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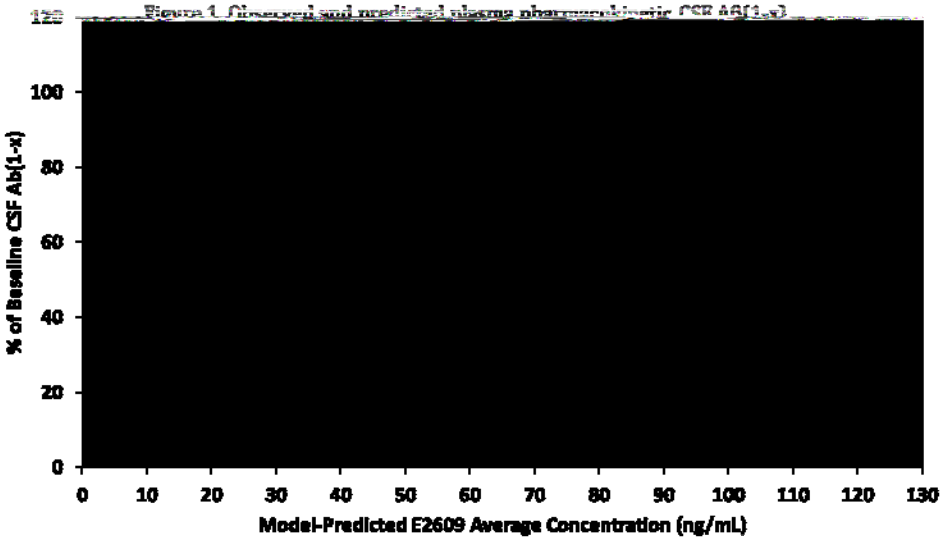
Eisai Co., Ltd.

EISAI PRESENTS LATEST DATA ON BACE INHIBITOR ELENBECESTAT E2609 AT 9TH CLINICAL TRIALS ON ALZHEIMER'S DISEASE

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that it has presented the latest two clinical trials (Study 202 and Study 006) data on its in-house discovered oral BACE (beta amyloid cleaving enzyme) inhibitor elenbecestat (development code: E2609) at the 9th Clinical Trials on Alzheimer's Disease (CTAD 2016) held from December 8 to 10 in San Diego, the United States.

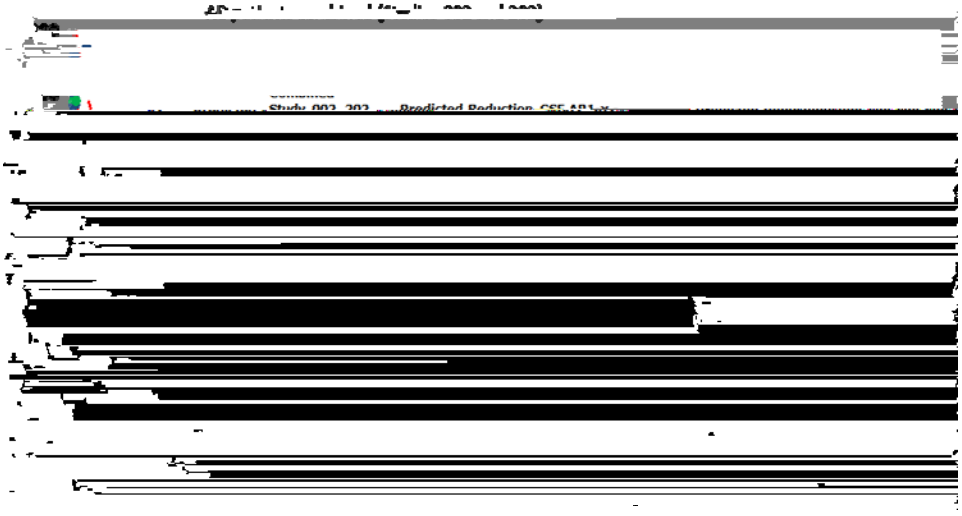
Study 202 is a multicenter, randomized, double-blind, placebo-controlled parallel-group phase II clinical study to evaluate the safety of elenbecestat and the change from baseline in cerebrospinal fluid (CSF) amyloid beta Aβ(1-x)* level in patients with mild cognitive impairment (MCI) due to Alzheimer's disease or mild to moderate dementia due to Alzheimer's disease with confirmed accumulation of amyloid beta (Aβ) by PET (positron emission tomography) screening. Patients are administered 5, 15 or 50 mg of elenbecestat daily. The change in Aβ(1-x) level is evaluated by analyzing the concentrations of Aβ(1-x) in plasma and CSF before and after elenbecestat administration. The presentation highlighted the results from a preliminary analysis of pharmacokinetic and pharmacodynamics data of Study 202 at the CTAD 2016 (poster presentation number: P3-28).
In Study 202, the pharmacokinetic profile of elenbecestat was similar to the results obtained from Phase I studies in healthy volunteers. A correlation between plasma concentration of elenbecestat and the decrease in CSF Aβ(1-x) was observed, which overlapped with exposure-response models combining data from this study and Phase I clinical study data (figure 1).

* Aβ(1-x) refers to Aβ peptides of all lengths



Furthermore, a dose-response model was established to explain the relationship between dosage of elenbecestat and the decrease in CSF Aβ

Figure 2. Observed and predicted E2609 dose-CSF Aβ(1-x) relationship following repeat E2609 administration in healthy adults (Study 002) and



Media Inquiries:
Public Relations Department,
Eisai Co., Ltd.
+81-(0)3-3817-5120

[Notes to editors]

1. About the Phase III Clinical Trial Program MISSION **AD for elenbecestat (E2609)**

The Phase III clinical trial program MISSION **AD** for elenbecestat consists of two global Phase III studies, MISSION **AD1** (Study 301) and MISSION **AD2** (Study 302).

The first study of the MISSION **AD** program, MISSION **AD1**, is a multicenter, placebo-controlled, double-blind, parallel-group clinical study aiming to assess the efficacy and safety of elenbecestat in 1,330 patients with biomarker confirmed early Alzheimer's disease. Patients will be randomized 1:1 to receive either a dosage of 50 mg of elenbecestat or placebo daily during the treatment period of 24 months, and the primary endpoint will utilize the Clinical Dementia Rating Sum of Boxes (CDR-SB).

2. 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 (Aβ) 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 candidates for Alzheimer's disease, the anti-Aβ antibody aducanumab and an anti-tau antibody.