Early Alzheimer's Patients Continue to Benefit from Four Years of LEQEMBI® (lecanemab-irmb) Therapy New Clinical Data Presented at AAIC

Data Showed LEQEMBI Slowed Clinical Decline by 1.75 Points on CDR-SB at Four Years Compared to the Natural History of Alzheimer's Disease

56% of Patients with Low Tau Continued to Demonstrate Improved Cognitive and Daily Living Function at Four Years

TOKYO and CAMBRIDGE, Mass., July 31, 2025 - Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") and Biogen Inc. (Nasdaq: BIIB, Headquarters: Cambridge, Massachusetts, CEO: Christopher A. Viehbacher, "Biogen") announced today that the latest findings demonstrating the benefits of continuous treatment with lecanemab-irmb (U.S. brand name: LEQEMBI®), an anti-amyloid beta (Aβ) protofibril* antibody for the treatment of early Alzheimer's disease (AD), were presented at the Alzheimer's Association International Conference (AAIC) 2025, held in Toronto, Canada, and virtually. Only lecanemab fights AD in two ways – targeting both amyloid plaque and protofibrils*, which can impact tau downstream.

Four Years of Lecanemab Therapy Helped Patients Slow the Progression of AD and Remain in the Early Stages of AD Longer Compared to AD's Natural Course

Clarity AD is a global Phase 3 placebo-controlled, double-blind, parallel-group, randomized study to evaluate lecanemab 10 mg/kg bi-weekly IV treatment of early Alzheimer's disease, which involved 1,795 patients (treatment group: 898, placebo group: 897). 95% of patients who completed the core study (18 months) chose to continue in the open-label extension study (OLE), with 478 patients still receiving treatment for four years. In the Clarity AD core study, the mean change from baseline between the lecanemab treated group and the placebo group after 18 months was -0.45 (P=0.00005) on the primary endpoint of CDR-SB global cognitive and functional scale.

To provide context, a change from 0.5 to 1 on the Clinical Dementia Rating (CDR) score domains of Memory, Community Affairs and Home/Hobbies reflects a shift from mild impairment to loss of independence. This can affect a person's ability to be left alone safely, recall recent events, participate in daily activities, manage household tasks, and engage in hobbies and intellectual interests.[1,2]

Over three years of treatment, including both the core study and the OLE, data showed lecanemab demonstrated a reduction in cognitive decline—measured by CDR-SB—of 1.01 points compared to the expected decline observed in the Alzheimer's Disease Neuroimaging Initiative (ADNI)** cohort. This benefit grew more pronounced after four years, with a reduction of 1.75 points. Similarly, when benchmarked against the expected decline in the BioFINDER*** cohort, lecanemab showed a reduction of 1.40 points at three years and an even greater reduction of 2.17 points at the four years mark.

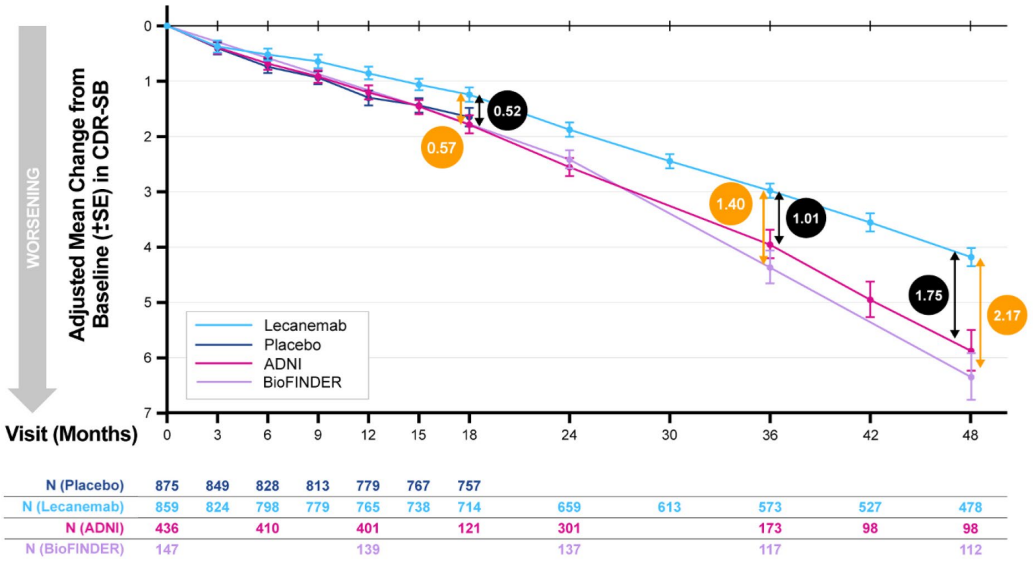

Figure 1. Changes in CDR-SB over 4 years of Lecanemab Administration

Consistent Safety Profile Observed over Four Years of Lecanemab Treatment

No new safety findings were observed in the OLE with continued lecanemab treatment over four years. Rates of amyloid-related imaging abnormalities (ARIA) decreased after the initial 12 months and remained consistent throughout four years of continuous treatment. As stated in the FDA product label, the incidence and timing of ARIA vary among treatments.[3]

