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Eisai, Biogen discontinue clinical studies on AD drug candidate

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Discontinuation of studies based on Data Safety Monitoring Board recommendation

Japan headquartered Eisai Co., Ltd. and US based Biogen Inc. have announced the decision to discontinue the Phase III clinical studies (MISSION AD1, AD2) on the investigational oral BACE (beta amyloid cleaving enzyme) inhibitor elenbecestat (development code: E2609) in patients with early Alzheimer's disease (AD).

The decision is based on the results of a safety review conducted by the Data Safety Monitoring Board (DSMB), which recommended to discontinue these trials due to an unfavorable risk-benefit ratio. Detailed data of these studies will be presented at future medical meetings.

The Phase III clinical trial program for elenbecestat (MISSION AD) consisted of two global Phase III clinical studies with identical protocols, MISSION AD1 (Study 301) and MISSION AD2 (Study 302). Both studies were multicenter, placebo-controlled, double-blind, parallel-group Phase III clinical studies designed to assess the efficacy and safety of elenbecestat for treatment in a total of about 2,100 patients with mild cognitive impairment (MCI) or mild AD (collectively known as early AD) with confirmed amyloid pathology in the brain. Patients were randomized to receive either 50 mg of elenbecestat or placebo daily during the treatment period of 24 months, and the primary endpoint was the Clinical Dementia Rating Sum of Boxes (CDR-SB).

As part of this decision, the long-term extension of the Phase II clinical trial of elenbecestat (Study 202) will also be discontinued. This determination does not impact the program of the anti-amyloid beta (A?) protofibril monoclonal antibody BAN2401, and the Phase III Clarity AD trial of BAN2401 will continue.