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Eisai Co., Ltd.

CHINA JSFDA ACCEPTS EISAI'S APPLICATION SEEKING ADDITIONAL INDICATION OF SEVERE ALZHEIMER'S DISEASE FOR ARICEPT®

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that its New Drug Application for the additional indication of severe Alzheimer's Disease (AD) for Aricept® (donepezil hydrochloride, brand name in China: 安理申®) has been accepted for review by the Jiangsu Food and Drug Administration in China.

The Phase III study (Study 339) that this additional indication application was based on was a multi-center, randomized, double-blind, placebo controlled, parallel-group study to evaluate the efficacy and safety of Aricept 10 mg tablets in 313 Chinese patients with severe AD. In this study, Aricept demonstrated a statistically significant improvement in total Severe Impairment Battery scores after 24 weeks compared to placebo, which was the primary endpoint of the study. The most commonly observed adverse events in the study were bradycardia, anorexia, QT interval prolongation, dizziness, diarrhea and weight loss.

In China, it has been estimated that approximately 7 million people suffer from dementia[1], which is the highest incidence in the world. Furthermore, with the progressive aging of the population, this figure is expected to greatly increase in the future.

While Aricept is currently approved for the indication of mild to moderate AD in China, if this application seeking the additional indication of severe AD is approved, Aricept will have a wide indication that covers mild to severe AD. As the originator of Aricept, Eisai strives for making further contribution to the improvement of treatment and care as well as increasing public awareness towards the disease.

[1] Jia J, Wang F, Wei C, et al. The prevalence of dementia in urban and rural areas of China. *Alzheimers Dement* 2014; 10: 1-9.

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