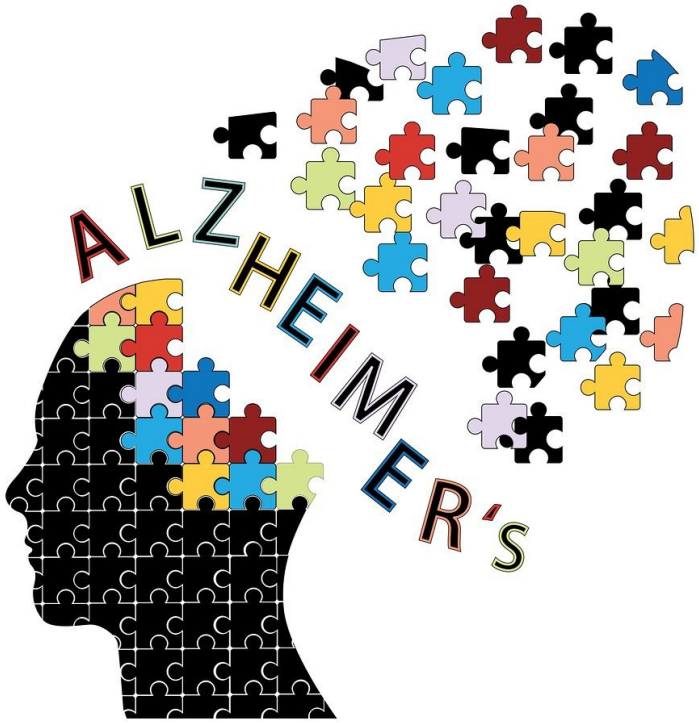
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Latest Data on Eisai's Alzheimer's disease to be presented at AAIC 2018

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Thirteen presentations to be given including on Phase II study results of BAN2401 and elenbecestat



Eisai Co., Ltd. announces that a total of 13 presentations highlighting results from a Phase II clinical study (Study 201) of the anti-amyloid beta (Abeta) protofibril antibody BAN2401 and a Phase II clinical study (Study 202) of the oral BACE (beta amyloid cleaving enzyme) inhibitor elenbecestat (development code: E2609) in addition to the latest data on its Alzheimer's disease / dementia pipeline including anti-Abeta antibody aducanumab, will be given at the Alzheimer's Association International Conference (AAIC) 2018, in Chicago from July 22 to 26, 2018. BAN2401, elenbecestat and aducanumab are being jointly developed by Eisai and Biogen Inc.

As previously announced on July 10, an oral presentation will be given on the results of Study 201 (ClinicalTrials.gov identifier: NCT01767311) on BAN2401 in early Alzheimer's disease (mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's disease dementia) as a late-breaking abstract.

Eisai and Biogen announced on July 6 that Study 201 achieved statistical significance on key predefined endpoints evaluating efficacy at 18 months on slowing progression in Alzheimer's Disease Composite Score (ADCOMS) and on reduction of amyloid accumulated in the brain as measured using amyloid-PET (positron emission tomography).

This study was first late-stage study data successfully demonstrating potential disease-modifying effects on both clinical function and amyloid beta accumulation in the brain. The most commonly reported adverse events were infusion reactions and amyloid related imaging abnormalities (ARIA).

For elenbecestat, a poster presentation will similarly be given as a late-breaking abstract on the results of Study 202 (ClinicalTrials.gov identifier NCT02322021) on elenbecestat in patients with mild cognitive impairment and mild-to-moderate dementia due to Alzheimer's disease.

On June 6, 2018, it was announced that from the positive topline results of Study 202 at 18 months, elenbecestat demonstrated acceptable safety and tolerability (primary endpoint), as well as a statistically significant effect on Abeta levels in the brain as measured by amyloid-PET (exploratory endpoint).

A numerical slowing of decline in functional clinical scales of a potentially clinically important difference was also observed, although this effect was not statistically significant. The six most common adverse events observed were contact dermatitis, upper respiratory infection, headache, diarrhea, fall, and dermatitis. Elenbecestat is currently being investigated in two ongoing Phase III clinical studies (MISSION AD1/2) in patients with early Alzheimer's disease.

In addition, regarding aducanumab, an oral presentation and a poster presentation will be made on the long-term administration of aducanumab from a Phase Ib clinical study being conducted by Biogen. Currently, Eisai and Biogen are advancing two Phase III clinical studies (ENGAGE/EMERGE) on aducanumab.

Furthermore, presentations will also be made on the novel phosphodiesterase-9 inhibitor E2027, including an oral presentation on the results of a Phase I clinical study as well as poster presentations on non-clinical studies. Discovered and developed solely by Eisai, E2027 is currently being investigated in a Phase II/III clinical study as a potential treatment for dementia with Lewy bodies.

Regarding the investigational sleep-wake agent lemborexant, baseline data from a Phase II clinical study (Study 202) in patients with irregular sleep-wake rhythm disorder (ISWRD) and Alzheimer's disease will also be presented at AAIC 2018. Discovered by Eisai, lemborexant has been jointly developed with Purdue Pharma L.P. since August 2015.

Eisai is aiming to realize prevention and cure of dementia through a holistic approach to dementia drug discovery research based on a foundation of over 30 years of experience of drug discovery activities in the area of Alzheimer's disease / dementia.

Eisai is striving to create innovative medicines as soon as possible in order to further contribute to addressing the unmet medical needs of, as well as increasing the benefits provided to, patients and their families.