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Eisai Co., Ltd.

U.S. FDA GRANTS FAST TRACK DESIGNATION FOR THE DEVELOPMENT OF EISAI'S BACE INHIBITOR E2609 FOR EARLY ALZHEIMER'S DISEASE

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the development of the beta secretase cleaving enzyme (BACE) inhibitor E2609 which was discovered by Eisai and is being jointly developed by Eisai and Biogen Inc. (Headquarters: Massachusetts, United States, CEO: George A. Scangos, "Biogen"). E2609 is currently being investigated in Phase III clinical studies for early Alzheimer's disease.

Fast Track is a process designed to facilitate the development and review of drugs to treat serious conditions and tackle key unmet medical needs by allowing for frequent interactions with the FDA. It may also enable Priority Review by the FDA if supported by clinical data at the time of New Drug Application submission.

Discovered in-house by Eisai, E2609 is an investigational next-generation oral candidate for the treatment of Alzheimer's disease that is believed to inhibit BACE, a key enzyme in the production of amyloid beta (Aβ). By inhibiting BACE, E2609 may decrease the formation of toxic Aβ peptide aggregates and amyloid plaques in the brain, thereby potentially slowing disease progression. The first Phase III study for E2609 in the clinical trial program called MISSION **AD** began in October 2016 and will enroll 1,330 patients with biomarkers confirmed for early Alzheimer's disease.

"We are excited that the FDA has granted Fast Track designation to E2609" said Lynn Kramer, M.D., Chief Clinical Officer and Chief Medical Officer of the Eisai Neurology Business Group. "We look forward to working closely with the FDA to expedite this clinical program and hope to offer an important treatment option for patients who suffer from early Alzheimer's disease as soon as possible."

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[Notes to editors]

1. About the U.S. Food and Drug Administration's Fast Track Designation

Fast Track is a special measure provided by the U.S. Food and Drug Administration (FDA) to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The Fast Track designation is available not only when treatments do not exist, but also for drugs that demonstrate a potential advantage over existing treatments. Once a drug has granted Fast Track designation, the FDA will increase the frequency of meetings to discuss development, and if supported by clinical data at the time of New Drug Application submission, the drug may also be eligible for Accelerated Approval and Priority Review.

2. About the Clinical Trial Program for E2609 (MISSION **AD**)

The clinical trial program for E2609 (MISSION **AD**) consists of two global Phase III studies, MISSION **AD1** (Study 301) and MISSION **AD2** (Study 302).

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

3. 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 (Aβ) 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-Aβ antibody aducanumab and an anti-tau antibody.