More than 50% of Patients who Started Treatment in the Earlier Stages of AD Continued to Show Improvement in Clinical Scores After Four Years of Lecanemab Therapy

The Clarity AD study included an optional tau PET substudy and used the MK6240 tracer to identify patients with low levels of tau accumulation in the brain, an indicator of early-stage AD Among these patients, after four years of lecanemab treatment, 69% of these patients showed improvement or no decline, and 56% showed improvement from baseline on the CDR-SB. The benefit observed at 18 months was sustained through four years of treatment. On the ADAS-Cog14 scale, 51% of patients showed improvement or no decline, and 51% showed improvement. On the ADCS MCI-ADL scale, 64% of patients showed improvement or no decline, and 58% showed improvement. These findings suggest that initiating and maintaining treatment with lecanemab in early-stage AD may help slow clinical decline and may provide sustained benefits over the long term.

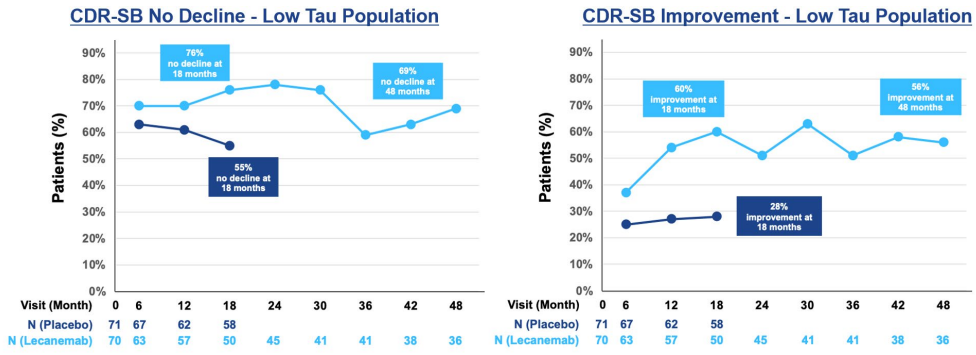

Figure 2. Changes in the proportion of low tau population showing "No Decline" or "Improvement" in CDR-SB

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

* Protofibrils are thought to be the most toxic Aβ species that contribute to brain damage in AD and play a major role in the cognitive decline of this progressive and devastating disease. Protofibrils can cause neuronal and synaptic damage in the brain, which can subsequently adversely affect cognitive function through multiple mechanisms.[4] The mechanism by which this occurs has been reported not only by increasing the formation of insoluble Aβ plaques, but also by directly damaging signaling between neurons and other cells. It is believed that reducing protofibrils may reduce neuronal damage and cognitive impairment, potentially preventing the progression of AD.[5]

**ADNI is a clinical research project launched in 2005 to develop methods to predict the onset and progression of AD and to confirm the effectiveness of treatments. The project involves a multi-year longitudinal observation targeting healthy elderly individuals as well as patients with mild cognitive impairment (MCI) and early stages of AD.

*** BioFINDER subjects are similar to Study 301 and ADNI subjects, except all BioFINDER subjects are in the MCI stage and no mild AD subjects are included, and their baseline CDR-SB is lower. BioFINDER is a large-scale, long-term prospective study led by Lund University in Sweden, aiming to establish early diagnosis and elucidate pathophysiology of neurodegenerative diseases. In addition to AD, the study also focuses on conditions including Parkinson's Disease. Individuals participating in the study undergo regular clinical assessments, cognitive function tests, brain imaging (MRI, Aβ PET, Tau PET), and collection of biomarkers from blood and cerebrospinal fluid (CSF).

MEDIA CONTACTS

Eisai Co., Ltd.
Public Relations Department
TEL: +81 (0)3-3817-5120

Biogen Inc.
Madeleine Shin
+1-781-464-3260
public.affairs@biogen.com

Eisai Europe, Ltd.
EMEA Communications Department
+44 (0) 797 487 9419
Emea-comms@eisai.net

Eisai Inc. (U.S.)
Libby Holman
+1-201-753-1945
Libby_Holman@Eisai.com

INVESTOR CONTACTS

Eisai Co., Ltd.
Investor Relations Department
TEL: +81 (0) 3-3817-5122

Biogen Inc.
Tim Power
+ 1-781-464-2442
IR@biogen.com

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.[4] 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.[5]

It is believed the reduction of protofibrils may prevent the progression of AD by reducing damage to neurons in the brain and cognitive dysfunction.

Lecanemab has been approved in 46 countries and is under regulatory review in 10 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 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.

