

No.16-80

October 31, 2016  
Eisai Co., Ltd.

## **ENROLLMENT COMMENCES IN PHASE III CLINICAL STUDY OF EISAI'S BACE INHIBITOR E2609 IN EARLY ALZHEIMER'S DISEASE**

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that enrollment has commenced in **MISSION AD**, a Phase III clinical program of the beta secretase cleaving enzyme (BACE) inhibitor E2609 in patients with early Alzheimer's disease in the United States. E2609 was discovered by Eisai and is being jointly developed by Eisai and Biogen Inc. (Headquarters: Massachusetts, United States, CEO: George A. Scangos, "Biogen") as a potential Alzheimer's disease modifying treatment. Regarding the global conduct of the studies, Eisai and Biogen are currently in consultation with the regulatory authorities in the EU and Japan.

The first study of the **MISSION AD** program entitled **MISSION AD1** (Study 301) is a global, multicenter, placebo-controlled, double-blind, parallel-group Phase III clinical study aiming to assess the efficacy and safety of E2609 in 1,330 patients with biomarker confirmed early Alzheimer's disease. The treatment group will be administered a dosage of 50 mg of E2609 daily during the treatment period of 24 months, and the primary endpoint will utilize the Clinical Dementia Rating Sum of Boxes (CDR-SB).

Discovered in-house by Eisai, E2609 is an investigational next-generation oral candidate for the treatment of AD that is believed to inhibit BACE, a key enzyme in the production of amyloid beta (A $\beta$ ). By inhibiting BACE, E2609 may decrease the formation of toxic A $\beta$  peptide aggregates and amyloid plaques in the brain, thereby potentially slowing disease progression.

Lynn Kramer, M.D., Chief Clinical Officer and Chief Medical Officer of the Eisai Neurology Business Group, commented, "We are committed to helping those with Alzheimer's through the continued development of clinical studies with our BACE inhibitor targeting the production of A $\beta$  proteins. Through the initiation of **MISSION AD1** and similar clinical trials, we hope to demonstrate the value of this compound for those who suffer from early Alzheimer's disease."

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**[Notes to editors]**

**1. About the Joint Development Agreement between Eisai and Biogen**

Based on this agreement, Eisai and Biogen will co-develop Eisai's investigational next generation AD treatment candidates E2609, a BACE inhibitor, and BAN2401, an anti-amyloid beta (A $\beta$ ) protofibril antibody, in major markets, such as the United States, the European Union and Japan. If approved, the companies will also co-promote the products. Both companies will share overall costs, including research and development expenses. Eisai will book all sales for E2609 and BAN2401 following marketing approval and launch, and profits will be shared between the companies. Also, Eisai has received from Biogen an additional one-time payment as well as the right to receive additional development milestone payments. Under the same agreement, Eisai also holds options to jointly develop and commercialize two of Biogen's candidates for Alzheimer's disease, the anti- A $\beta$  antibody aducanumab and an anti-tau antibody.