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Eisai Co., Ltd.

LATEST DATA ON EISAI'S ALZHEIMER'S DISEASE / DEMENTIA PIPELINE TO BE PRESENTED AT ALZHEIMER'S ASSOCIATION INTERNATIONAL CONFERENCE (AAIC) 2019

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that a total of 13 presentations[*1] containing two oral presentations including the latest data of the anti-amyloid beta (Aβ) protofibril antibody BAN2401 and the oral BACE (beta amyloid cleaving enzyme) inhibitor elenbecestat, will be given at the Alzheimer's Association International Conference (AAIC) 2019, in Los Angeles, California, the United States from July 14 to 18, 2019. BAN2401 and elenbecestat are being jointly developed by Eisai and Biogen Inc. (Headquarters: Cambridge, Massachusetts, the United States, "Biogen").

Regarding BAN2401, presentations will be held including the biomarker analysis in cerebrospinal fluid (CSF) in clinical phase II study, the nonclinical research on binding of Aβ aggregate species of BAN2401 by BioArctic AB (Headquarters: Sweden) from which was in-licensed. Currently, the global clinical phase III study (Clarity AD) of BAN2401 in early Alzheimer's disease is underway.
Also regarding elenbecestat, presentations including the tau deposition state in subjects at the baseline in ongoing clinical phase III study (MISSION AD) program.

In addition, the latest data from the joint research with Sysmex Corporation (Hyogo, Japan) about correlation of Aβ ratios between in plasma and CSF using automated immunoassay systems HISCL™ series (trademark of Sysmex Corporation) for creating a simple blood diagnostics for AD will be given. This will be the first conference presentation.

The nonclinical research results of anti-tau antibody E2814, first clinical candidate from the drug discovery collaboration with University College London, will be presented.
A presentation on the additional analysis results from clinical phase II study of dual orexin receptor antagonist lemborexant in patients with irregular sleep-wake rhythm disorder (ISWRD) and Alzheimer's disease will also be scheduled.

Also in the sessions to review of developments in disease modifying strategy targeting amyloid and to discuss of challenges and opportunities of BACE inhibitor clinical trial organized by AAIC the presentations and discussions about BAN2401 and elenbecestat will be given. Eisai will sponsor a symposium to discuss the rationale and opportunities for drug development for pre-clinical AD.[*2]

Eisai is aiming to realize 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 Alzheimer's disease / dementia. Eisai is striving 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, patients and their families with our rich development pipeline[*3] for wider scope depending on dementia disease and stage.

[*1] Presentations at AAIC 2019 is listed in page 2.
[*2] AAIC's Sessions and Eisai Sponsored Symposium is listed in page 3.
[*3] Development Eisai's pipeline is listed in Notes to editors 1 in page 3.

■Presentations at AAIC2019:

Topic / Presentation Number	Abstract Title and Scheduled Presentation Date and Time (Local Time)
BAN2401 Oral Presentation No.: DT-01-01	BAN2401 in Early Alzheimer's Disease: Neurodegeneration Biomarker Analysis From Randomized Phase 2 Study Oral Presentation: July 17 (Wed), 2:00 - 2:15pm
BAN2401 (Presented by BioArctic) Poster Presentation No.: P4-704	BAN2401 Binding to Soluble Aggregated Aβ Species Poster Presentation: July 17 (Wed) 1:00pm - 2:00pm
BAN2401 Poster Presentation No.: P4-657	Population Pharmacokinetic/ Pharmacodynamic Analyses of BAN2401 in Patients with Early Alzheimer's Disease: Correlation of BAN2401 Exposure, PET Standard Uptake Value Ratio and Cognitive Outcomes Poster Presentation: July 17(Wed), 1:00pm - 2:00pm
Elenbecestat Oral Presentation No.: O4-12-05	Evaluation of Tau Deposition in Amyloid Positive MCI or Mild-AD Dementia Subjects from the Elenbecestat MissionAD Program Using [18F]PI-2620 PET Oral Presentation: July 17 (Wed) 5:15pm - 5:30pm Presentation at preconference by AAIC is also planned on July 13 (Sat)
Elenbecestat Poster Presentation No.: P1-041	ApoE4 Status and Amyloid Burden Differences Across Regions in the Elenbecestat MissionAD Phase 3 Program Poster Presentation: July 14 (Sun) 9:30am – 10:30am
Elenbecestat Poster Presentation No.: P1-047	Regional Cognitive Differences in Referrals to the Elenbecestat Mission AD Phase 3 Program in Early Alzheimer's Disease Poster Presentation: July 14 (Sun) 9:30am - 10:30am
Elenbecestat Poster Presentation No.: P2-064	Novel Model for Evaluating the Effects of BACE Inhibitor Candidates on Synaptic Function and Aβ Levels in Mouse Brain Poster Presentation: July 15 (Mon) 9:30am - 10:30am
Elenbecestat Poster Presentation No.: P3-459	Equivalence of Different Language Versions of the International Shopping List Test in the Phase 3 MissionAD Studies Poster Presentation: July 16 (Tue) 1:00pm - 2:00pm
General AD Poster Presentation No.: P4-548	Correlation of Cerebrospinal Fluid and Plasma Amyloid Beta Levels Measured by Newly Developed Automated Protein Assay System Poster Presentation: July 17 (Wed) 1:00pm - 2:00pm
General AD Poster Presentation No.: P2-577	The Variability in Input Parameter Values in Models Estimating the Effectiveness of Hypothetical Disease Modifying Treatments for Alzheimer's Disease Poster Presentation: July 15 (Mon) 1:00pm - 2:00pm
E2814 Poster Presentation No.: P4-695	E2814: A Novel Anti-Tau Therapeutic Antibody for Alzheimer's Disease Poster Presentation: July 17 (Wed) 1:00pm - 2:00pm
E2814 Poster Presentation No.: P4-696	Quantification of Tau Microtubule Binding Region in CSF and Subsequent Validation of Target Engagement Assay for E2814, A Novel Anti-Tau Therapeutic Antibody Poster Presentation: July 17 (Wed) 1:00pm - 2:00pm
Lemborexant Poster Presentation No.: P2-617	Response to Treatment with Lemborexant: Subjects with Irregular Sleep-Wake Rhythm Disorder and Alzheimer's Disease Dementia Poster Presentation: July 15 (Mon) 1:00pm - 2:00pm

