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Eisai Co., Ltd.

Aricept[®] Receives Approval for Additional Efficacy and Dosage

[®] 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. ficant 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 $Aricept^{(R)}$ in clinical practice.

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

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About Additional Approval

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