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Eisai Co., Ltd.

Eisai to Present the Latest Research Results, Including Long-Term and Real-Word Data on Lecanemab and Biomarkers for Alzheimer's Disease at the AD/PD™ 2025 Annual Meeting

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 (Aβ) protofibril* antibody for the treatment of Alzheimer's disease (AD), at the 2025 International Conference on Alzheimer's and Parkinson's Diseases and related neurological disorders (AD/PD™) from April 1-5 in Vienna, Austria, and online. The lecanemab data and additional research findings from Eisai's AD portfolio will be featured in 16 presentations, including 6 oral presentations.

Oral and Poster Presentations

Eisai will present three oral presentations and one poster presentation on lecanemab, among other results. These presentations will include the latest findings from real-world clinical evidence of lecanemab in the United States, efficacy and safety outcomes in apolipoprotein E ε4 (ApoEε4) heterozygous carriers and non-carriers in the Phase III Clarity AD clinical study, and a subgroup analysis of Clarity AD open label extension study in the Asian region. In addition to the presentations, the clinical study design of a Phase II study of the anti-MTBR tau antibody E2814 in combination with lecanemab in people living with sporadic early AD, and research results to predict future brain tau accumulation using the ratio of phosphorylated tau 217 to non-phosphorylated tau 217 (pTau217 ratio) in plasma will be presented.

Eisai Symposium – Bridging the Gap in Alzheimer's Disease: From Pathophysiology to Treatment Strategy

Eisai is sponsoring a symposium featuring three leading global experts in the field of AD, on the topics of the pathophysiology of AD, treatment advancements and clinical implications for targeting AD pathology. The symposium aims to enhance understanding by providing expert insights into the key drivers and mechanisms of AD pathophysiology and neurodegeneration, the rationale for targeted approaches to anti-amyloid-β therapies, lessons from past drug development, and emerging treatment strategies.

Eisai Symposium – Transforming Outcomes in Early AD: A Focus on Intervention and Management

Eisai is sponsoring a symposium featuring prominent clinical experts in the field of AD. The symposium will provide updates and insights into early AD treatment from various perspectives, as well as information on future treatment directions.

AD/PD 2025 Presentations Relating to Eisai's Key Compounds and Research

Oral Presentations

Asset, Session, Time (Central Europe Time: CET)	Presentation Title
Lecanemab Abeta Targeting Therapies in AD Thursday, April 3, 15:05 – 15:20	Real-World Evidence of Lecanemab Use in the United States

Lecanemab Abeta and Tau Immunotherapies Saturday, April 5, 11:10 – 11:25	Lecanemab-Associated Amyloid-Beta Protofibril in CSF is a Proximal Biomarker of Neurodegeneration Unlike Other Plaque-Associated Biomarkers.
Lecanemab Advances in AD Drug Development Saturday, April 5, 16:40 – 16:55	Lecanemab for Treatment of Individuals with Early Alzheimer's Disease (AD): Results in Apolipoprotein E ε4 (ApoE ε4) Non-carriers or Heterozygotes
E2814 & Lecanemab Tauopathies: Challenges in Targeting Tau Saturday, April 5, 12:40 – 12:55	Clinical Trial Design for Concurrent Anti-Amyloid and Anti-Tau Antibody Therapy for Sporadic Alzheimer's Disease
Biomarkers and Imaging Fluid Biomarkers and Multimodal Imaging for Diagnosis, Prognosis and Disease Progression Thursday, April 3, 15:35 – 15:50	Plasma pTau217 Ratio Predicts the Future Progression of Brain Tau Accumulation in Early Alzheimer's Disease
Biomarkers and Imaging On-demand oral (virtual only) + onsite poster	Simultaneous Prediction of Continuous Brain Amyloid and Tau Levels Using Plasma pTau217 Ratio in Preclinical and Early Alzheimer's Disease

