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Eisai Co., Ltd.

EISAI ANNOUNCES LAUNCH OF HIGHER-DOSE ARICEPT® 23 mg TABLET FOR MODERATE-TO-SEVERE ALZHEIMER'S DISEASE IN SOUTH KOREA

REALIZES FURTHER CONTRIBUTION TO PATIENTS WITH DEMENTIA IN ASIA REGION

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that its marketing subsidiary in South Korea, Eisai Korea Inc. ("Eisai Korea"), has launched a higher-dose, once-daily Aricept® (donepezil hydrochloride) 23 mg tablet formulation for treatment of moderate-to-severe Alzheimer's disease (AD) in South Korea.

South Korea is the first country in the Asia region to launch the formulation. More than 9% of South Korea's population over 65, or approximately 540,000 patients, are reported to be living with AD, with approximately 220,000 patients of that number estimated to be living with moderate-to-severe stages of the disease[*1]. Eisai Korea has been locally marketing Aricept 5 mg and 10 mg tablet formulations since 1998 and Aricept Evess 5 mg and 10 mg orally disintegrating formulations since 2008. The launch of the Aricept 23 mg tablet will provide a more beneficial treatment option for patients with moderate-to-severe AD, including patients who have stopped treatment with existing formulations due to reduced drug efficacy as the disease progresses.

Eisai has already received approval for the formulation in Hong Kong and is in the process of submitting further applications in India, Indonesia, Malaysia, Thailand, the Philippines and other countries in the Asia region. In a head-to-head trial (Study 326), the Aricept 23 mg tablet was shown to possess superior benefit in cognitive function of patients with moderate-to-severe AD. The formulation was subsequently approved in the United States in July 2010 as a treatment option for patients with moderate-to-severe AD.

There are approximately 15,940,000 patients with dementia in the Asia region and it is estimated that this number will significantly increase to approximately 33,040,000 patients by 2030[*2]. As the originator and developer of Aricept, Eisai is a leader in AD treatment and the company remains actively committed to the development of AD treatments in the Asia region and their promotion and widespread use through disease and diagnosis education, with the aim of making further contributions to increasing the benefits provided to patients with AD and their families.

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*1 *Korea Ministry of Health and Welfare, 2012*
*2 *Dementia: A Public Health Priority 2012, World Health Organization*

[Please refer to the following notes for further information on Aricept and Study 326.]

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[Notes to editors]

1. About Aricept®

Aricept is an acetylcholinesterase inhibitor discovered and developed by Eisai. It increases brain levels of the neurotransmitter acetylcholine by inhibiting its breakdown by acetylcholinesterase to slow the overall progression of symptoms associated with AD. Aricept is currently approved in more than 90 countries and territories around the world for the treatment of mild-to-moderate AD. It is also approved as a treatment for patients with severe AD in Japan, the United States, Canada, countries in Central and South America, South Korea and other Asian countries, and other regions.

2. About Study 326

The approval of the Aricept 23 mg tablet in the United States is based on data from a head-to-head study (Study 326) of 1,467 patients with moderate-to-severe AD. In evaluations of cognitive function, the Aricept 23 mg tablet was shown to possess superior benefit over the existing Aricept tablet 10 mg formulation. The study was conducted with two primary endpoints: Severe Impairment Battery (SIB), which evaluates severely impaired cognitive function, and Clinician's Interview-Based Impression of Change Plus Caregiver Input (CIBIC plus), which evaluates changes in overall clinical symptoms. SIB results of the study demonstrated that the 23 mg tablet possessed statistically significant benefit versus the Aricept tablet 10 mg formulation. On the other hand, the 23 mg tablet did not exhibit a statistically significant level of difference in CIBIC plus results. The SIB results (higher scores are better) were 2.6 ± 0.58 in the 23 mg group and 0.4 ± 0.66 in the 10 mg group, with a difference of 2.2 ($p = 0.0001$). The CIBIC plus results (lower scores are better) were 4.23 ± 1.07 in the 23 mg group and 4.29 ± 1.07 in the 10 mg group, with a difference of 0.06 ($p = 0.1789$).

The most frequently observed adverse effects (5% or more) in the study included nausea, vomiting, diarrhea, anorexia, and other digestive symptoms commonly seen in patients taking acetylcholine esterase inhibitors.