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LATEST DATA ON EISAI'S ALZHEIMER'S DISEASE / DEMENTIA PIPELINE TO BE PRESENTED AT ALZHEIMER'S ASSOCIATION INTERNATIONAL CONFERENCE (AAIC) 2018

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

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announces today that a total of 13 presentations highlighting results from a Phase II clinical study (Study 201) of the anti-amyloid beta ($A\beta$) 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-A β 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. (Headquarters: Cambridge, Massachusetts, United States, "Biogen").

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).

The BAN2401 study 201 data presentation will be webcast live. To access the live webcasts, please visit the Investors section of Eisai's website on the day at https://www.eisai.com/ir/index.html.

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 Aβ 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. (Headquarters: Connecticut, United States, "Purdue Pharma") 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.

Product/Presentation number	Abstract title and scheduled presentation date and time (local time)
BAN2401	Treatment of Early AD Subjects with BAN2401, an Anti-Aβ Protofibril
Abstract ID: 27531	Monoclonal Antibody, Significantly Clears Amyloid Plaque and Reduces
Oral Presentation No.: DT-01-07	Clinical Decline
(Late Breaking Abstract)	Oral Presentation July 25 (Wed), 3:30-4:00 PM
Elenbecestat	Elenbecestat, E2609, a BACE Inhibitor: Results from a Phase-2 Study in
Abstract ID: 27524	Subjects with Mild Cognitive Impairment and Mild-to-Moderate Dementia Due
Poster No.: P4-389	to Alzheimer's Disease
(Late Breaking Abstract)	Poster Presentation July 25 (Wed), 1:00-2:00 PM
Elenbecestat Abstract ID: 24768	Elenbecestat, a Novel BACE Inhibitor, Demonstrates Similar
	Pharmacokinetics and Tolerability in Japanese Subjects with Multiple Dosings
Poster No.: P1-040	Poster Presentation July 22 (Sun), 9:30-10:30 AM
Aducanumab Abstract ID: 22962 Oral Presentation No.: O1-09-06	24-Month Analysis of Change from Baseline in Clinical Dementia Rating
	Scale Cognitive and Functional Domains in PRIME: A Randomized Phase 1B
	Study of the Anti-Amyloid Beta Monoclonal Antibody Aducanumab
	Oral Presentation July 22 (Sun), 3:15-3:30 PM
Aducanumab	24-Month Analysis of APOE ε4 Carriers in PRIME: A Randomized Phase 1B
Abstract ID: 22959	Study of the Anti-Amyloid Beta Monoclonal Antibody Aducanumab
Poster No.: P1-041	Poster Presentation July 22 (Sun), 9:30-10:30 AM
Aducanumab / General	Cognitive and Other Neuropsychological Assessments Documented in
Alzheimer's disease	Electronic Health Records Prior to or at Alzheimer's Disease Diagnosis Poster Presentation July 22 (Sun), 12:00-1:00 PM
Abstract ID: 22897	
Poster No.: P1-339	

Presentations at AAIC2018:

(continued on following page)

Product/Presentation number	Abstract title and scheduled presentation date and time (local time)
E2027 Abstract ID: 24975 Oral Presentation No.: O1-12-06	Phase 1 Multiple Ascending Dose (MAD) Study of Phosphodiesterase-9 Inhibitor E2027: Confirmation of Target Engagement and Selection of Phase 2 Dose in Dementia with Lewy Bodies Oral Presentation July 22 (Sun), 5:30-5:45 PM
E2027 Abstract ID: 24835 Poster No.: P1-055	E2027, a Novel Phosphodiesterase-9 (PDE9) Inhibitor in Development for Treatment of Dementia with Lewy Bodies (DLB), Showed No Clinically Significant Drug Interaction with Diltiazem Poster Presentation July 22 (Sun), 9:30-10:30 PM
E2027	Effect of Repeated Administration of E2027, a Novel Phosphodiesterase-9
Abstract ID: 24657	Inhibitor, on Cyclic GMP Levels in Rat Cerebrospinal Fluid
Poster No.: P3-062	Poster Presentation July 24 (Tue), 9:30-10:30 AM
Lemborexant	Circadian Rhythm Characteristics Measured with Actigraphy in Patients with
Abstract ID: 21595	Irregular Sleep-Wake Rhythm Disorder and Alzheimer's Disease
Poster No.: P3-015	Poster Presentation July 24 (Tue), 9:30-10:30 AM
General Alzheimer's disease Abstract ID: 25196 Poster No.: P1-361	Assessing Function in Early AD: Analysis of Alzheimer's Disease Neuroimaging Initiative (ADNI) 3 Data for the Financial Capacity Instrument Short Form (FCI-SF) Poster Presentation July 22 (Sun), 12:00-1:00 PM
General Alzheimer's disease	Lumipulse [®] G Total Tau to β-Amyloid 1-42 Ratio Cut-Point Determination for
Abstract ID: 23164	Amyloid Eligibility Screening
Poster No.: P4-075	Poster Presentation July 25 (Wed), 9:30-10:30 AM
General Alzheimer's disease	Baseline Florbetapir Amyloid PET Standard Uptake Value Ratio SUVR Can
Abstract ID: 27140	Predict Clinical Progression in Prodromal AD
Poster No.: P4-291	Poster Presentation July 25 (Wed), 1:00-2:00 PM

