## FOR IMMEDIATE RELEASE

February 1, 2008

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 Natrat Aitherinthracycline, 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 an

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