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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.

Aricept® Receives Approval for Additional Efficacy and Dosage For Treatment of Severe Alzheimer's Disease in Japan

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito) today announced that the company received approval for additional efficacy and dosage of *Aricept*® (donepezil hydrochloride) for the treatment of severe Alzheimer's disease (AD) in Japan. With this approval, *Aricept*® is now approved to treat all stages of AD including mild, moderate and severe in Japan.

The approval was based on the results of clinical trials conducted in Japan and abroad. The trial in Japan, involving approximately 300 patients with severe AD, compared the efficacy of the dosage of 5 mg/day and 10 mg/day (administered as two 5 mg/day tablets) vs placebo in a six-month, multi-center, randomized, double-blind, placebo-controlled study.

In this study, the patients treated with 5 mg/day and 10 mg/day doses of *Aricept*® showed a statistically significant improvement in cognitive function compared to those taking placebo. In addition, the patients treated with the 10 mg/day dose showed a statistically significant improvement in global function compared to the placebo group. Regarding the safety profile, no statistically significant difference was observed between the 5 mg/day dose group and the placebo group in the rate of adverse events. In the 10 mg/day dose group, the patients experienced a statistically higher incidence of adverse events compared to the placebo group. The most commonly observed adverse events in the 10 mg /day group were gastrointestinal in nature and were mild to moderate in severity.

Aricept®, an acetylcholinesterase inhibitor developed by Eisai Co., Ltd., is the only approved prescription medicine for the treatment AD in Japan. It is believed to work by inhibiting the breakdown of acetylcholine, thereby increasing available levels of this chemical in the brain. There is an established association between the loss of acetylcholine, a brain chemical involved in memory and thinking, and AD. In Japan, it has been reported that approximately 1.25 million people have been affected by AD and approximately 300,000 of those are in the severe stage.

Today's approval will enable Eisai to make further contributions to increasing the benefits of patients in all stages of AD and their families, and will enhance the value of *Aricept*® in clinical practice.

[Please see the following note for the details of the additional approval of *Aricept*®]

Contacts:

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<Notes to Editor>

About Additional Approval

- Products that received the additional approval:
  "*Aricept*® (donepezil hydrochloride) Tablet 3 mg", "*Aricept*® Tablet 5 mg", "*Aricept*® D Tablet 3 mg", "*Aricept*® D Tablet 5 mg", "*Aricept*® Fine granules 0.5%", "*Aricept*® Tablet 10 mg", "*Aricept*® D Tablet 10 mg"
- Additional efficacy: inhabitation of progress of cognitive disorder in Alzheimer's disease
- Dosage & administration:
  The recommended initial dose for adult patients is 3 mg donepezil hydrochloride administered orally once daily. After 1 to 2 weeks, the dose should be increased to 5 mg once daily. For severe Alzheimer's disease patients, administration should be started with 5 mg once daily, and after 4 weeks, the daily dose should be increased to 10 mg. This dose may be decreased when necessary.

Relevant Information:

In the United States., *Aricept*® received approval for the treatment of severe Alzheimer's disease in October 2006.

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