

No.11-78

December 13, 2011  
Eisai Co., Ltd.

## **EISAI SUBMITS APPLICATION IN JAPAN FOR NEW DRY SYRUP FORMULATION OF ITS ALZHEIMER'S DISEASE TREATMENT ARICEPT®**

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") today submitted a marketing and manufacturing authorization application to Japan's Ministry of Health, Labour and Welfare seeking approval of a new dry syrup formulation of its Alzheimer's disease (AD) treatment Aricept® (donepezil hydrochloride).

In August 2007, the indication of Aricept® was expanded to include severe AD. The simultaneous approval of additional dosage, which states that once daily dosage of donepezil hydrochloride may be increased to a maximum of 10 mg and reduced appropriately according to patients' symptoms, also made it possible to adjust Aricept® dosage amounts. This newest Aricept® formulation is a dry syrup formulation that can be administered by suspending dry syrup powder with water, and that allows dosage to be adjusted within the range of the approved dosage amounts at time of administration depending on the needs of individual patients. It was designed as a suspension to make it easier for patients who find powder too dry or bulky to swallow, and so that it can be taken with water in the same way as the existing Aricept® fine granules formulation, reflecting the diversified needs of AD patients. These characteristic features are expected to improve drug compliance amongst patients, while at the same time reducing the burden on caregivers who help administer the drug to patients.

Aricept®, originally discovered and developed by Eisai, is an acetylcholinesterase inhibitor that contains donepezil hydrochloride as its main ingredient, and is the only prescription medicine approved in Japan for the treatment of all stages of AD, from mild through severe. As part of efforts to address the needs of dementia patients, the number of which is increasing year-on-year as Japan's population grows older, Eisai, as the creator of Aricept, is committed to developing new formulations and indications to increase the benefits provided to patients. Currently, the company is conducting two clinical development projects for Aricept® in Japan with the aim of obtaining approval to use this medicine for the treatment of dementia with Lewy bodies (Phase III) as well as of a new higher dose 23 mg tablet (Phase II), and will endeavor to further enhance the value of this drug even beyond expiration of the drug's composition of matter patent.

The development of the new Aricept® dry syrup formulation demonstrates Eisai's commitment to providing new dosing options to AD patients and their caregivers that complement the existing Aricept® lineup comprising tablets, orally disintegrating tablets, fine granules, and an oral jelly formulation. Eisai will leverage the vast experience it has accumulated over the years through the development and marketing of Aricept® as it seeks to make further contributions to improve the quality of life of AD patients, their families and caregivers.

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