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July 22, 2020
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) 2020

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that the company will conduct a total of 9 presentations, including the latest data of the investigational anti-amyloid beta (Aβ) protofibril antibody BAN2401, at the Alzheimer's Association International Conference (AAIC) to be held virtually from July 27 to 31, 2020.

Regarding BAN2401, the clinical study design of the newly initiated Phase III clinical study AHEAD 3-45 for preclinical Alzheimer's disease (AD) patients will be presented orally. The latest data on the analysis of occurrence of amyloid-related imaging abnormalities-edema (ARIA-E) and brain Aβ levels from the ongoing open-label extension study (OLE) portion of the Phase II study (Study 201) will also be presented.

The safety and efficacy results from a Phase II clinical study on lemborexant (orexin receptor antagonist) targeting Irregular Sleep Wake Rhythm Disorder (ISWRD) associated with AD will be presented.

Eisai is also planning to host a satellite symposium "Development of the A/T/N/x Classification System for Different Context of Use Across the Alzheimer's Disease Continuum: State-of-the-Art and future Perspectives for Clinical Practice and Therapy Development". Dr. Jeffrey Cummings (Chair), Dr. Clifford Jack, and Dr. Kaj Blennow, three renowned AD researchers and clinicians, will provide a comprehensive overview of the significance and conceptual framework of the A/T/N/x categorization system in the AD continuum. Finally, they will hold a discussion on the future outlook of this classification system for Alzheimer's pharmacological trials and clinical practice.

Regarding aducanumab, for which submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for approval as an Alzheimer's Disease treatment was completed in July 2020, Biogen Inc. (Headquarters: Cambridge, Massachusetts, United States) will conduct an oral presentation of the previously publicized topline results of Phase III studies EMERGE and ENGAGE. This data has been shared at prior medical congresses.

BAN2401 and aducanumab are being jointly developed by Eisai and Biogen Inc.

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 Presentation topics

Asset in Development / Topic Number	Topic/Planned Date and Time (Eastern Standard Time)
Elenbecestat Session: P2 Poster No.: 43305	Amyloid Burden Assessed by Three Amyloid PET Tracers in the Elenbecestat MissionAD Phase 3 Program Poster presentation: July 28 (Tue.)
BAN2401 Session: ODO3-03 Virtual Oral Presentation Number:44511 Chat Room: 48069 Session: SCR3-13 Presentation: SCR3-13-05	AHEAD 3-45 Study Design: A Global Study to Evaluate Efficacy and Safety of Treatment with BAN2401 for 216 Weeks in Preclinical Alzheimer's Disease with Intermediate Amyloid (A3 Trial) and Elevated Amyloid (A45 Trial) Oral presentation: July 29 (Wed.) Chat Room: July 29 (Wed.) 11:00 AM - 11:25 AM
Lemborexant Session: P3 Poster No.: 39039	Long-Term Safety and Efficacy of Lemborexant in Subjects with Irregular Sleep-Wake Rhythm Disorder and Alzheimer's Disease Dementia Poster presentation: July 29 (Wed.)
Elenbecestat Session: P3 Poster No.: 45446	Initial Exploration of a Brain Age Score Based on Validated Computerized Cognitive Assessments in Japanese Individuals Poster presentation: July 29 (Wed.)
BAN2401 Session: P3 Poster No.: 46059	A Preliminary Account of ARIA-E in the Ongoing Open Label Extension Phase of BAN2401-G000-201 in Subjects with Early Alzheimer's Disease Poster presentation: July 29 (Wed.)
BAN2401 Session: P4 Poster No.: 46209	Preliminary Assessment of Longitudinal Amyloid Status in the Ongoing Open-Label Extension Phase in Subjects with Early Alzheimer's Disease Poster presentation: July 29 (Wed.)
General AD Session: P4 Poster No.: 38365	Impact on the Disease Severity on Quality of Life, Activity of Daily Living and Medical Costs for People Living with Dementia in Japanese Nursing Homes Poster presentation: July 30 (Thu.)
General AD Session: P4 Poster No.: 39448	Evaluation of Patient Burden Using Online Social Media in Cognitive Impairment Poster presentation: July 30 (Thu.)
General AD Session: P4 Poster No.: 40698	Healthcare Expenditures Attributable to Alzheimer's Disease in Japan: LIFE Study Poster presentation: July 30 (Thu.)

■ Satellite Symposium hosted by Eisai

Session/Symposium	Symposium name/Planned Date and Time (Eastern Standard Time)
Eisai Satellite Symposium	Development of the A/T/N/x Classification System for Different Contexts of Use Across the Alzheimer’s Disease Continuum: State-of-the-Art and future Perspectives for Clinical Practice and Therapy Development available for on demand viewing beginning July 27 for 30 days post AAIC

■ Biogen presentation topics

Asset in Development / Topic Number	Topic/Planned Date and Time (Eastern Standard Time)
ADUCANUMAB Virtual Oral Presentation Number:S03-02-03 Virtual Room: Amsterdam	EMERGE and ENGAGE Topline Results: Phase 3 Studies of Aducanumab in Early Alzheimer's Disease Oral presentation: July 29 (Wed.) 7:00 AM - 8:00 AM ENCORE PRESENTATION

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[Notes to editors]

1. About BAN2401

BAN2401 is a humanized monoclonal antibody for Alzheimer's disease (AD) that is the result of a strategic research alliance between Eisai and BioArctic AB (Headquarters: Sweden). BAN2401 selectively binds to neutralize and eliminate soluble, toxic Aβ aggregates (protofibril) that are thought to contribute to the neurodegenerative process in AD. 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 AD pursuant to an agreement concluded with BioArctic in December 2007. Currently, a global clinical Phase III study (Clarity AD) of BAN2401 in early AD is underway. BAN2401 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).

2. 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.

3. About Aducanumab

Aducanumab (BIIB037) is an investigational human monoclonal antibody studied for the treatment of Alzheimer's disease. 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).