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Eisai Co., Ltd.

Eisai To Present Four-Year Efficacy And Safety Data On Continuous Treatment With Lecanemab At The Alzheimer's Association International Conference 2025

Latest findings from Eisai's robust Alzheimer's disease (AD) pipeline include results from lecanemab long-term data, an immunoassay for measuring amyloid-β protofibrils in cerebrospinal fluid, and a subcutaneousl form of lecanemab for continued treatment of AD
AD is a progressive, relentless disease caused by a continuous underlying neurotoxic process that begins before and continues after plaque deposition

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that the company will present the latest findings from its robust Alzheimer's disease (AD) pipeline and research, including our dual-acting, anti-amyloid beta (Aβ) protofibril antibody for the treatment of AD, lecanemab (generic name, U.S. brand name: LEQEMBI®), and anti-MTBR (microtubule binding region) tau antibody, etalanetug (E2814), at the Alzheimer's Association International Conference (AAIC), being held in Toronto and virtually from July 27-31. Eisai will present 21 oral presentations, 24 posters, three (3) symposia and two (2) lecanemab product theaters.

Key Oral Lecanemab Presentations

- **Four-year Data**: On Wednesday July 30 (8:00 – 8:45 AM EDT), as part of the "Developing Topics Session: Innovative Therapeutic Approaches", initial four-year findings will be presented on lecanemab from the Phase III Clarity AD Open-Label Extension in Early Alzheimer's Disease trial.
- **Subcutaneous Maintenance Dosing**: A Featured Research Session on Wednesday, July 30 (9:00 – 10:30 AM EDT) will include data on the potential of a new and convenient option for ongoing lecanemab treatment, the subcutaneous formulation for maintenance dosing.
- **Real World Case Studies**: A Developing Topics Session on Sunday, July 27 (9:00 – 10:30 AM EDT) will include data on real-world case studies and patient pathway learnings from diverse U.S. clinical settings two years post-approval of lecanemab.

Key Lecanemab Poster Presentation

- A Poster Presentation on Monday, July 28 (viewing available from 7:30 AM – 4:15 PM EDT) will share findings on cerebrospinal fluid (CSF) samples collected from the Clarity AD trial and analyzed using the novel, sensitive immunoassay developed to measure amyloid-β protofibrils in CSF.

Key Oral E2814 Presentation

- A Featured Research Session on Wednesday, July 30 (4:15 PM – 5:45 PM EDT) will include findings from "Anti-Tau Etalanetug (E2814) with Lecanemab Therapy in Individuals with Dominantly Inherited Alzheimer's Disease: A First Look at Baseline Characteristics and Impact of 6-Month Lecanemab Treatment on Amyloid PET and Safety in the DIAN-TU-001 NexGen Trial."

"The data presented at AAIC 2025 will highlight long-term findings from lecanemab's open-label extension trial, real-world lecanemab case studies as well as results on a subcutaneous formulation and dosing

regimen that may offer patients more flexibility to continue treatment to fight Alzhierm's disease," said Lynn D. Kramer, M.D., FAAN, Chief Clinical Officer, Deep Human Biology Learning (DHBL), Eisai. "Eisai will also share preliminary results from the DIAN-TU-001 NexGen Trial, exploring etalanetug with background lecanemab therapy to slow or prevent the progression of Alzhierm's disease. As we gain more experience using dual-acting lecanemab in different clinical settings and continue to explore new avenues to improve the diagnosis and treatment of Alzhierm's disease, we are hopeful about the future. We remain committed to patients and their loved ones who are impacted by this progressive, relentless disease, caused by a continuous underlying neurotoxic process that begins before and continues after plaque is removed from the brain."

