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Eisai Co., Ltd.

EISAI TO PRESENT NEW LECANEMAB DATA, INCLUDING RESEARCH EVALUATING SAFETY PROFILE, CLINICAL OUTCOMES AND QUALITY OF LIFE MEASURES, AS WELL AS OTHER IMPORTANT ALZHEIMER'S DISEASE RESEARCH, AT THE AD/PD™ 2023 ANNUAL MEETING

Presentations Explore ARIA with the Use of Antiplatelets or Anticoagulants and Isolated ARIA-H in Patients from Eisai's Lecanemab Phase 3 Confirmatory Clarity AD Study in Early Alzheimer's Disease

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today the company will present the latest findings on lecanemab (generic name, U.S. brand name: LEQEMBI™), Eisai's anti-amyloid beta (A β) protofibril* antibody for the treatment of Alzheimer's disease (AD), at the 2023 International Conference on Alzheimer's and Parkinson's Diseases and related neurological disorders (AD/PD™) from March 28-April 1 in Gothenburg, Sweden and virtually. Eisai will present new findings from the company's large, global Phase III confirmatory study of lecanemab, Clarity AD, including research into the management and monitoring of amyloid-related imaging abnormalities (ARIA) and health-related quality of life (HRQoL) measures. Eisai will also host a symposium, titled "Patient Clinical Care Pathway in Alzheimer's disease: Dialogue Amongst Experts," which will address the evolving landscape in AD. The lecanemab data and additional research findings from Eisai's AD portfolio will be featured in 11 presentations, including seven oral and four poster presentations.

"Our latest research examines the real-world outcomes based on lecanemab's impact on clinical results and safety, including its effect on health-related quality of life. Through our ongoing research, we hope to help simplify the patient journey and improve the lives of those living with Alzheimer's disease," said Michael Irizarry, M.D., Deputy Chief Clinical Officer and Senior Vice President of Clinical Research at Eisai Inc. "In addition to lecanemab, Eisai is presenting on several other key issues that will shape the future of Alzheimer's disease and brain health, including the next generation of clinical care and diagnostic pathways, exploration of unique populations affected by the disease, and accelerating drug development. We look forward to sharing our latest findings, including new insights from Eisai's Clarity AD trial of lecanemab, with the scientific community at AD/PD 2023."

Key Eisai Lecanemab and AD Presentations

- Two presentations related to ARIA in the Clarity AD trial will be presented during an oral session on Thursday, March 30:
 - An analysis evaluating the use of antiplatelet and anticoagulant drugs in patients who experienced ARIA.
 - An analysis of isolated ARIA-H events in the Clarity AD trial.
- Research evaluating caregiver burden and HRQoL across multiple scales using Clarity AD data will be presented during an oral session on Thursday, March 30.
- Research studying the characterization of A β protofibrils and the unique binding properties and mechanisms of A β clearance of lecanemab on Friday, March 31.
- Designing The Next Generation Clinical Care and Diagnostic Pathway for Alzheimer's Disease: A

presentation focused on a new pathway which interweaves clinical, biological and digital assessments to guide an individualized AD patient journey on Friday, March 31.

Eisai Symposium – Patient Clinical Care Pathway in AD: Dialogue Amongst Experts

Eisai is sponsoring a symposium featuring three prominent clinical experts in the field of AD, Dr. Alireza Atri, Dr. Sharon Cohen and Dr. Lutz Frölich, who will provide insights on the AD landscape, evolving diagnostic workflow, identifying appropriate patients, and addressing patient needs on Wednesday, March 29. The session aims to provide guidance on the clinical management of patients and drive effective communication between physicians and patients.

AD/PD 2023 Presentations Relating to Eisai's Key Compounds and Research

Oral Presentations

Asset in Development, Session, Time (CEST)	Presentation Title
<p>Lecanemab On-site Symposium: Aβ Targeting Therapies in AD 01 Thu, Mar 30 Session Time: 13:50 - 15:50 Lecture Time: 14:50 - 15:05</p>	Lecanemab Phase 3 Clarity AD Trial: ARIA with the Use of Antiplatelets or Anticoagulants in Early Alzheimer's Disease
<p>Lecanemab On-site Symposium: Aβ Targeting Therapies in AD 01 Thu, Mar 30 Session Time: 13:50 - 15:50 Lecture Time: 15:05 - 15:20</p>	Isolated ARIA-H in Patients Treated with Lecanemab in the Phase 3 Clarity AD Study in Early Alzheimer's Disease
<p>Lecanemab On-site Symposium: Aβ and Tau Targeting Therapies in AD Thu, Mar 30 Session Time: 18:35 - 19:35 Lecture Time: 19:05 - 19:20</p>	Lecanemab Clarity AD: Quality-of-Life Results from a Randomized, Double-blind, Phase 3 Trial in Early Alzheimer's Disease
<p>Lecanemab On-site Symposium: Aβ Targeting Therapies in AD 02 Fri, Mar 31 Session Time: 13:50 - 15:50 Lecture Time: 14:35 - 14:50</p>	Lecanemab, an Amyloid-beta Protofibril Selective Antibody, Its Mechanism of Action and Characterization of the Targeted Protofibrils in Alzheimer's Disease Brain
<p>Lecanemab On-site Symposium: Clinical Trial Designs Fri, Mar 31 Session Time: 16:20 - 18:20 Lecture Time: 17:35 - 17:50</p>	Amyloid, Tau and Cognitive Decline During the Preclinical Stages of Alzheimer's Disease
<p>General AD On-site Symposium: Clinical Trial Designs Fri, Mar 31 Session Time: 16:20 - 18:20 Lecture Time: 18:05 - 18:20</p>	Designing The Next Generation Clinical Care and Diagnostic Pathway for Alzheimer's Disease

