ARICEPT APPROVED IN JAPAN AS TREATMENT FOR DEMENTIA WITH LEWY BODIES

WORLD S FIRST TREATMENT FOR BOTH ALZHEIMER S DISEASE AND DEMENTIA WITH LEWY BODIES

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, “Eisai”) announced today that its anti-Alzheimer’s agent Aricept® (donepezil hydrochloride) has received approval for a new indication for dementia with Lewy bodies (DLB) in Japan. This marks the first time a treatment has been approved for DLB anywhere in the world.

DLB was discovered by Dr. Kenji Kosaka, Professor Emeritus of Yokohama City University. DLB is considered to be one of Japan's three major types of dementia, alongside Alzheimer's disease and vascular dementia. According to a number of report

[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. Of these, cognitive fluctuations, visual hallucinations and idiopathic parkinsonism have a high rate of incidence and are considered to be core symptoms of the disease[3]. 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].

2. Aricept Product Outline (New Information Related to Additional Indication Underlined)

1) Indications and usage

Suppression of progression of dementia symptoms in dementia of the Alzheimer's type and dementia with

3. About the Results of Clinical Studies on Aricept in Dementia with Lewy Bodies Conducted in Japan

In an exploratory Phase II study (Study 431) of Aricept in Japanese patients with DLB, Aricept demonstrated significant improvement over placebo in core efficacy outcome measures such as cognitive function, behavioral and neuropsychiatric symptoms, and global function.

Based on the positive results of Study 431, Eisai conducted a Phase III study (Study 341) to assess the superiority of 12-week Aricept treatment over placebo in patients with DLB. The co-primary endpoints set for Study 341 were cognitive function and behavioral and neuropsychiatric symptoms. In addition, the safety and efficacy of long-term Aricept administration (52 weeks) were also investigated. Based on the results of Study 341, the expected objective of simultaneous improvement in both cognitive function as well as behavioral and neuropsychiatric symptoms was not achieved. Regarding cognitive function, statistically significant improvement was observed in the Aricept 10mg group compared to the placebo group at the final evaluation point after 12 weeks of treatment, and cognitive function was also observed to be maintained at a level higher than at baseline after 52 weeks of treatment. On the other hand, improved behavioral and neuropsychiatric symptoms were observed in all treatment groups, both Aricept and placebo, and suggested no statistically significant difference among groups at the final evaluation point after 12 weeks of treatment.

From a combined analysis of the results of Study 431 and