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ASIA EDITION

Eisai announces Data from the Phase II Clinical Trial of BAN2401

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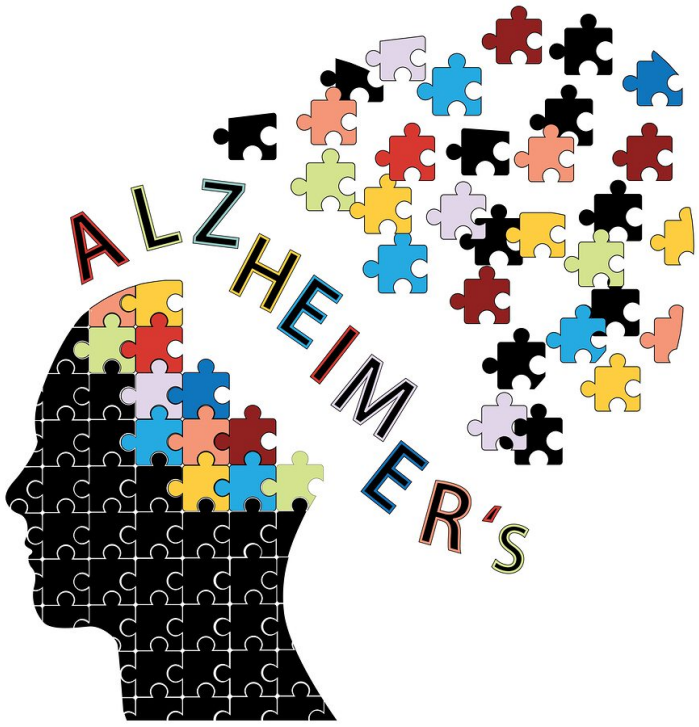
Clinical Study 201 is a placebo-controlled, double-blind, parallel-group, randomized study in 856 patients with mild cognitive impairment (MCI) due to Alzheimer's disease (AD) with confirmed amyloid pathology in the brain



Eisai Co., Ltd. and Biogen Inc. announced that Eisai presented the latest data from the Phase II clinical study (Study 201) of BAN2401, an anti-amyloid beta protofibril antibody, in 856 patients with early Alzheimer's disease, at a symposium session titled "Clinical and Biomarker Updates from BAN2401 Study 201 in Early Alzheimer's Disease" held on October 25 at the 11th Clinical Trials on Alzheimer's Disease (CTAD) conference in Barcelona, Spain.

Study 201 is a placebo-controlled, double-blind, parallel-group, randomized study in 856 patients with mild cognitive impairment (MCI) due to Alzheimer's disease (AD) or mild Alzheimer's dementia (collectively known as early Alzheimer's disease) with confirmed amyloid pathology in the brain. Patients were randomized to five dose regimens, 2.5 mg/kg bi-weekly, 5 mg/kg monthly, 5 mg/kg bi-weekly, 10 mg/kg monthly and 10 mg/kg bi-weekly, or placebo. This study used a Bayesian Adaptive Randomization Design to automatically allocate newly enrolled patients into the study to treatment arms showing higher probability of efficacy based on the results of interim analyses. The 10 mg/kg monthly and 10 mg/kg bi-weekly doses were determined to have greater efficacy, and as a result, the proportion of patients allocated to those treatment arms was greater.

Conventional statistical methods on predefined clinical outcomes at the 18 months final efficacy time point included Alzheimer's Disease Composite Score (ADCOMS), Alzheimer's Disease Assessment Scale-Cognitive subscale (ADAS-Cog),

and Clinical Dementia Rating Sum of Boxes (CDR-SB).

Eisai and Biogen are currently discussing the next steps for BAN2401 with regulatory authorities. An open-label extension for patients previously enrolled in Study 201 is being planned, with enrollment expected to begin this year.