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Eisai Co., Ltd.

EISAI TO PRESENT LATEST DATA ON PIPELINE ASSETS IN THE AREA OF ALZHEIMER'S DISEASE AND DEMENTIA AT THE 13TH CLINICAL TRIALS ON ALZHEIMER'S DISEASE CONFERENCE

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that the company will conduct a total of 7 presentations, including the latest data of the investigational anti-amyloid beta (Aβ) protofibril antibody lecanemab (Development Code: BAN2401), at the 13th Clinical Trials on Alzheimer's Disease (CTAD) conference to be held virtually from November 4 to 7, 2020.

Regarding lecanemab, Eisai will conduct four oral presentations. The first oral presentation will cover clinical study design and initial screening results of the newly initiated Phase III clinical study AHEAD 3-45 for preclinical Alzheimer's disease (AD) patients. The second oral presentation will cover the latest analysis results on expression of amyloid-related imaging abnormalities-edema (ARIA-E) from the Phase II study (Study 201) conducted on early AD patients. The third oral presentation will cover changes in brain-Aβ amounts and preliminary analysis results on ARIA-E expression as observed in the first 12-month treatment period of the ongoing open-label extension (OLE) study of Study 201. The fourth oral presentation will cover baseline characteristics of currently enrolled subjects in the Phase III study Clarity AD being conducted on early AD patients.

Other presentation topics include the effectiveness of lemborexant on irregular-sleep-wake-rhythm-disorder (ISWRD) in AD as observed in mouse models in relation to clinical trials, as well results from a Phase I, First-In-Human (FIH), Single Ascending Dose (SAD) study of the novel anti-microtubule binding region (MTBR) tau antibody E2814.

Regarding aducanumab, Biogen Inc. (Headquarters: Cambridge, Massachusetts, United States) will conduct an oral presentation on the design of its Phase IIIb redosing study EMBARK. A Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA), for approval of aducanumab as an AD treatment, was accepted and received priority review designation in August 2020.
Lecanemab and aducanumab are being jointly developed by Eisai and Biogen Inc.

Regarding the joint research effort with Sysmex Corporation (Headquarters: Hyogo, "Sysmex") for creation of simplified diagnosis of AD using blood, a poster will be presented on prediction of Amyloid Positivity Defined by Amyloid PET Centiloid through Plasma Aβ Ratio Measurement on a Fully Automated Immunoassay, HISCL™*.

Eisai aims to realize the prevention and cure of dementia through a multi-dimensional and holistic approach with a foundation of over 35 years of experience of drug discovery activities in the area of AD and dementia. Eisai strives to create innovative medicines as soon as possible to further contribute to addressing the unmet medical needs of, as well as increasing the benefits provided to, those living with the disease and their families.

*HISCL™ is a trademark of Sysmex Corporation.

■ Eisai oral presentation topics

Asset in Development, Session Number	Topic/Planned Date and Time (Eastern Standard Time)
BAN2401 OC 2	The AHEAD 3-45 Study of BAN2401 in Preclinical Alzheimer's Disease: Study Design and Initial Screening Results Live oral presentation: November 4 (Wed.) 10:00 AM-10:15 AM Q&A Session: November 4 (Wed.) 11:25 AM-11:40 AM
BAN2401 OC 10	Baseline Characteristics for Clarity AD: A Phase 3 Placebo-Controlled, Double-Blind, Parallel-Group, 18-Month Study Evaluating BAN2401 in Early Alzheimer's Disease Oral presentation available for on-demand viewing November 4 (Wed.) 1:00 AM
BAN2401 OC 14	BAN2401 and ARIA-E in Early Alzheimer's Disease: Pharmacokinetic / Pharmacodynamic Time-to-Event Analysis From the Phase 2 Study in Early Alzheimer's Disease Live oral presentation: November 5 (Thu.) 9:45 AM-10:00 AM Q&A Session: November 5 (Thu.) 11:15 AM-11:30 AM
BAN2401 LB 24	Preliminary Analysis of BAN2401 Effects On Brain Amyloid And ARIA-E Findings Over 12 Months Of Treatment In The Open-Label Extension Of The Phase2b Study BAN2401-G000-201 In Subjects With Early Alzheimer's Disease Live oral presentation: November 7 (Sat.) 12:10 PM-12:25 PM Q&A Session: November 7 (Sat.) 12:25 PM-12:50 PM
Lemborexant LB 15	Irregular Sleep-Wake Rhythm Disorder in Alzheimer's Disease: SAMP8 Mouse Strain as an Animal Model and Efficacy of the Dual Orexin (Hypocretin) Receptor Antagonist Lemborexant Oral presentation available for on-demand viewing November 6 (Fri.) 1:00 AM
E2814 LB 23	A Phase 1, First-In-Human (FIH), Single Ascending Dose (SAD) Study of the Novel Anti-Tau Therapeutic Antibody E2814 in Healthy Volunteers Live oral presentation: November 7 (Sat.) 11:55 AM-12:10 PM Q&A Session: November 7 (Sat.) 12:25 PM-12:50 PM

■ Eisai poster presentation topics

Asset in Development, Poster Number	Topic/Planned Date and Time (Eastern Standard Time)
General P 60	Congruence of Clinical Assessment Instruments with Online Narratives Over Social Media by Patients with Alzheimer's Disease and Their Caregivers Available for on-demand viewing beginning November 4 (Wed.)

