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Eisai Co., Ltd.

Eisai Corporation of North America

Eisai Announces Change in U.S. Submission Schedule for E7389 New Drug Application

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito) and Eisai's U.S. subsidiary, Eisai Corporation of North America (Headquarters: New Jersey, the United States, Chairman & CEO: Hajime Shimizu), today announced a change in the schedule for submission to the U.S. Food and Drug Administration (FDA) of a New Drug Application (NDA) for E7389 (generic name: eribulin mesylate) for third-line treatment of advanced breast cancer in patients who were pretreated with anthracycline, taxane and capecitabine.

Eisai is committed to developing E7389 as a potential treatment for patients with advanced breast cancer. In a Phase II study of 299 patients with advanced breast cancer who had been heavily pretreated, the compound has shown promising anti-tumor activity, with a response rate of 14.1% by investigator evaluation and 9.3% by independent radiologist evaluation. It has also been shown in the Phase II study to be generally well-tolerated, with the most common Grades 3 and 4 drug-related adverse events being 54% in neutropenia and, 14% in leucopenia. Grade 3 peripheral neuropathy occurred in 6% of study participants, and there were no Grade 4 events.

Eisai had planned to submit an NDA under Subpart H*, based on Phase II clinical trial data, to seek accelerated approval for E7389 as a third-line breast cancer treatment (monotherapy), but is precluded from doing so, because FDA approved another drug for this specific indication last October. Eisai remains committed to advancing two Phase III clinical trials for E7389, which are ongoing in the U.S. and in Europe, Study 301 for second-line and Study 305 for third-line breast cancer treatment. Eisai now plans to submit an NDA to FDA with data from these trials and Phase II clinical trial data in fiscal year 2009-2010. In addition, Eisai continues to evaluate E7389 as a potential treatment for a variety of other solid tumors, including non-small cell lung cancer, prostate cancer and sarcoma.

E7389 is a novel compound developed by Eisai as a new potential anti-cancer agent that suppresses the growth of microtubule which is involved in various cellular processes in the body, such as cell division. E7389 is a synthetic analog of halichondrin B, a naturally-occurring compound which was first isolated from a type of marine sponge in 1992.

Eisai has a strong commitment to the development of new oncology medicines to address the unmet medical needs of patients with cancer. Currently, seven other Eisai oncology compounds are in clinical development, in addition to E7389.

*Accelerated Approval under Subpart H:
One of the programs within the FDA that allows earlier, or accelerated, approval of new drugs for serious or life-threatening illnesses that meet certain criteria designated by the regulatory agency.

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