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Eisai Co., Ltd.

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

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that enrollment has commenced in Japan for MISSION **AD1**, a global Phase III clinical study of the in-house developed oral beta secretase cleaving enzyme (BACE) inhibitor elenbecestat\* (development code: E2609) in patients with early Alzheimer's disease (AD).

The Phase III clinical trial program for elenbecestat (MISSION **AD**) consists of two global Phase III clinical studies with the same protocols, MISSION **AD1** (Study 301) and MISSION **AD2** (Study 302). Both studies are multicenter, placebo-controlled, double-blind, parallel-group Phase III clinical studies aiming to assess the efficacy and safety of elenbecestat for treatment of early AD, including mild cognitive impairment due to AD and a subset of very mild AD, in 1,330 patients with positive biomarkers for brain amyloid pathology. Patients are administered a dosage of 50 mg of elenbecestat daily during the treatment period of 24 months, and the primary endpoint will utilize the Clinical Dementia Rating Sum of Boxes (CDR-SB). MISSION **AD1** commenced first in the U.S. in October 2016 and the enrollment has been progressing steadily. MISSION **AD2** commenced in the U.S. in December 2016, and will commence in Japan shortly. Additionally, in Europe, applications for both clinical studies have been submitted, and preparations to begin are underway.

Elenbecestat is an oral BACE inhibitor currently being investigated in Phase III clinical studies for AD. By inhibiting BACE, a key enzyme in the production of A $\beta$  peptides, elenbecestat reduces A $\beta$  production, which is thought to lead to a reduction in amyloid plaque formations caused by the aggregation of toxic oligomers and protofibrils in the brain. Elenbecestat is being jointly developed by Eisai and Biogen Inc. (Headquarters: Massachusetts, United States, CEO: Michel Vounatsos, "Biogen"). In addition, the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the development of elenbecestat, a process allowing priority reviews by the FDA for drugs deemed to treat serious conditions and tackle key unmet medical needs.

Juntendo University, School of Medicine Professor Heii Arai, M.D., Ph.D., who is serving as an advisory board member for MISSION **AD** in Japan, commented, "Including Japan, populations are aging worldwide, and along with that, the number of dementia and mild cognitive impairment patients are increasing significantly and this is an important issue. Through the MISSION **AD** clinical studies, development of the Japanese-originated BACE inhibitor for the suppression of A $\beta$  production will be further advanced, and I anticipate that it will contribute to patients with early AD."

\* The generic name is not yet fixed at this time.

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**[Notes to editors]**

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

Based on the collaboration agreement, Eisai will serve as the operational and regulatory lead in the co-development of elenbecestat, a BACE inhibitor, and BAN2401, an anti-amyloid beta (A $\beta$ ) protofibril antibody, and will pursue marketing authorizations for both compounds worldwide. If approved, the companies will also co-promote the products, in major markets, such as the United States, the European Union and Japan. Both companies will equally split overall costs, including research and development expenses. Eisai will book all sales for elenbecestat and BAN2401 following marketing approval and launch, and profits will be equally shared between the companies. Also, Eisai has received from Biogen an upfront payment as well as the right to receive additional development, approval and commercial milestone payments. Under the same agreement, Eisai also holds options to jointly develop and commercialize two of Biogen's investigational treatments for Alzheimer's disease, the anti-A $\beta$  antibody aducanumab and an anti-tau antibody.