Please note AAIC embargo policy: All materials submitted to AAIC are embargoed for publication and broadcast until the officially scheduled date and time of presentation.

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[Notes to editors]

1. About BAN2401

BAN2401 is a humanized monoclonal antibody for Alzheimer's disease that is the result of a strategic research alliance between Eisai and BioArctic. BAN2401 selectively binds to neutralize and eliminate soluble, toxic A β aggregates that are thought to contribute to the neurodegenerative process in Alzheimer's disease. As such, BAN2401 may have the potential to have an effect on disease pathology and to slow down the progression of the disease. Eisai obtained the global rights to study, develop, manufacture and market BAN2401 for the treatment of Alzheimer's disease pursuant to an agreement concluded with BioArctic in December 2007.

2. About elenbecestat (generic name, development code: E2609)

Elenbecestat is an oral BACE (beta amyloid cleaving enzyme) inhibitor currently being investigated in Phase III clinical studies for Alzheimer's disease discovered by Eisai. By inhibiting BACE, a key enzyme in the production of A β peptides, elenbecestat reduces A β production, which is thought to lead to a reduction in amyloid plaque formations caused by the aggregation of toxic oligomers and protofibrils in the brain. Currently, two global Phase III clinical

studies (MISSION AD1/2) of elenbecestat in early Alzheimer's disease including mild cognitive impairment (MCI) due to AD/Prodromal AD and the early stages of mild AD are underway. In addition, the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the development of elenbecestat, a process to facilitate development and expedite review by FDA for drugs deemed as having potential to treat serious conditions and addressing unmet medical needs.

3. About Aducanumab (BIIB037)

Aducanumab is an investigational compound being developed for the treatment of Alzheimer's disease. 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 thought to target aggregated forms of beta amyloid including soluble oligomers and insoluble fibrils which can form into amyloid plaque in the brain of Alzheimer's disease 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.

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

4. About the Joint Development Agreement between Eisai and Biogen for Alzheimer's Disease

Eisai and Biogen are widely collaborating on the joint development and commercialization of Alzheimer's disease treatments. Eisai serves as the lead in the co-development of elenbecestat, a BACE inhibitor, and BAN2401, an anti-A β protofibril antibody, while Biogen serves as the lead for co-development of aducanumab, Biogen's investigational anti-A β antibody for patients with Alzheimer's disease, and the companies plan to pursue marketing authorizations for the three 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.

5. About E2027

Discovered by Eisai, E2027 is a selective phosphodiesterase (PDE) 9 inhibitor. Inhibiting PDE9 reduces the degradation of cyclic GMP which is critical to signal transmission among cells. By helping maintain the concentration of cyclic GMP in the brain, E2027 has the potential to be a new treatment for dementia with Lewy bodies.

6. About Lemborexant (generic name, development code: E2006)

Lemborexant, a dual orexin receptor antagonist, is Eisai's in-house discovered and developed small molecule compound that inhibits orexin neurotransmission by binding competitively to the two subtypes of orexin receptors (orexin receptor 1 and 2). In individuals with sleep disorders, it is possible that the orexin system that regulates sleep and wakefulness is not functioning normally. During normal periods of sleep, orexin system activity is suppressed, suggesting it is possible to purposefully counteract inappropriate wakefulness and facilitate the initiation and maintenance of sleep by interfering with orexin neurotransmission. Therefore, Eisai and Purdue have been developing lemborexant as a treatment for multiple sleep disorders.

In addition, a Phase II clinical study of lemborexant in patients with irregular sleep-wake rhythm disorder (ISWRD) and mild to moderate Alzheimer's dementia is underway.