Eisai Co., Ltd.

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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 to Resume Clinical Study to Evaluate E2012 as a Potential Next Generation Alzheimer's Disease Treatment

Eisai Co., Ltd. (Headquarters: Tokyo, President and CEO: Haruo Naito) announced that on April 2, 2008 (the U.S. Eastern Time), Eisai Medical Research Inc. (Headquarters: New Jersey, President: Masanori Tsuno), the U.S. clinical research subsidiary of Eisai, received a notification from the U.S. Food and Drug Administration (FDA) that it may proceed with the clinical study for E2012. E2012 is Eisai's potential next generation Alzheimer's disease treatment. The company had suspended the Phase I study for E2012 in the United States in February, 2007 and has been requesting for resuming the study with data required by the FDA. With this response from the FDA, Eisai will start preparations for resuming the study.

The need for a next generation disease modifying treatment that improves the underlying Alzheimer's disease is increasing. E2012, a novel compound discovered by Eisai, is a gamma-secretase modulator that suppresses the production of beta-amyloid, which is believed to be one of the causes of Alzheimer's disease.

As the leader in Alzheimer's disease therapy with its marketed product, *Aricept*® (donepezil hydrochloride), Eisai is pursuing the development of new therapies for the disease through multi-faceted approaches including investigation of genes responsible for the onset of the disease, immunotherapy and vaccine therapy. Through these efforts, the company is committed to contributing to increasing the benefit to Alzheimer's disease patients and their families.

[Please see the following note for the background information]

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<Note to Editor>

Background Information

Lenticular opacity was observed in a high-dose group of a 13-week safety preclinical study in rats which ran in parallel with the Phase I study. Eisai immediately suspended the phase I clinical study, reported to the FDA and received an order of clinical hold from the FDA. No medical issues were observed in subjects who received E2012 in the phase I study in an examination which was conducted at the point when the study was suspended. Lenticular opacity was not observed in a 13-week safety study in monkeys. Additionally, lenticular opacity was not observed in the single dose administration at maximum tolerated dosing and 4-week administration in high doses as well as in their long term follow-up examination in rats. Eisai conducted an additional 13-week multiple dosing study in rats to reevaluate repeatability and recoverability potential and examined the no adverse effective level, the mechanism causing lenticular opacity, and an exploratory marker. Examination of follow-up data from the Phase I study was also conducted. After submitting these data to the agency on February 29, 2008, Eisai received the response from the FDA.