4. About Eisai Co., Ltd.

Eisai's Corporate Concept is "to give first thought to patients and people in the daily living domain, and to increase the benefits that health care provides." Under this Concept (also known as *human health care* (*hhc*) Concept), we aim to effectively achieve social good in the form of relieving anxiety over health and reducing health disparities. With a global network of R&D facilities, manufacturing sites and marketing subsidiaries, we strive to create and deliver innovative products to target diseases with high unmet medical needs, with a particular focus in our strategic areas of Neurology and Oncology.

In addition, we demonstrate our commitment to the elimination of neglected tropical diseases (NTDs), which is a target (3.3) of the United Nations Sustainable Development Goals (SDGs), by working on various activities together with global partners.

For more information about Eisai, please visit www.eisai.com (for global headquarters: Eisai Co., Ltd.), and connect with us on X, LinkedIn and Facebook. The website and social media channels are intended for audiences outside of the UK and Europe. For audiences based in the UK and Europe, please visit www.eisai.eu and Eisai EMEA LinkedIn.

5. About Biogen

Founded in 1978, Biogen is a leading biotechnology company that pioneers innovative science to deliver new medicines to transform patient's lives and to create value for shareholders and our communities. We apply deep understanding of human biology and leverage different modalities to advance first-in-class treatments or therapies that deliver superior outcomes. Our approach is to take bold risks, balanced with return on investment to deliver long-term growth.

The company routinely posts information that may be important to investors on its website at www.biogen.com. Follow Biogen on social media – Facebook, LinkedIn, X, YouTube.

Biogen Safe Harbor

This news release contains forward-looking statements, including about the potential clinical effects of lecanemab; the potential benefits, safety and efficacy of lecanemab and continued treatment with lecanemab; potential regulatory discussions, submissions and approvals and the timing thereof; the treatment of Alzheimer's disease; the anticipated benefits, risks and potential of Biogen's collaboration arrangements with Eisai; the potential of Biogen's commercial business and pipeline programs, including lecanemab; and risks and uncertainties associated with drug development and commercialization. These forward-looking statements may be accompanied by such words as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “forecast,” “goal,” “guidance,” “hope,” “intend,” “may,” “objective,” “plan,” “possible,” “potential,” “predict,” “project,” “prospect,” “should,” “target,” “will,” “would,” and other words and terms of similar meaning. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements. Given their forward-looking nature, these statements involve substantial risks and uncertainties that may be based on inaccurate assumptions and could cause actual results to differ materially from those reflected in such statements.

These forward-looking statements are based on management's current beliefs and assumptions and on information currently available to management. Given their nature, we cannot assure that any outcome expressed in these forward-looking statements will be realized in whole or in part. We caution that these statements are subject to risks and uncertainties, many of which are outside of our control and could cause future events or results to be materially different from those stated or implied in this document, including, among others, uncertainty of long-term success in developing, licensing, or acquiring other product candidates or additional indications for existing products; expectations, plans and prospects relating to product approvals, approvals of additional indications for our existing products, sales, pricing, growth, reimbursement and launch of our marketed and pipeline products; our ability to effectively implement our corporate strategy; the successful execution of our strategic and growth initiatives, including acquisitions; the risks associated with third party collaborations; the risk that positive results in a clinical trial may not be replicated in subsequent or confirmatory trials or success in early stage clinical trials may not be predictive of results in later stage or large scale clinical trials or trials in other potential indications; risks associated with clinical trials, including our ability to adequately manage clinical activities, unexpected concerns that may arise from additional data or analysis obtained during clinical trials, regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates; the occurrence of adverse safety events, restrictions on use with our products, or product liability claims; and any other risks and uncertainties that are described in other reports we have filed with the U.S. Securities and Exchange Commission.

These statements speak only as of the date of this press release and are based on information and estimates available to us at this time. Should known or unknown risks or uncertainties materialize or should underlying assumptions prove inaccurate, actual results could vary materially from past results and those anticipated, estimated or projected. Investors are cautioned not to put undue reliance on forward-looking statements. A further list and description of risks, uncertainties and other matters can be found in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024 and in our subsequent reports on Form 10-Q and Form 10-K, in each case including in the sections thereof captioned “Note Regarding Forward-Looking Statements” and “Item 1A. Risk Factors,” and in our subsequent reports on Form 8-K. Except as required by law, we do not undertake any obligation to publicly update any forward-looking statements whether as a result of any new information, future events, changed circumstances or otherwise.

References

1. Cohen S., et al. *J Prev Alzheimers Dis*.2022;9(3):507-522.

2. Morris JC. *Neurology*. 1993;43(11):2412-4.
3. LEQEMBI (lecanemab-irmb) injection, for intravenous use [package insert]. Nutley, NJ: Eisai Inc.
4. 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
5. 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.