Poster Presentations

Asset / Project	Presentation Title
Lecanemab	Lecanemab Long-Term Efficacy and Safety in the Asia Region: A Subgroup Analysis from the Phase 3 Clarity AD Trial
Tau / Taupathies	An Intraneuronal Tau Aggregation Model of Human IPSC-Derived Neurons Without Tau Seed Addition
Biomarkers and Imaging	Reviewing Scientific and Regulatory Aspects of Tau PET Implementation as a Surrogate Endpoint in Alzheimer's Disease Clinical Studies
Biomarkers	A Prospective, Observational Study Investigating the Real-World Implementation of Confirmatory Diagnostic Blood-Based Biomarkers for Early Alzheimer's Disease: A Feasibility Assessment
Biomarkers	Health Care Providers' Perspectives on the Real-World Use of Confirmatory Diagnostic Blood-Based Biomarkers for Early Alzheimer's Disease
General AD	Natural History of All-Cause Mortality in Patients with Mild Cognitive Impairment and Alzheimer's Dementia Among United States Medicare Beneficiaries
General AD	Estimating the Treatable Population for Anti-Amyloid Therapy in France
General AD	Comparison of Contemporary Clinical Dementia Rating Scale-Sum of Boxes (CDR-SB) Disease Progression Models in Alzheimer's Disease
Biomarkers (Sysmex)	Development of a Highly Specific P-Tau205 Assay Using a Fully Automated Immunoassay System
Biomarkers (Shimadzu)	Performance of Plasma Aβ Biomarkers in Predicting Amyloid Positivity and Clinical Progression

Eisai-Sponsored Symposium: Industry Symposium 09

Thursday, April 3, 18:40 – 20:15 (CET)

Symposium Title: Bridging the Gap in Alzheimer’s Disease: From Pathophysiology to Treatment Strategy
Session
Complex pathophysiological process leading to AD
AD treatment development and era of targeted strategies

Implications and considerations with disease modifying AD therapies

Eisai-Sponsored Symposium: Industry Symposium 12
Friday, Apr 4, 13:50 – 15:50 PM (CET)

Symposium Title: Transforming Outcomes in Early AD: A Focus on Intervention and Management
Session
Unveiling the science: Elevate early Alzheimer's disease treatment with amyloid beta antibody
Unlocking potential: Identify individuals for early intervention
Multidisciplinary coordination for early Alzheimer's disease: Insights from the first treatment centres

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 believed to contribute to the brain injury that occurs with AD and are considered to be the most toxic form of Aβ, having a primary role in the cognitive decline associated with this progressive, debilitating condition.[1] Protofibrils cause injury to neurons in the brain, which in turn, can negatively impact cognitive function via multiple mechanisms, not only increasing the development of insoluble Aβ plaques but also increasing direct damage to brain cell membranes and the connections that transmit signals between nerve cells or nerve cells and other cells. It is believed the reduction of protofibrils may prevent the progression of AD by reducing damage to neurons in the brain and cognitive dysfunction.[2]

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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. LEQEMBI is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble (protofibril) and insoluble forms of amyloid-beta (Aβ).

Lecanemab is approved in the U.S., Japan, China, South Korea, Hong Kong, Israel, the United Arab Emirates, the United Kingdom, Mexico, Macau and Oman. Eisai has submitted applications for approval of lecanemab in 16 countries and regions. In the EU, in February 2025, the Committee for Medicinal Products for Human Use reaffirmed its positive opinion for lecanemab in early AD, adopted in November 2024, and the European Commission is proceeding with the decision-making process for lecanemab's marketing authorization. In January 2025, the supplemental Biologics License Application (sBLA) for intravenous (IV) maintenance dosing of the treatment was approved in the U.S. After an 18 months initiation phase with once every two weeks of dosing, a transition to the maintenance dosing regimen of 10 mg/kg once every four weeks or continuing 10 mg/kg once every two weeks may be considered. Additionally, the U.S. Food and Drug Administration (FDA) accepted Eisai's Biologics License Application (BLA) for the LEQEMBI subcutaneous autoinjector for weekly maintenance dosing in January 2025 and set a PDUFA action date for August 31, 2025.

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 and includes lecanemab as the backbone anti-amyloid therapy.

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 LEQEMBI 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. Amin L, Harris DA. Aβ receptors specifically recognize molecular features displayed by fibril ends and neurotoxic oligomers. *Nat Commun*. 2021;12:3451. doi:10.1038/s41467-021-23507-z

2. Ono K, Tsuji M. Protofibrils of Amyloid-β are Important Targets of a Disease-Modifying Approach for Alzheimer's Disease. *Int J Mol Sci.* 2020;21(3):952. doi: 10.3390/ijms21030952. PMID: 32023927; PMCID: PMC7037706.

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