■AAIC's Sessions and Eisai Sponsored Symposium

Sessions or Symposium	Session / Symposium Title Scheduled Time and Date (Local Time)
AAIC's Focused Topic Session Session No.: FTS5-01	Review of Developments in Disease-Modifying Strategies for Alzheimer's Disease: A Focus on Anti-Amyloid Strategies (Related to BAN2401) July 18 (Thu) 8:30am – 10:00am
AAIC's Focused Topic Session Session No.: FTS3-01	Discussion of BACEi Trial Findings: Challenges and Opportunities. (Presentation for elenbecestat will be given) July 16 (Tue) 4:15pm – 5:45pm
Eisai Sponsored Symposium	Targeted Therapy for Preclinical Alzheimer's Disease (Related to BAN2401 and elenbecestat) July 16 (Tue) 12:00pm – 1:45pm

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[Notes to editors]

1. About Eisai's Drug Discovery in the Dementia Area

With over 35 years of knowledge and know-how of drug creation activities in the dementia area accumulated since 1983 when it began researching dementia at the Tsukuba Research Laboratories, Eisai is aiming to realize prevention and cure of dementia through a multi-dimensional and holistic approach. Specifically, Eisai is working on the four keys of 1) the process of accumulation of aggressive factors, 2) transformation of symptoms over time, 3) immunodementia therapy and 4) the brain maintenance system. The following is a list of Eisai's development pipeline products currently being investigated in clinical studies.

Generic Name, Development Code	Mechanism of Action	Indications	Development Stage
Elenbecestat*	BACE inhibitor	Early Alzheimer's disease	Phase III
BAN2401*	Anti-Aβ protofibril antibody	Early Alzheimer's disease	Phase III
Lemborexant	Dural Orexin receptor antagonist	Insomnia disorder (including elderly people)	Submitted in Japan and U.S.
		Irregular Sleep-Wake Rhythm Disorder (ISWRD) and Alzheimer's disease	Phase II
E2027	PDE9 inhibitor	Dementia with Lewy bodies	Phase II/III
E2814	Anti-tauantibody	Alzheimer's disease / dementia	Preparing for Phase I

Revised Eisai's Financial Results Presentation for FY2019Q1 (July 31, 2019).

* Joint development with Biogen Inc.

2. About BAN2401

BAN2401 is an investigational humanized monoclonal antibody for Alzheimer's disease (AD) that is the result of a strategic research alliance between Eisai and BioArctic (Sweden). BAN2401 selectively binds to neutralize and eliminate soluble, toxic Aβ aggregates (protofibril) that are through 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.

3. About elenbecestat (generic name, development code: E2609)

Discovered by Eisai, elenbecestat is an investigational next-generation oral candidate for the treatment of Alzheimer's disease (AD) that inhibits BACE (beta amyloid cleaving enzyme). By inhibiting BACE, a key enzyme in the production of Aβ peptides, elenbecestat reduces Aβ production, and by reducing amyloid plaque formations in the brain, exerts disease modifying effects of potentially slowing the progression of AD. Currently, two global Phase III clinical studies (MISSION AD1/2) of elenbecestat in early AD including mild cognitive impairment (MCI) due to AD or the mild AD are underway. In addition, the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the development of elenbecestat, a process allowing priority reviews by the FDA for drugs deemed as having potential to treat serious conditions and tackle key unmet medical needs.

4. About joint development agreement between Eisai and Biogen for Alzheimer's disease

Eisai and Biogen are collaborating on the joint development and commercialization of Alzheimer's disease treatments. Eisai serves as the lead in the co-development of elenbecestat, a BACE inhibitor, and BAN2401, an anti-amyloid beta (Aβ) protofibril antibody, 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. As to BAN2401 and elenbecestat, both companies will equally split overall costs, including research and development expenses. Eisai will book all sales for elenbecestat and BAN2401 following marketing approval and launch, and profits will be equally shared between the companies.

5. 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.

6. About E2814

An investigational anti-tau monoclonal antibody, E2814 is being developed as a disease modifying agent for Alzheimer's disease and other tauopathies, Phase I clinical studies are under preparation. The drug candidate was discovered as part of the research collaboration between Eisai and University College London, and is designed to prevent the spreading of tau protein "seeds" within the brains of affected individuals.

7. About Lemborexant

Lemborexant is a novel investigational small molecule compound, discovered and developed by Eisai, that inhibits orexin signaling by binding competitively to both orexin receptor subtypes (orexin receptors 1 and 2). In individuals with normal daily sleep-wake rhythms, orexin signaling is believed to promote periods of wakefulness. In individuals with sleep-wake disorders, it is possible that orexin signaling that regulates wakefulness is not functioning normally, suggesting that inhibiting inappropriate orexin signaling may enable initiation and maintenance of sleep. Eisai is investigating lemborexant as a potential treatment option for multiple sleep-wake disorders, such as insomnia. Applications seeking approval of lemborexant for use in the treatment of insomnia disorder were submitted in the United States and Japan, respectively. Additionally, a Phase 2 clinical study of lemborexant in patients with irregular sleep-wake rhythm disorder (ISWRD) and mild to moderate Alzheimer's dementia is underway.