No.16-83

November 18, 2016
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