin mesylate ("eribulin"), also known as E7389, seeking approval for this novel anti-cancer agent as a treatment for locally advanced and metastatic breast cancer. This submission was made with data derived primarily from Study 211 (Phase II trial).

Eribulin, a microtubule dynamics inhibitor, is a new chemical compound discovered and developed by Eisai. It is believed to exert an anti-tumour effect by arresting the cell cycle through inhibition of the growth of microtubules, which are involved in intracellular processes such as cell division. Eribulin is a synthesised derivative of halichondrin B, a naturally-derived compound that was first isolated from a marine sponge.

Eisai defines oncology as a therapeutic area of focus and promotes its active business deployment in research and development and marketing in this area. This is the first marketing authorisation application of an in-house anti-cancer agent for Eisai. Eisai is currently conducting a Phase III trial of eribulin for breast cancer in the United States and Europe, as well as a Phase II trial in Japan. Eisai intends to submit marketing authorisation applications simultaneously in the U.S., Europe, and Japan before the end of March 2010. In addition to breast cancer, Eisai is also conducting Phase II trials of this compound in non-small cell lung cancer (U.S.), prostate cancer (U.S. and Europe), and sarcoma (Europe).

Study 211 was conducted in patients with locally advanced or metastatic breast cancer previously treated with anthracycline, taxane and capecitabine. Data from Study 211 reported an overall response rate (ORR) of 9.3 percent by independent review in 291

patients treated with E7389 (all partial response [PR]). Stable disease (SD) was seen in 45.7 percent of patients. Clinical efficacy (complete response + PR+SD over six months) was 17.2 percent. ORR assessed by principal investigators was 14.1 percent and complete response was observed in two patients.

The most frequently reported Grade 3 (severe) or Grade 4 (life-threatening or disabling) adverse events seen in 291 patients treated with E7389 included neutropenia (54 percent), leukopenia (14 percent), fatigue (10 percent, no Grade 4 observed), febrile neutropenia (5.5 percent). Peripheral neuropathy, which is said to decrease the quality of life of many patients receiving chemotherapy, occurred in 5.5 percent of cases (all Grade 3) and no Grade 4 was observed. These results suggest that eribulin has a manageable tolerability profile.

Breast cancer is one of the most common cancers among women. It is estimated that breast cancer has an incidence of approximately 13.7 in every 10,000 people in Switzerland. Although advances are being made every year, the treatment of breast cancer remains a challenge. The development of more useful treatments or anti-cancer drugs is much anticipated.

Eisai demonstrates its commitment to the area of oncology by developing anti-cancer drugs such as eribulin and treatments for supportive care in an endeavour to provide a better quality of life to patients with cancer and to satisfy their unmet medical needs. With these efforts, Eisai will make further contributions to addressing the diversified needs of and improving benefits to patients and families affected by cancer.

[Please refer to the following notes for E7389]

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<Notes to Editors>

E7389 (generic name: eribulin mesylate)

E7389, a microtubule dynamics inhibitor, is a new chemical compound discovered and developed by Eisai. It is believed to exert an anti-tumour effect by arresting the cell cycle through inhibition of the growth of microtubules, which is involved in intracellular processes such as cell division. E7389 is a synthesised derivative of halichondrin B, a naturally-derived compound that was first isolated from a marine sponge in 1986.

Despite its remarkable anti-tumour effect, it was difficult to supply halichondrin B in quantity due to its complicated chemical structure. However, the total synthesis of halichondrin B in 1992 led Eisai to start developing a novel anti-cancer drug at its research institute in Boston, thereby enabling Eisai to identify its active structure and to fully synthesise chemically and biologically optimised E7389.