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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 15TH INTERNATIONAL CONFERENCE ON ALZHEIMER'S AND PARKINSON'S DISEASE

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that the latest data from its Alzheimer's disease (AD) and dementia pipeline, including the investigational anti-amyloid beta (Aβ) protofibril antibody lecanemab (Development Code: BAN2401), will be presented at the 15th International Conference on Alzheimer's and Parkinson's Disease (AD/PD2021) to be held virtually from March 9 to 14, 2021.

Regarding lecanemab, preliminary analysis results of changes in brain-Aβ amounts as observed in subjects of the ongoing open-label extension (OLE) of the Phase II study (Study 201) will be presented orally.
Regarding aducanumab, for which applications are currently underway in the U.S., Europe and Japan, Biogen Inc. (Headquarters: Cambridge, Massachusetts, United States, "Biogen") will conduct presentations on the correlation of amyloid PET and cerebrospinal fluid (CSF) biomarkers in the Phase III studies (EMERGE/ENGAGE), as well as evaluations of the safety and efficacy of aducanumab in early AD. Lecanemab and aducanumab are being jointly developed by Eisai and Biogen.

Additionally, regarding the joint research effort with Sysmex Corporation (Headquarters: Hyogo, "Sysmex") for creation of simplified diagnosis of Alzheimer's disease (AD) using blood, a presentation is planned on new data regarding prediction of amyloid positivity through plasma Aβ ratio measurement on a fully automated immunoassay incorporating APOE4 status, HISCL™*.

In addition to presenting the latest data, Eisai and Biogen are planning to host a symposium focusing on the role of Aβ in the AD pathology, entitled "The Science Behind the Aβ Pathway in AD". Dr. Jeffrey Cummings, Dr. John Hardy, Dr. Colin Masters, and Dr. Philip Schelten, four renowned faculty in this field, will provide a discussion about the loss of Aβ homeostasis as an early pathophysiological event within the AD continuum, along with a state-of-the-art presentation on the in vivo biomarkers of Aβ.

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 Name	Topic/Planned Date and Time (European Central Time)
Lecanemab “Aβ Targeting Therapies in AD 2”	Preliminary Amyloid PET Analysis in BAN2401 Phase 2 Open-Label Extension in Subjects who Participated in the Core Imaging Subgroup Session time: March 13 (Sat.) 12:00-13:30 Oral presentation: 13:15-13:30, Live Q&A Session: 17:30-18:00
Elenbecestat “Aβ Targeting Therapies in AD 1”	Efficacy and Safety of Elenbecestat in Subjects with Early Alzheimer's Disease: Results from the MissionAD Phase 3 Program Session time: March 10 (Wed.) 12:00-13:15 Oral presentation: 12:30-12:45 Live Q&A Session: 17:00-17:30
AD - General “Epidemiology and Genetics of Neurodegeneration”	Epidemiology of Mild Cognitive Impairment, Alzheimer’s Disease, and Related Dementia in U.S. Veteran Patients Session time: March 13 (Sat.) 12:00-14:00 Oral presentation: 12:00-12:15, Live Q&A Session: 17:30-18:00

■ Eisai poster presentation topics

Asset in Development, Poster Number	Topic/Planned Date and Time (European Central Time)
Elenbecestat P 220 / #1487	Performance of CSF AD Biomarkers in Predicting Amyloid PET Positivity in Early AD: Data From Eisai's MissionAD Program Available for on-demand viewing beginning March 9 (Tues.)
E2027 P153 / #535	Effect of E2027, A Novel Phosphodiesterase-9 Inhibitor, on Cognitive Function and Hippocampal Cyclic GMP in TG2576 Mouse Model of Alzheimer's Disease Available for on-demand viewing beginning March 9 (Tues.)
General P704 / #1636	Modeling the Association of Selected Medications on the Occurrence of Possible Alzheimer's Disease: Atorvastatin and Lisinopril Outperform Simvastatin Available for on-demand viewing beginning March 9 (Tues.)
General P696 / #1644	Health System Preparedness for Alzheimer’s Disease Treatment: Veterans Health Administration Available for on-demand viewing beginning March 9 (Tues.)

■ Biogen oral presentation topics

Asset in Development, Session Name	Topic/Planned Date and Time (European Central Time)
Aducanumab “Aβ Targeting Therapies in AD 1”	Cerebrospinal Fluid Biomarker Concordance with Amyloid PET in EMERGE/ENGAGE, Phase 3 Studies of Aducanumab in Patients with Early Alzheimer's Disease Session time: March 10 (Wed.) 12:00-13:15 Oral presentation: 12:45-13:00, Live Q&A Session: 17:00-17:30
Aducanumab “Aβ Targeting Therapies in AD 2”	Evaluation of Aducanumab Efficacy in Early Alzheimer’s Disease Session time: March 13 (Sat.) 12:00-13:30 Oral presentation: 12:45-13:00 Live Q&A Session: 17:30-18:00
Aducanumab “Aβ Targeting Therapies in AD 2”	Evaluation of Aducanumab Safety in Early Alzheimer's Disease Session time: March 13 (Sat.) 12:00-13:30 Oral presentation: 13:00-13:15 Live Q&A Session: 17:30-18:00

■ Sysmex-Eisai oral presentation topic

Asset in Development, Session Name	Topic/Planned Date and Time (Eastern Standard Time)
AD Diagnostics “Amyloid, Tau, and Synapse PET Imaging”	A Fully Automated Plasma Aβ Assay Incorporating APOE4 Status Shows High Performance to Predict Amyloid Positivity Determined by Centiloids of Amyloid PET Session time: March 12 (Fri.) 10:00-12:00 Oral presentation: 11:15-11:30, Live Q&A Session: 16:30-17:00

■ Eisai-Biogen joint symposium

Session/Symposium	Topic/Planned Date and Time (Eastern Standard Time)
Virtual Symposium	The Science Behind the Aβ Pathway in AD March 13 (Sat.) 14:00-15:30 Available for on-demand viewing until 90 days post AD/PD2021

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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, Europe 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. Study 201 demonstrated a statistically significant slowing of disease progression and decreasing of brain Aβ accumulation as the first late-stage large-scale clinical study for early AD, and successfully showed potential disease-modifying effects. 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, an open-label extension study (OLE) of the Phase II study (Study 201) and a pivotal clinical Phase III study (Clarity AD) of lecanemab in early AD is underway. The National Institutes of Health, National Institute of Aging are providing funding for the A45 Study and A3 Study. Eisai and Biogen Inc. have entered into a collaboration to develop and commercialize BAN2401.

4. About Aducanumab

Aducanumab (BIIB037) is an investigational human monoclonal antibody studied for the treatment of Alzheimer's disease. Based on clinical data from patients with Mild Cognitive Impairment due to Alzheimer's disease and mild Alzheimer's disease, 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 disease.

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.