PHASE III TRIAL OF ARICEPT® IN PATIENTS WITH SEVERE ALZHEIMER'S DISEASE IN CHINA MEETS PRIMARY ENDPOINT

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, “Eisai”) announced today that a Phase III clinical trial (Study 339) conducted in China of Aricept® (donepezil hydrochloride) in patients with severe Alzheimer’s Disease (AD) met its primary endpoint. Based on the results of the study, Eisai plans to submit an application during fiscal 2014 to the regulatory authority in China for an indication expansion to include the treatment of severe AD.

The trial was a multi-center, randomized, double5omestudy.1n the study, the most common observed adverse events were QT interval prolongation, dizziness, diarrhea and weight loss.

Regarding the results of the study, the lead principal investigator of the study, Professor Jianping Jia of the Department of Neurology, Xuan Wu Hospital, Capital Medical University, said “Despite the large number of patients with severe AD in China, no medicine has been proven to be effective for the indication of severe AD in a Phase III placebo controlled trial for Chinese patients so far. According to this study, a medical treatment based on clear evidence may be available for patients in China.”

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

Since the launch of Aricept, Eisai has been working to maximize the value of the drug to patients through the development of new formulations and indications, disease awareness activities for earlier diagnosis and treatment as well as the improvement of diagnostic techniques. On September 19, 2014, Aricept was approved in Japan for the new indication of dementia with Lewy bodies (DLB), marking the first time a