General AD On-demand Oral: OD127, #2283 Thu, Mar 30 Session Time: 7:00 - 8:30	Empirically Derived Structural Brain Network Hubs Enhance Prognostic Production of Progression in Amyloid Positive Subjects with Mild Cognitive Impairment
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Poster Presentations

Asset in Development, Topic, Poster Number	Presentation Title
General AD Posters Topic: A05.I. Genetics, Epidemiology: Other P0523, #604	Estimating Transition Probabilities Across the Alzheimer's Disease Continuum Using a Nationally Representative Real-World Database in the United States
General AD Posters Topic: A05.I. Genetics, Epidemiology: Other P0524, #609	Assessing Out-of-Pocket Expenses and Indirect Costs Over the Alzheimer's Disease Continuum in the United States
General AD Posters Topic: K01.J. Dementia and Cognitive Dysfunction: Other P1151, #1122	A Deep-Learning Natural Language Processing Algorithm to Improve Keyword-based Identification of Patients with Alzheimer's Disease from Electronic Health Records
General AD Posters Topic: A03.N. Drug Development, Clinical Trials: Regulatory Aspects P0325, #231	Accelerating Drug Development Through Precompetitive Data Sharing and Collaboration in the Critical Path for Alzheimer's Disease (CPAD) Consortium

Eisai-Sponsored Symposium

Session, Time (CEST)	Title, Presenter
Industry Symposium 03 - Hall C Wed, Mar 29 Session Time: 17:20 - 19:20	Patient Clinical Care Pathway in Alzheimer's Disease: Dialogue Amongst Experts Presenters: Alireza Atri, Sharon Cohen and Lutz Frölich

Eisai serves as the lead of lecanemab development and regulatory submissions globally with both Eisai and Biogen co-commercializing and co-promoting the product and Eisai having final decision-making authority.

* Protofibrils are large A β aggregated soluble species of 75-5000 Kd.¹

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[Notes to editors]

1. About Lecanemab

Lecanemab (brand name in the U.S.: LEQEMBI™) is the result of a strategic research alliance between Eisai and BioArctic. Lecanemab is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble (protofibril) and insoluble forms of amyloid-beta (Aβ). In the U.S., LEQEMBI was granted accelerated approval by the U.S. Food and Drug Administration (FDA) on January 6, 2023. LEQEMBI is indicated for the treatment of Alzheimer's disease (AD) in the U.S. Treatment with LEQEMBI should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied. This indication is approved in the U.S. under Accelerated Approval based on reduction in Aβ plaques observed in patients treated with LEQEMBI. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial.

Please see full [Prescribing Information](#).

The Clarity AD study of lecanemab met its primary endpoint and all key secondary endpoints with highly statistically significant results. In the U.S., Eisai submitted a supplemental Biologics License Application (sBLA) to the FDA for approval under the traditional pathway on January 6, 2023. On March 3, 2023, the FDA accepted Eisai's sBLA based on the Clarity AD clinical data, and the LEQEMBI application has been granted Priority Review, with a Prescription Drug User Fee Act (PDUFA) action date of July 6, 2023. Eisai submitted an application for manufacturing and marketing approval to the Pharmaceuticals and Medical Devices Agency (PMDA) on January 16, 2023, in Japan. The Priority Review was granted by the Ministry of Health, Labour and Welfare (MHLW) on January 26, 2023. Eisai utilized the prior assessment consultation system of PMDA, with the aim of shortening the review period for lecanemab. In Europe, Eisai submitted a marketing authorization application (MAA) to the European Medicines Agency (EMA) on January 9, 2023, and accepted on January 26, 2023. In China, Eisai initiated submission of data for a BLA to the National Medical Products Administration (NMPA) of China in December 2022, and the Priority Review was granted on February 27, 2023.

Eisai has completed lecanemab subcutaneous bioavailability study, and subcutaneous dosing is currently being evaluated in the Clarity AD (Study 301) OLE.

Since 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, is ongoing. AHEAD 3-45 is conducted as a public-private partnership between the Alzheimer's Clinical Trial Consortium that provides the infrastructure for academic clinical trials in AD and related dementias in the U.S, funded by the National Institute on Aging, part of the National Institutes of Health, Eisai and Biogen.

Since January 2022, the Tau NexGen clinical study for Dominantly Inherited AD (DIAD), that is conducted by Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU), led by Washington University School of Medicine in St. Louis, is ongoing.

2. About the Collaboration between Eisai and Biogen for AD

Eisai and Biogen have been collaborating on the joint development and commercialization of AD treatments since 2014. Eisai serves as the lead of lecanemab development and regulatory submissions globally with both companies co-commercializing and co-promoting the product and Eisai having final decision-making authority.

3. About the Collaboration between Eisai and BioArctic for AD

Since 2005, Eisai and BioArctic have had a long-term collaboration regarding the development and commercialization of AD treatments. Eisai obtained the global rights to study, develop, manufacture and market lecanemab for the treatment

of AD pursuant to an agreement with BioArctic in December 2007. The development and commercialization agreement on the antibody lecanemab back-up was signed in May 2015.

References

¹ Söderberg, L., Johannesson, M., Nygren, P. et al. Lecanemab, Aducanumab, and Gantenerumab — Binding Profiles to Different Forms of Amyloid-Beta Might Explain Efficacy and Side Effects in Clinical Trials for Alzheimer's Disease. *Neurotherapeutics* (2022). <https://doi.org/10.1007/s13311-022-01308-6>. Accessed February 9, 2023

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