New Data Presented at AAIC Demonstrates Investigational LEQEMBI® (lecanemab-irmb) 360 mg Subcutaneous Maintenance Dosing Could Offer a New Option for Ongoing Treatment of Early Alzheimer's Disease

July 30, 2025

Lecanemab subcutaneous autoinjector has the potential to become a new expanded treatment option for patients with early Alzheimer's disease, their care partners and healthcare professionals, with results showing a comparable efficacy and safety profile to the intravenous formulation

TOKYO and CAMBRIDGE, Mass., July 30, 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 results on investigational maintenance therapy with subcutaneous autoinjector (SC-AI) of 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, and virtually. Only lecanemab fights AD in two ways— targeting both protofibrils and plaque, which can impact tau accumulation downstream.

Importance of Ongoing Treatment and SC Development Program

Due to the reaccumulation of AD biomarkers and return to placebo rate of decline after therapy is stopped[1], Eisai is investigating a new lecanemab SC maintenance treatment option following 18 months of IV therapy so patients can continue to fight this progressive, relentless disease.

Clinical trials of lecanemab SC were conducted as a sub-study of the open-label extension (OLE) following the core Phase 3 Clarity AD study in individuals with early AD, to evaluate a range of doses administered by SC vial or autoinjector. Eisai has developed a SC-AI for maintenance therapy at a dose of 360 mg weekly and a 500 mg SC-AI is being developed for initiation dosing.

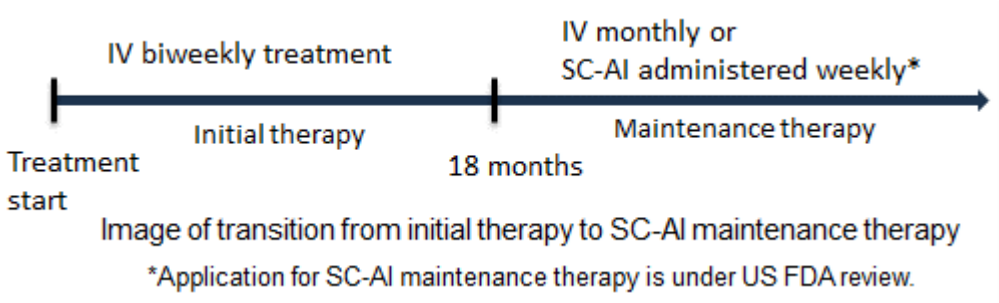


Image of transition from initial therapy to SC-AI maintenance therapy

*Application for SC-AI maintenance therapy is under US FDA review.

Similar Impact on Clinical Outcomes and Biomarkers with IV and SC Dosing

The pharmacology (PK/PD), clinical (efficacy endpoints such as CDR-SB) and biomarker (amyloid PET and blood biomarkers) relationships established with extensive clinical data supported the FDA approval of IV maintenance therapy after the initial 18 months of treatment and support the investigational SC maintenance dose option.

- Data supports that transitioning to a weekly 360 mg SC AI dose of lecanemab after 18 months of initiation dose (10 mg/kg IV biweekly) maintains clinical and biomarker benefits comparable to continued biweekly IV dosing.
- Clinical and biomarker responses at 48 months with monthly IV maintenance dosing are similar to the responses with ongoing biweekly dosing whether patients are amyloid positive (>30 CL) or negative (<30 CL) at 18 months.
- Data shows the 500 mg SC AI has equivalent exposure as the initial treatment regimen of 10 mg/kg IV biweekly up to 18 months for amyloid removal, efficacy, and ARIA-E.

Safety Matters

The safety profile of 360 mg weekly SC maintenance dosing was shown to be consistent with that of IV maintenance therapy, with <1% systemic injection/infusion reactions. Across all SC doses, the rate of systemic injection/infusion reactions is 1% compared to 26% with IV. The 360 mg SC maintenance dose was initiated after 18 months of IV treatment, beyond the high-risk period for ARIA. There were 0 cases of ARIA-E observed out of 49 treated with 360 mg SC weekly maintenance for a mean of 6 months.

Study Participants Successfully Administered SC-AI and Found it Easy to Use

To optimize the safe and effective use of SC autoinjector (SC-AI), additional studies were conducted, including a human factors (HF) study and a tolerability assessment of the device.

The HF Study involved 110 participants (63 early AD patients, 32 care partners, and 15 healthcare professionals: HCPs) to assess the appropriate administration of lecanemab SC-AI. Overall, 95% (104/110) of participants successfully administered the maintenance dose.

The Autoinjector Device Acceptability Study involved 126 participants (25 early AD patients, 50 care partners, and 51 HCPs), to evaluate the device's ease of use, convenience and feasibility of administration. As an interim outcome, over 95% of participants reported that the SC-AI is easy to administer. They were highly satisfied with it and had no concerns about administration, even at home. Furthermore, all patients responded that they welcomed the introduction of SC-AI.

These studies and evaluations of lecanemab SC-AI have demonstrated that the investigational SC-AI offers efficacy and safety comparable to IV administration with the potential to reduce the incidence of infusion site adverse events. From the perspective of patients and care partners, benefits included the ability to use the device at home, shortening treatment time, and to continue treatment without having to worry about visiting an infusion center. From the perspective of HCPs, they reported that the device has the potential to provide a new option for patients who are benefiting from lecanemab to continue the treatment. The SC formulation has the potential to reduce medical preparation and administration time related to IV therapy. These factors suggest that the SC AI may play an important role in continuing treatment for early AD.

This release is based on the content of the presentations given at AAIC, "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," held at 9:00 AM on Wednesday, July 30, and also includes some content from the Developing Topics session held at 8:00 AM on Sunday, July 27, entitled "Patient, Care Partner, and Health Care Professional Opinion of the Lecanemab Autoinjector for Subcutaneous Delivery in Early Alzheimer's Disease Patients."

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.[1] 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. [2]

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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.[2] 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 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 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; potential regulatory discussions, submissions and approvals and the timing thereof; the treatment of Alzheimer's disease; the anticipated benefits 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 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. 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.