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Eisai Co., Ltd.

NEW DATA FROM LONG-TERM EXTENSION OF PHASE 1b STUDY OF INVESTIGATIONAL ALZHEIMER'S DISEASE TREATMENT ADUCANUMAB PRESENTED AT 10TH CLINICAL TRIALS ON ALZHEIMER'S DISEASE

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that Biogen Inc. (Nasdaq: BIIB) (Headquarters: Cambridge, Massachusetts, United States, CEO: Michel Vounatsos, "Biogen") presented new data from the long-term extension (LTE) of its ongoing Phase 1b study of aducanumab, an investigational treatment for Alzheimer's disease at the 10th Clinical Trials on Alzheimer's Disease (CTAD) meeting, Boston, Massachusetts, United States, from November 1 to 4.

As of October 23, 2017, Eisai and Biogen entered into a global collaboration agreement to jointly develop and commercialize aducanumab.

The data include results from patients in the Phase 1b study of aducanumab who were treated with a gradually increased dose of aducanumab for up to 24 months and those who were treated with a fixed dose of 3, 6 or 10 mg/kg aducanumab for up to 36 months.

- Two-year data from Phase 1b study suggest a continued benefit on amyloid plaque reduction and the rate of clinical decline in the titration regimen group, which received a gradually increased aducanumab dose
- The results at two years in the titration regimen group were consistent with the dose- and time-dependent results observed in the treatment groups that received a fixed-dose of 3, 6 or 10 mg/kg aducanumab during the same time period
- Results from treatment groups that received a fixed-dose of 3, 6 or 10 mg/kg aducanumab for up to three years were consistent with previously reported analyses from the Phase 1b study and support the design of the ongoing Phase 3 studies of aducanumab for early Alzheimer's disease

The results from the Phase 1b study of aducanumab including the new data from the LTE have further deepened Eisai's conviction in the amyloid hypothesis. Eisai plans to advance co-development with Biogen and hopes to create the world's potentially first new treatment for Alzheimer's disease based on the amyloid hypothesis as early as possible.

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[Notes to editors]

1. About aducanumab (BIIB037)

Aducanumab (BIIB037) is an investigational drug being developed for the treatment of AD. Aducanumab is a human recombinant monoclonal antibody (mAb) derived from a de-identified library of B cells collected from healthy elderly subjects with no signs of cognitive impairment or cognitively impaired elderly subjects with unusually slow cognitive decline using Neurimmune's technology platform called Reverse Translational Medicine (RTM). Biogen licensed aducanumab from Neurimmune under a collaborative development and license agreement. Aducanumab is being jointly developed by Biogen and Eisai, with Eisai having exercised its option to co-develop and co-promote aducanumab on October 23, 2017.

Aducanumab is thought to target aggregated forms of beta amyloid including soluble oligomers and insoluble fibrils which can form into amyloid plaque in the brain of AD patients. Based on pre-clinical and Phase 1b data to date, treatment with aducanumab has been shown to reduce amyloid plaque levels.

In August 2016 aducanumab was accepted into the European Medicines Agency's PRIME program. In September 2016 the U.S. Food and Drug Administration accepted aducanumab into its Fast Track program and in April 2017 aducanumab was accepted into the Japanese Ministry of Health, Labour and Welfare's (MHLW) SAKIGAKE* Designation System.

* SAKIGAKE aims at shortening premarket review period for innovative new medical products that satisfy certain criteria, such as severity of intended indication, by designating such products during the early stages of development, and providing prioritized consultation services and premarket pharmaceutical affairs review. The target review period for the designated products may be reduced to as short as 6 months, half the standard review period of 12 months for typical new pharmaceutical products.

2. About the Phase 1b study

The Phase 1b study is a randomized, double-blind, placebo-controlled, multiple-dose study evaluating the safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PD) and clinical effects of aducanumab in patients with prodromal or mild Alzheimer's disease. The study includes fixed dosing at 1, 3, 6 and 10 mg/kg as well as an arm with a titration regimen in which patients received a gradually increased dose of aducanumab until they reach a maximum dose of 10 mg/kg.

In the Phase 1b LTE, the most commonly reported adverse events were headache, fall and amyloid-related imaging abnormalities (ARIA). Of the 185 patients dosed with aducanumab in the Phase 1b study, 46 patients experienced ARIA-E (edema). There were no new cases of ARIA-E in patients who continued on the same dose of aducanumab.