Featured Research Session (FRS) #1-31-FRS-A:
Anti-Amyloid Therapies in Clinical Practice: Real World Evidence and Implementation Consideration (Abstract ID 103048)
4:15 - 5:45 PM EDT, Sunday, July 27

Session Program
Indirect Treatment Comparison of ARIA Outcomes for Lecanemab Compared to Donanemab Based on Reported Results

Featured Research Session, #4-13-FRS-C:
Lecanemab Subcutaneous Formulation for Maintenance Dosing: The Potential of a New and Convenient Option for Ongoing Treatment in Early Alzheimer's Disease
9:00 – 10:30 AM EDT, Wednesday, July 30

Session Program
Development of Subcutaneous Lecanemab: Establishing the Comparability of Subcutaneous and Intravenous Lecanemab Formulations (Abstract ID 104694)
Lecanemab Subcutaneous Formulation for Maintenance Dosing in Early Alzheimer's Disease (Abstract ID 104693)
Clinical and Pharmacologic Profile of a Subcutaneous Lecanemab Formulation (Abstract ID 104691)
Subcutaneous Lecanemab: Potential Benefits and Place in Therapy (Abstract ID 104695)

Featured Research Session, #4-31-FRS-B:
Anti-Tau Etalanetug (E2814) with Lecanemab Therapy in Individuals with Dominantly Inherited Alzheimer's Disease: A First Look at Baseline Characteristics and Impact of 6-Month Lecanemab Treatment on Amyloid PET and Safety in the DIAN-TU-001 NexGen Trial
4:15 - 5:45 PM EDT, Wednesday, July 30

Session Program
DIAN-TU-001 Trial (Tau NexGen) Rationale and Enrollment Experience (Abstract ID 105298)
Baseline Participant Clinical Characteristics in the DIAN-TU-001 Trial (Abstract ID 105299)
Baseline Imaging Characteristics of Participants in the Phase II/III DIAN-TU-001 Tau NexGen Trial for Dominantly Inherited Alzheimer's Disease (Abstract ID 105301)
Lecanemab in DIAD: 6-Month Amyloid PET Results from the DIAN-TU-001 Trial (Abstract ID 105303)
Safety of Lecanemab After 6-Month Treatment in the DIAN-TU-001 Trial (Abstract ID 105304)

Key Developing Topics Sessions
Real-World Data (Abstract ID 108809)
8:00 - 8:45 AM EDT on Sunday, July 27

Session Program

Patient, Care Partner, and Health Care Professional Opinion of the Lecanemab Autoinjector for Subcutaneous Delivery in Early Alzheimer's Disease Patients

Lecanemab Two Years Post-Approval: Real-World Case Series and Patient Pathway Learnings from Diverse US Clinical Settings (Abstract ID 108605)
9:00 - 10:30 AM EDT on Sunday, July 27

Session Program
Real-World Use of Lecanemab in Patients with Early Alzheimer's Disease in the United States: A Case Series Review (Abstract ID 108599)
Real-World Use of Lecanemab with Consideration of Race, Ethnicity and Geographical Diversity (Abstract ID 108602)
Real-World Use of Lecanemab in APOE ε4 Homozygotes and in Patients on Antithrombotic Therapy (Abstract ID 108603)
Physician Satisfaction with Lecanemab in Early Alzheimer's Disease: Real-World Insights from Prescribers in the United States (Abstract ID 108605)
Real-World Insights on the Lecanemab Patient Pathway in Early Alzheimer's Disease in the United States (Abstract ID 108606)
Blood-Based Biomarkers in the Lecanemab Patient Pathway for Early Alzheimer's Disease in the United States (Abstract ID 108607)

Innovative Therapeutic Approaches (Abstract ID 108905)
8:00 - 8:45 AM EDT, Wednesday, July 30

Session Program
The Lecanemab Clarity AD Open-Label Extension in Early Alzheimer's Disease: Initial Findings from the 48-Month Analysis

