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Eisai Co., Ltd.

DATA SAFETY MONITORING BOARD RECOMMENDS CONTINUATION OF PHASE III CLINICAL STUDIES OF BACE INHIBITOR ELENBECESTAT IN EARLY ALZHEIMER'S DISEASE

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that in the 8th meeting of the Data Safety Monitoring Board (DSMB) for the global Phase III clinical studies (MISSION AD) on the investigational oral BACE (beta amyloid cleaving enzyme) inhibitor elenbecestat (development code: E2609) in early Alzheimer's disease (AD), the DSMB reviewed safety data including the potential for decline in cognition, and recommended the continuation of the studies. Elenbecestat is being jointly developed by Eisai and Biogen Inc. (Headquarters: Cambridge, Massachusetts, United States).

The Phase III clinical trial program for elenbecestat (MISSION AD) consists of two global Phase III clinical studies with identical 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 in patients with mild cognitive impairment (MCI) due to AD or mild AD dementia (collectively known as early AD) with confirmed amyloid pathology in the brain. Patients are allocated randomly to receive either 50 mg of elenbecestat or placebo daily during the treatment period of 24 months, and the primary endpoint utilizes the Clinical Dementia Rating Sum of Boxes (CDR-SB).
Enrollment in MISSION AD is scheduled to be completed in March 2019.

Eisai aims to create innovative medicines for Alzheimer's disease as soon as possible in order to further contribute to addressing the unmet medical needs of, as well as potentially increasing the benefits provided to, patients and their families.

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[Notes to editors]

1. About Elenbecestat (generic name, development code: E2609)

Discovered by Eisai, elenbecestat is an investigational next-generation oral candidate for the treatment of Alzheimer's disease (AD) that inhibits BACE (beta amyloid cleaving enzyme). By inhibiting BACE, a key enzyme in the production of Aβ peptides, elenbecestat reduces Aβ production, and by reducing amyloid plaque formations in the brain, exerts disease modifying effects of potentially slowing the progression of AD. Currently, two global Phase III clinical studies (MISSION AD1/2) of elenbecestat in early AD including mild cognitive impairment (MCI) due to AD or the mild AD are underway. 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 as having potential to treat serious conditions and tackle key unmet medical needs.

2. About MISSION AD

Initiated in October 2016, the Phase III clinical trial program for elenbecestat (MISSION AD) consists of two global Phase III clinical studies with identical protocols, MISSION AD1 (Study 301) and MISSION AD2 (Study 302), and is being conducted at over 400 sites in 30 countries worldwide. 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 in patients with mild cognitive impairment (MCI) due to AD or mild AD dementia (collectively known as early AD) with confirmed amyloid pathology in the brain. Patients are allocated randomly to receive either 50 mg of elenbecestat or placebo daily during the treatment period of 24 months, and the primary endpoint utilizes the Clinical Dementia Rating Sum of Boxes (CDR-SB).