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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 ALZHEIMER'S ASSOCIATION INTERNATIONAL CONFERENCE (AAIC) 2021

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that the company will conduct a total of 11 presentations, including the latest data of the investigational anti-amyloid beta (Aβ) protofibril antibody lecanemab (development code: BAN2401) for which the U.S. Food and Drug Administration has granted Breakthrough Therapy designation, at the Alzheimer's Association International Conference (AAIC) to be held in Denver, Colorado and virtually from July 26 to 30, 2021.

Major presentations regarding lecanemab include oral presentations about the preliminary assessment of the clinical effect of lecanemab following 18 months of treatment in the open-label extension of the Phase 2b proof of concept study (201 study) in subjects with early Alzheimer's disease (AD) and preliminary screening and baseline characteristics of the Phase 3 clinical study, AHEAD 3-45, for preclinical AD will be given. In addition, an oral presentation regarding the design of the clinical study for the investigational MTBR targeted anti-tau antibody E2814, which has been selected by the Dominantly Inherited Alzheimer Network Trials Unit "DIAN-TU" as the first investigational medicine among anti-tau drugs for the DIAN-TU tau study, will be given. A poster presentation will also be given on the results of an *in vivo* study of E2511, Eisai's in-house discovered and developed investigational novel oral synapse regenerant. A Phase 1 study for E2511 is underway

Additionally, Eisai and Biogen Inc. (Nasdaq: BIIB, Corporate headquarters: Cambridge, Massachusetts, "Biogen") will hold a virtual symposium, "Defining the next-generation clinical care pathway for Alzheimer's disease: biological, technological, and healthcare perspectives," focusing on the AD treatment landscape. As the possibilities for treatment development increase, it is critical to transform the AD patient journey from a symptoms-based approach to a clinical care pathway that is guided by next-generation biomarkers and enabled with technology. Rhoda Au, Ph.D, MBA; Jeffrey Cummings, M.D, D.Sc; Soeren Mattke, M.D, D.Sc; and Wiesje van der Flier, Ph.D; four esteemed AD researchers, will review the latest advances and challenges in the integration of biomarkers and emerging digital tools into the larger healthcare ecosystem for AD.

Eisai serves as the lead in the co-development of lecanemab, an anti-Aβ protofibril antibody, which is being jointly developed by Eisai and Biogen.

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.

■ Eisai Oral Presentation topics

Asset in Development / Topic Number	Presentation Title/Scheduled Date and Time (U.S. Mountain Daylight Time
Lecanemab Oral presentation No.53143	AHEAD 3-45 Study: Preliminary Screening and Baseline Characteristics from a Placebo-Controlled, Double-Blind Study Evaluating Lecanemab Treatment in Participants with Preclinical Alzheimer's Disease and Elevated (A45 Trial) and Intermediate (A3 Trial) Amyloid Oral presentation: July 29 (Thu) 8:00 AM-9:15 AM
Lecanemab Oral presentation No.57780	Preliminary Assessment of the Clinical Effects of Lecanemab Following 18 Months of Treatment in the Open Label Extension of the Phase 2 Proof of Concept Study, BAN2401-G000-201, in Subjects with Early Alzheimer's Disease Oral presentation: July 29 (Thu) 1:00 PM-2:15 PM
E2814 Oral presentation No.57320	The Design of a Dominantly Inherited Alzheimer's Disease Trial of the Anti-Tau Antibody, E-2814, on the DIAN-TU Tau Next Generation Platform Oral presentation: July 29 (Thu) 10:00 AM-11:15 AM

■ Eisai Poster Presentation topics

Asset in Development / Topic Number	Poster Title
Lecanemab Poster No.54331	Baseline Characteristics for Clarity AD: A Phase 3 Placebo-Controlled, Double-Blind, Parallel-Group, 18-Month Study Evaluating Lecanemab (BAN2401)
Lecanemab Poster No.57760	Plasma Aβ42:40 Ratio Tracks with Changes in Brain Amyloid PET SUVr in the Core and Open Label Extension of the Phase 2 Proof of Concept Study BAN2401-G000-201 Following Treatment with Lecanemab in Subjects with Early Alzheimer's Disease
E2511 Poster No.51985	E2511, A Novel Small Compound TrkA Allosteric Modulator, Induces a Specific Trophic Signaling via Direct Binding to TrkA, and Can Reverse the Loss of Choline Acetyltransferase (ChAT) Positive Neurons in Transgenic Models of AD
Lemborexant Poster No.49917	Irregular Sleep Wake Rhythm Disorder (ISWRD) Signs and Symptoms Reported Directly from Patients with Dementia and Caregivers
AD general Poster No.53842	Developing a Blood-Derived Gene Expression Biomarker Specific for Alzheimer's Disease
AD general Poster No 54149	Care Processes Related to Clinical Detection of Alzheimer's Disease in the US Veterans Affairs Healthcare System
AD general Poster No.55092	Challenges of Defining Healthcare Costs for People with Mild Cognitive Impairment (MCI) Based on the Claim Database Analysis in Japan
AD general Poster No.55998	Understanding the Impact of COVID-19 Pandemic on Patients with Alzheimer's Disease and Caregivers Using Online Narratives On Social Media