Additional Featured Research and Developing Topics Sessions

Asset/Project, Presentation Date and Time (EDT)	Abstract Number, Title
Biomarkers July 28 (Mon.) 9:00 – 10:30 AM	Featured Research Session, #2-17-FRS-A (Abstract ID 102560): Sex Specific Risk and Protective Factors in Alzheimer's Disease Sex-Stratified GWAS Meta-Analyses Reveal Novel Sex-Specific Association with CSF Biomarkers of Alzheimer's Disease
Lecanemab July 29 (Tues.) 2:00 – 3:30 PM	Developing Topics Session: Tau Biomarkers (Abstract ID 108909) Variations in Plasma p-Tau217 by Sociodemographic Factors Across World Regions in a Preclinical AD Clinical Trials Program: The AHEAD 3-45 Study
Clinical Trials July 30 (Weds.) 2:00 – 3:30 PM	Featured Research Session, #4-26-FRS-A: Innovative Use of Statistical Models and Machine Learning to Enhance AD Clinical Trials (Abstract ID 99560) Baseline Predictions of PACC Progression Trajectories in Preclinical AD Improve the Precision and Power of Treatment Effect Assessments

Poster Presentations

Asset/Project, Presentation Date	Abstract Number, Title
Lecanemab July 27 (Sun.)	Results from a Human Factor Study Supporting Safe and Effective Use of the Lecanemab Subcutaneous Autoinjector (Abstract ID 106273)

Lecanemab July 27 (Sun.)	Delphi Consensus for Implementation of Anti-Amyloid mAb Initiation in Private Practice Neurology: Preliminary Recommendations from Experienced Providers (Abstract ID 108789)
Lecanemab July 28 (Mon.)	Target Engagement of Lecanemab on CSF Aβ Protofibril Toxic Species in Clarity AD (Abstract ID 108918)
Lecanemab July 28 (Mon.)	Understanding Real-World Clinical Experience with Lecanemab: Capturing the Patient and Care Partner Voice Through Social Media Listening (Abstract ID 102018)
Lecanemab July 29 (Tues.)	Patient and Care Partner Expectations and Emotional Experiences of Lecanemab: A Social Media Listening Study (Abstract ID 101001)
Lecanemab July 29 (Tues.)	Lecanemab Real-World Use Perspectives from a New England Alzheimer's Disease Center: A Retrospective Chart Review (Abstract ID 101388)
Lecanemab July 30 (Weds.)	Transitioning from Clinical Trial to Clinical Practice for Long-Term Lecanemab Treatment in Early Alzheimer's Disease: Perspectives from an Alzheimer's Disease Treatment Center (Abstract ID 101400)
E2814 July 30 (Weds.)	E2814 Mitigates Tau Pathology: Inhibiting Tau Uptake and Promoting MTBR-Tau Clearance Through Microglial Pathways in vitro (Abstract ID 102696)
E2025 July 29 (Tues.)	Quantification of EphA4 Turnover Rate and Subsequent Validation of Target Engagement for E2025, a Novel Anti-EphA4 Antibody, in Human Neural Cells (Abstract ID 96834)
Biomarkers and Imaging July 27 (Sun.)	External Validation of Joint Propagation Model-Based Tau PET CenTauR Units (Abstract ID 106362)
Biomarkers July 27 (Sun.)	Observational Study Evaluating Blood-Based Biomarker Use for Confirmatory Alzheimer's Disease Diagnosis in Real-World Clinical Practice Within the United States (Abstract ID 99857)
Biomarkers and Imaging July 28 (Mon.)	Identifying Differentially Expressed Proteins Between Amyloid Positive and Amyloid Negative Subjects Based on Alamar Multiplex Assay Data Using MissionAD Samples (Abstract ID 107031)
Biomarkers July 28 (Mon.)	A De Novo-Assisted Strategy to Identify Novel LncRNA-Encoded Peptides in Cerebrospinal Fluid of Demented Subjects With or Without Amyloid Positivity (Abstract ID 106893)
Biomarkers July 28 (Mon.)	Impact of Blood-Based Biomarkers on Access to Alzheimer's Disease Treatments: A Simulation Study in Japan (Abstract ID 102553)
Biomarkers and Imaging July 29 (Tues.)	Influence of Demographics and Scan Time on MK6240 Off-Target Signal and Reference Region Selection (Abstract ID 100424)
Biomarkers July 29 (Tues.)	Implementation Science Study Evaluating the Real-World Use of Blood-Based Biomarkers as Confirmatory Diagnostic Tools for Alzheimer's Disease in the United States (Abstract ID 99804)
Biomarkers July 29 (Tues.)	Characterization of Lewy Body Copathology in Early AD Clinical Trial Population Demonstrates Similarities and Differences Compared to Natural History Studies in Alzheimer’s Disease Patients (Abstract ID 107102)
Biomarkers July 30 (Weds.)	Value of Blood-Based Biomarker Testing to Diagnose, Identify and Monitor Patients with Alzheimer's Disease: A Structured Literature Review (Abstract ID 99842)
Biomarkers July 30 (Weds.)	Alzheimer's Disease Molecular Subtypes in a Clinical Trial Cohort (Abstract ID 105257)
General AD July 27 (Sun.)	Operational Consideration and Best Practices for Implementation of an Early Alzheimer's Disease Patient Care Pathway (Abstract ID 108093)