■ Biogen oral presentation topics

Asset in Development, Session Number	Topic/Planned Date and Time (Eastern Standard Time)
Aducanumab OC 3	EMBARK: A Phase 3b, Open-Label, Single-Arm, Safety Study to Evaluate the Long-Term Safety and Efficacy of Aducanumab in Eligible Participants with Alzheimer's Disease Live oral presentation: November 4 (Wed.) 10:15 AM-10:30 AM Q&A Session: November 4 (Wed.) 11:25 AM-11:40 AM

■ Biogen poster presentation topics

Asset in Development, Poster Number	Topic/Planned Date and Time (Eastern Standard Time)
General P 70	Estimating progression rates across the spectrum of Alzheimer's disease for amyloid positive individuals using National Alzheimer's Coordinating Center data Available for on-demand viewing beginning November 4 (Wed.)

■ Sysmex-Eisai poster presentation topics

Asset in Development, Poster Number	Topic/Planned Date and Time (Eastern Standard Time)
General LP 10	Plasma Aβ Ratio Measured on a Fully Automated Immunoassay Predicts Amyloid Positivity Defined by Amyloid PET Centiloid Available for on-demand viewing beginning November 4 (Wed.)

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[Notes to editors]

1. About the Joint Development Agreement between Eisai and Biogen for AD

Eisai and Biogen are widely collaborating on the joint development and commercialization of AD treatments. Eisai serves as the lead in the co-development of lecanemab (Development Code: BAN2401), an anti-Aβ protofibril antibody, while Biogen serves as the lead for co-development of aducanumab, Biogen's investigational anti-Aβ antibody for patients with AD, and the companies plan to pursue marketing authorizations for the two 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.

2. About the collaboration between Eisai and Sysmex

Eisai and Sysmex have entered into a comprehensive non-exclusive collaboration agreement aimed at the creation of new diagnostics in the field of dementia in February 2016. Leveraging each other's technologies and knowledge, the two companies aim to discover next-generation diagnostics that will enable early diagnosis, selection of treatment options and the regular monitoring of the effects of treatment for dementia.

3. About lecanemab (Development Code: BAN2401)

Lecanemab is a humanized monoclonal antibody for AD that is the result of a strategic research alliance between Eisai and BioArctic AB (Headquarters: Sweden). Lecanemab selectively binds to neutralize and eliminate soluble, toxic Aβ aggregates (protofibril) that are thought to contribute to the neurodegenerative process in AD. As such, lecanemab 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 lecanemab for the treatment of AD pursuant to an agreement concluded with BioArctic in December 2007. Currently, a global clinical Phase III study (Clarity AD) of lecanemab in early AD is underway. Lecanemab is being jointly developed by Eisai and Biogen Inc. The National Institutes of Health, National Institute of Aging are providing funding for the A45 Study (grant number R01AG061848) and A3 Study (grant number R01AG054029).

4. About Lemborexant

Lemborexant, an orexin receptor antagonist, is Eisai's in-house discovered and developed small molecule that inhibits orexin neurotransmission by binding competitively to the two subtypes of orexin receptors (orexin receptor 1 and 2). Faster on/off receptor kinetics of lemborexant to orexin receptor 2, which also suppresses non-REM sleep, may influence lemborexant's potential to facilitate improvements in sleep onset and maintenance. In June 2020, lemborexant was launched under the product name DAYVIGO™ in the U.S. for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance; and in July 2020, it was launched under the product name DAYVIGO® in Japan for the treatment of insomnia. Eisai has submitted new drug applications seeking approval of DAYVIGO in Canada, Australia and Hong Kong. In addition, a Phase II clinical study of lemborexant in patients with ISWRD associated with mild to moderate Alzheimer's dementia is underway.

5. About Aducanumab (Development Code: BIIB037)

Aducanumab is an investigational human monoclonal antibody studied for the treatment of AD. Based on clinical data, aducanumab has the potential to impact underlying disease pathophysiology, slow cognitive and functional decline and provide benefits on patients' ability to perform activities of daily living, including conducting personal finances, performing household chores, such as cleaning, shopping and doing laundry, and independently traveling out of the home. If approved, aducanumab would be the first treatment to meaningfully change the course of the disease for individuals living with Alzheimer's.

Biogen licensed aducanumab from Neurimmune under a collaborative development and license agreement. Since October 2017 Biogen and Eisai have collaborated on the development and commercialization of aducanumab globally.

EMERGE and ENGAGE were Phase III multicenter, randomized, double-blind, placebo-controlled, parallel-group studies designed to evaluate the efficacy and safety of aducanumab. The primary objective of the studies was to evaluate the efficacy of monthly doses of aducanumab as compared with placebo in reducing cognitive and functional impairment as measured by changes in the Clinical Dementia Rating-Sum of Boxes (CDR-SB) score. Secondary objectives were to assess the effect of monthly doses of aducanumab as compared to placebo on clinical decline as measured by the Mini-Mental State Examination (MMSE), Alzheimer's Disease Assessment Scale-Cognitive Subscale 13 Items (ADAS-Cog 13) and Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory Mild Cognitive Impairment Version (ADCS-ADL-MCI).