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Eisai Co., Ltd.

**ARICEPT® APPROVED IN THE PHILIPPINES FOR NEW INDICATION
AS TREATMENT FOR DEMENTIA WITH LEWY BODIES
SECOND COUNTRY IN THE WORLD AFTER JAPAN
TO APPROVE ARICEPT FOR DEMENTIA WITH LEWY BODIES**

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that its subsidiary in the Philippines, HI-Eisai Pharmaceutical Inc., has received approval for a new indication for the symptomatic treatment of dementia with Lewy bodies (DLB) for anti-Alzheimer's agent Aricept® (donepezil hydrochloride) in the Philippines, and has commenced information provision activities. Following the approval of Aricept for DLB in Japan in September 2014, this marks the second country in which Aricept has been approved for DLB.

Since it was first launched in the Philippines in March 1999 as a treatment for Alzheimer's disease, Aricept has widely contributed to patients through additional approval for vascular dementia, and other formulations including orally disintegrating tablets. An application seeking approval for DLB based on clinical trial data from Japan was submitted in November 2015 and subsequently approved in February 2016. An application seeking approval of Aricept for the treatment of DLB is currently undergoing regulatory review in Thailand.

DLB is considered to be one of the major types of dementia worldwide, alongside Alzheimer's disease and vascular dementia. It is pointed out that DLB is difficult to be diagnosed because the disease presents characteristic symptoms such as cognitive fluctuations, visual hallucinations and parkinsonism in addition to progressive cognitive impairment.

The number of dementia patients in the Philippines is estimated to be approximately 400,000. Eisai will use this additional indication for DLB as an opportunity to enhance information provision activities on dementia diagnosis, treatment and care, as well as to further contribute to improving the quality of life of dementia patients in the Philippines, including those with DLB.

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[Notes to editors]

1. About Dementia with Lewy Bodies (DLB)

DLB is a degenerative form of dementia discovered in Japan that is pathologically characterized by decreased neurons in the brain and brainstem and the appearance of vast numbers of Lewy bodies. In neurochemistry, DLB is characterized by a loss of acetylcholine-producing neurons in the brain similar to that seen in patients with Alzheimer's disease. In addition to obligatory symptoms associated with progressive cognitive impairment, the disease also presents with behavioral and neuropsychiatric symptoms, motor disturbances, and dysautonomia. In particular, cognitive fluctuations, visual hallucinations and idiopathic parkinsonism have a high rate of incidence and are considered to be core symptoms of the disease. In Japan, DLB constitutes one of the three major types of dementia diagnosed, alongside Alzheimer's disease and vascular dementia, affecting between 4.3% (based on epidemiology) to 41.4% (based on autopsy) of elderly patients with dementia, according to various studies^{1,2}. While there are no reliable statistics available on the incidence of DLB in the Philippines, the number of patients with dementia is reported to be approximately 400,000.

^{*1} MHLW Grants System – Prevalence of dementia in urban areas and measurements for living impairment in dementia: The Report for Scientific Research, 2013

^{*2} Wakisaka Y, Furuta A, Tanizaki Y, Kiyohara Y, Iida M, Iwaki T. Age-associated prevalence and risk factors of Lewy body pathology in a general population: the Hisayama study. *Acta Neuropathol* 2003; 106:374-382