General AD July 27 (Sun.)	Estimating Clinical Transitions in Patients with Alzheimer's Using Instrumental Activities of Daily Living (IADL) (Abstract ID 107058)
General AD July 28 (Mon.)	Staging Alzheimer's Disease Using the Functional Assessment Screening Tool (FAST): A Crosswalk with the Montreal Cognitive Assessment (MoCA) (Abstract ID 107045)
General AD July 29 (Tues.)	Time to Alzheimer's Disease Diagnosis in Japan: A Retrospective Observational Study (Abstract ID 97026)
General AD July 30 (Weds.)	Alzheimer's Disease Staging by Instrumental Activities of Daily Living (IADL): A Crosswalk with the Montreal Cognitive Assessment (MoCA) (Abstract ID 107009)

Poster viewing time is set from 7:30AM to 4:15PM on the date of presentation.

Eisai-Sponsored Symposia

Asset/Project, Presentation Date and Time (EDT)	Presentation Number, Title
General AD July 28 (Mon.) 6:00 – 7:30 PM	Smoldering Alzheimer's Disease: The Ongoing Benefit of Addressing Multiple Pathologies.
General AD July 30 (Weds.) 6:15 – 7:45 AM	Unlock Your Brain: Exploring Alzheimer's Disease from the Inside Out
General AD July 30 (Weds.) 6:00 – 7:30 PM	Brain Health Navigator—Ensuring Efficient and Effective Alzheimer's Disease Diagnostic and Clinical Care Pathways

Eisai-Sponsored Product Theaters

Asset/Project, Presentation Date and Time (EDT)	Presentation Number, Title
Lecanemab July 27 (Sun.) 12:25 – 1:05 PM	Early Diagnosis, Early Treatment: Identifying Patients for Greater Benefit in Mild Cognitive Impairment Due to Alzheimer's Disease
Lecanemab July 28 (Mon.) 12:25 – 1:05 PM	Best Practices in Early Alzheimer's Disease Care: Creating a Plan from Screening Through Long-Term Treatment

Product theaters will feature presentations based on real-world clinical experience with lecanemab - providing attendees with an opportunity to hear best practices and expert guidance on using this therapy.

This release discusses investigational uses of agents in development and is not intended to convey conclusions about efficacy or safety. There is no guarantee that such investigational agents will successfully complete clinical development or gain health authority approval.

[Notes to editors]

1. About lecanemab (generic name, brand name: Leqembi®)

Lecanemab is the result of a strategic research alliance between Eisai and BioArctic. It is a humanized immunoglobulin gamma (IgG1) monoclonal antibody directed against aggregated soluble (protofibril) and insoluble forms of amyloid-beta (Aβ). 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]

Lecanemab has been approved in 45 countries, including Japan, the United States, China, the European Union, South Korea, and Taiwan, and been under regulatory review in 11 countries. 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 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.

3. 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.

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.