(continued on the following page)

■ Virtual Symposium hosted by Eisai and Biogen

Defining the next-generation clinical care pathway for Alzheimer's disease: biological, technological, and healthcare perspectives July 26 (Mon) 11:30 AM-12:15 PM (U.S. Mountain Daylight Time)

■ Biogen Presentation topics

Asset in Development / Topic Number	Presentation title/Scheduled Date and Time (U.S. Mountain Daylight Time)
Aducanumab Oral presentation: No.57522	ICARE AD-US: design of a prospective, single-arm, multicenter, noninterventional real-world study of aducanumab in the United States Oral presentation: July 29 (Thu) 8:00 AM-9:15 AM
Aducanumab Poster No.57619	Item-Level Analysis of Clinical Measures in Patients with Early Symptomatic Alzheimer's Disease Following Treatment with High-Dose Aducanumab in the Phase 3 Study EMERGE
Aducanumab Poster No.57496	Subgroup Analyses of the Amyloid PET Substudies From EMERGE and ENGAGE, Phase 3 Clinical Trials Evaluating Aducanumab in Patients With Early Alzheimer's Disease
Aducanumab Poster No.57498	Considerations for the Real-World Management of ARIA from the Aducanumab Phase 3 Studies EMERGE and ENGAGE
Aducanumab Poster No.57499	Reduction of AD Biomarkers Following Treatment with Aducanumab was Associated with Slowed Clinical Decline

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[Notes to editors]

1. About Lecanemab (development code: BAN2401)

Lecanemab is an investigational humanized monoclonal antibody for AD that is the result of a strategic research alliance between Eisai and BioArctic. Lecanemab selectively binds to neutralize and eliminate soluble, toxic amyloid-beta (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. In March 2014 Eisai and Biogen entered into a joint development and commercialization agreement for lecanemab and the parties amended that agreement in October 2017. Currently, lecanemab is being studied in a pivotal Phase 3 clinical study in symptomatic early AD (Clarity AD), following the outcome of the Phase 2 clinical study (Study 201). In July 2020 the Phase 3 clinical study (AHEAD 3-45) for individuals with preclinical AD, meaning they are clinically normal and have intermediate or elevated levels of amyloid in their brains, was initiated. AHEAD 3-45 is conducted as a public-private partnership between the Alzheimer's Clinical Trial Consortium, funded by the National Institute on Aging, part of the National Institutes of Health, and Eisai. In June 2021, FDA has granted Breakthrough Therapy designation.

2. About E2814

An investigational anti-tau antibody, E2814 is being developed as a potential disease-modifying agent for tauopathies including sporadic AD. E2814 was discovered as part of the research collaboration between Eisai and University College London. E2814 is designed to prevent the spreading of tau seeds within the brains of affected individuals. Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU) has selected E2814 as the first investigational medicine among anti-tau drugs for their DIAN-TU tau study. Phase Ib/II for dominantly inherited AD has been initiated.

3. About E2511

E2511 is Eisai's in-house discovered and developed investigational novel molecule that directly binds to tropomyosin receptor kinase A (TrkA); a nerve growth factor (NGF) located on the neural cell membrane. E2511 could potentially promote recovery and synaptic remodeling of damaged cholinergic neurons. A Phase 1 study for E2511 is underway.

4. About Lemborexant (Product name: Dayvigo® CIV)

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). Fast on/off receptor kinetics of lemborexant to orexin receptors may influence lemborexant's potential to facilitate improvements in sleep onset and maintenance with minimal morning residual effects.

5. About Aducanumab-avwa

Biogen licensed aducanumab, a human monoclonal antibody, from Neurimmune in 2007 under a collaborative development and license agreement. Since October 2017, Biogen and Eisai have collaborated on the development and commercialization of aducanumab globally.

6. About the Collaboration between Eisai and Biogen for AD

Eisai and Biogen are collaborating on the joint development and commercialization of AD treatments. Eisai serves as the lead in the co-development of lecanemab, an anti-Aβ protofibril antibody.

7. About the Collaboration between Eisai and BioArctic for AD

Since 2005, BioArctic has had a long-term collaboration with Eisai regarding the development and commercialization of drugs for the treatment of AD. The commercialization agreement on the lecanemab antibody was signed in December 2007, and the development and commercialization agreement on the antibody lecanemab back-up for AD was signed in May 2015. Eisai is responsible for the clinical development, application for market approval and commercialization of the products for AD. BioArctic has no development costs for lecanemab in AD.