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Eisai Co., Ltd.

U.S. FDA CONFIRMS SUFFICIENT DATA TO ADVANCE INVESTIGATIONAL BACE INHIBITOR E2609 FOR TREATMENT OF EARLY ALZHEIMER'S DISEASE TO PHASE III

PLANNING UNDERWAY TOWARDS PHASE III STUDY INITIATION IN FY2016

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that, at its recent meeting with the U.S. Food and Drug Administration (FDA), the FDA confirmed there was sufficient data to support the advancement of its novel investigational oral beta-secretase cleaving enzyme (BACE) inhibitor E2609 into Phase III clinical studies. E2609 was discovered by Eisai and is being jointly developed by Eisai and Biogen Inc. (Headquarters: Massachusetts, United States, CEO: George A. Scangos, "Biogen") for early Alzheimer's disease.

Based on the clinical and pre-clinical data presented to the FDA at the Study 202 end of Phase II meeting, the FDA confirmed that the data package was sufficient to commence Phase III studies, and acknowledged the outlines of the two Phase III clinical study protocol designs. The study protocol will be a placebo-controlled design in patients with early Alzheimer's disease where the treatment group will be administered a dosage of 50 mg/day of E2609 with the primary outcome endpoint assessed at 24 months. The primary endpoint will be the Clinical Dementia Rating Sum of Boxes (CDR-SB), with routine safety assessment.

Following this discussion with the FDA on the Phase III clinical study designs, Eisai and Biogen intend to have similar discussions with the regulatory authorities in Japan and the EU, and to conduct the study as a global, multicenter study.

Study 202 was a multicenter, randomized, double-blind, placebo-controlled parallel-group study to evaluate the safety of E2609 administered in patients with early to moderate Alzheimer's disease (including prodromal Alzheimer's disease) with confirmed accumulation of amyloid beta (Aβ) by PET (positron emission tomography) screening. The study included three doses of E2609: 5, 15, and 50mg/day. Plasma and cerebrospinal fluid (CSF) Aβ (Aβ1-x)* levels were measured in patients prior to receiving E2609 and during the study.

The results of an analysis of Study 202 presented at the end of Phase II meeting suggested favorable safety at all doses of E2609 and that total Aβ levels in the plasma and CSF were reduced in a dose-dependent manner. Furthermore, according to an analysis of safety and pharmacokinetic/pharmacodynamic data from pre-clinical studies as well as Study 202 and Phase I clinical studies overall, the optimal dose of E2609 was identified as 50 mg/day.

Lynn Kramer, M.D., Chief Clinical Officer and Chief Medical Officer of Eisai Neurology Business Group commented, "We believe that the Phase III clinical study design outline agreed upon will enable us to efficiently conduct studies on BACE inhibitors aimed at realizing preemptive medicine, and will accelerate the development of E2609. We are striving to deliver E2609 to patients around the world as soon as possible, and contribute to increasing the benefit for patients."

* Aβ1-x means total amount of Aβ peptides of different lengths

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[Notes to editors]

1. About E2609

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 beta-secretase cleaving enzyme (BACE), a key enzyme in the production of amyloid beta (Aβ). By inhibiting BACE, E2609 decreases Aβ proteins in the brain, potentially improving symptoms and slowing disease progression. Currently, E2609 is undergoing preparations to enter Phase III clinical studies.

2. About the Joint Development Agreement between Eisai and Biogen

Based on the agreement, Eisai and Biogen are co-developing Eisai's investigational next generation Alzheimer's disease treatment candidates E2609, a BACE inhibitor, and BAN2401, an anti-Aβ protofibril antibody, in major markets, such as the United States, the European Union and Japan. Upon regulatory approval, the companies will also co-promote the products following marketing approval. 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.