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Eisai Co., Ltd.

EISAI TO PRESENT LATEST DATA ON ALZHEIMER'S DISEASE / DEMENTIA PIPELINE AT 12TH CLINICAL TRIALS ON ALZHEIMER'S DISEASE CONFERENCE

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that three oral presentations and eight poster presentations, highlighting the latest data on its Alzheimer's disease / dementia pipeline including anti-amyloid beta (Aβ) protofibril antibody BAN2401, orexin receptor antagonist lemborexant and a simple blood diagnostic for Alzheimer's disease (AD), will be given at the 12th Clinical Trials on Alzheimer's Disease (CTAD) conference taking place in San Diego, California in the United States, from December 4 to 7, 2019. BAN2401 is being jointly developed by Eisai and Biogen Inc. (Headquarters: Cambridge, Massachusetts, United States). In addition, the simple blood diagnostics for AD are being jointly developing by Eisai and Sysmex Corporation (Headquarters: Hyogo, Japan, "Sysmex").

For BAN2401, the persistance of brain Aβ levels in patients with early AD at the beginning of the open label extension phase of the Phase II study (Study 201) will be presented in Late-Breaking Oral Communications Session. Study 201 is a first late-stage study which successfully demonstrated the potential disease-modifying effects on both clinical function and Aβ accumulation in the brain. In addition, the study design and current status of ongoing Clarity AD (Study 301) will be presented.

Meanwhile, for the investigational sleep-wake regulation agent lemborexant, the further data analysis results from Phase II clinical study (Study 202) for AD patients with irregular sleep-wake rhythm disorder (ISWRD) will be given.

In addition, regarding the creation of the simplified blood diagnostics for AD, jointly developed with Sysmex, the latest data of the fully automated protein assay system using the Sysmex's automated protein measurement immunoassay platform HISCL™ series will be presented.

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 35 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.

(continued on following page)

Oral presentations

Product, Session No.	Title and scheduled presentation date (local time: Pacific Time)
BAN2401 Session No. LB10	Persistence of BAN2401-Mediated Amyloid Reductions Post-Treatment: A Preliminary Comparison of Amyloid Status Between the Core Phase of BAN2401-G000-201 and Baseline of the Open-Label Extension Phase in Subjects with Early Alzheimer's Disease December 5 (Thu), 11:15-11:30
Elenbecestat Session No. LB16	Association Between Neuraceq Levels and [18F]PI-2620 Tau PET Tracer Accumulation in Baseline Scans of the Elenbecestat MISSION AD Program December 6 (Fri), 8:30-8:45
BAN2401 (presented by BioArctic) Session No.OC29	Binding Profiles of BAN2401 and Aducanumab to Different Amyloid-Beta Species December 7 (Sat), 11:30- 11:45

Poster presentations

Product/asset, Poster No.	Poster title and scheduled presentation date (local time: Pacific Time)
Lemborexant P3	Using Network Analysis and Machine Learning Methods to Evaluate the Efficacy of Lemborexant in Patients with Irregular Sleep Wake Rhythm Disorder and Alzheimer's Disease Dementia December 4 (Wed) and December 5 (Thu)
Elenbecestat P24	The Cognitive Task Force: A Novel Approach to Improving the Efficiency of Cognitive Screening for the Elenbecestat MISSION AD Global Phase 3 Studies in Early Alzheimer's Disease December 4 (Wed) and December 5 (Thu)
Elenbecestat P46	Amyloid Positive Subject Characteristics in the Elenbecestat MISSION AD Phase 3 Program December 4 (Wed) and December 5 (Thu)
Blood diagnostics P75	Prediction of Amyloid Pathology by the Plasma Aβ1-42/Aβ1-40 Ratio Measured with Fully Automated Immunoassay System (HISCL™ Series) December 4 (Wed) and December 5 (Thu)
Blood diagnostics P81	Clinical Utility of Plasma Amyloid Beta Measurements by Immunoaffinity Enrichment and LC-MS/MS December 4 (Wed) and December 5 (Thu)
Clinical assessment P136	Staging Early Alzheimer's Disease Using the Alzheimer's Disease Composite Score (ADCOMS) December 6 (Fri) and December 7 (Sat)
Elenbecestat P149	Asian and Non-Asian Countries Screen Subjects with Similar MMSE Scores for the Elenbecestat MISSION AD Global Phase 3 Studies in Early Alzheimer's Disease December 6 (Fri) and December 7 (Sat)
BAN2401 P179	BAN2401 in Early Alzheimer's Disease: A Placebo-Controlled, Double-Blind, Parallel-Group, 18-Month Study with an Open-Label Extension Phase to Confirm Safety and Efficacy December 6 (Fri) and December 7 (Sat)

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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. 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.

2. 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 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 thep United States, the European Union and Japan.

3. 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, indicate its potential to be facilitate the onset and maintenance of sleep. As a result of clinical studies, the effect of lemborexant are suggested not only for primary insomnia but also for insomnia which the diseases, such as depression, associated with. Eisai has submitted new drug applications seeking approval of lemborexant for use in the treatment of insomnia disorder in the United States (December 2018), Japan (March 2019), and Canada (August 2019), respectively. Additionally, a Phase II clinical study of lemborexant in patients with ISWRD associated with mild to moderate Alzheimer's dementia is underway.

4. About 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.