



LEQEMBI® Real-World LEADER Study Presented at AAIC® 2026 Finds Over 75% of Early Alzheimer's Patients Enrolled in the Study Remained Stable and Nearly 7% Improved Over an Average of 17 Months of Treatment

July 14, 2026

Real-World Findings Support Long-Term Benefits of Continuous Treatment with LEQEMBI and Provide Important Insights into Treatment Experience Outside of a Clinical Trial Setting

TOKYO and CAMBRIDGE, Mass., July 14, 2026 (GLOBE NEWSWIRE) -- Eisai Co., Ltd. and Biogen Inc. (Nasdaq: BIIB) announced today that results from the real-world Lecanemab in Early Alzheimer's Disease (LEADER) Study show that nearly 83% of early Alzheimer's disease (AD) patients enrolled in the study remained stable (75.9%) or improved (6.6%) while receiving LEQEMBI® therapy over an average of 17 months. The results were consistent across sex, race, ethnicity and APOE genotype. The data was presented during the "Developing Topics Session #3-33-DEV-A: Lecanemab Three Years Post-Approval: A Comprehensive Multicenter, Real-World, Retrospective Study (LEADER) in Diverse US Clinical Settings" at the Alzheimer's Association International Conference® (AAIC®) 2026 in London and online.

AD is a chronic, progressive disease that requires ongoing treatment. LEQEMBI targets the underlying pathology of the disease and works in two ways throughout treatment - by removing insoluble (plaque) and soluble amyloid beta (protofibrils), helping to slow cognitive decline and loss of daily functioning. Data show continued treatment with LEQEMBI may be able to help keep patients in early AD for longer. Early AD includes mild cognitive impairment (MCI) due to AD and mild AD dementia.

LEADER Study Design

The three-year LEADER Study is a multicenter, retrospective real-world study designed to examine LEQEMBI utilization, treatment persistence, transition to maintenance therapy, safety, cognitive and functional assessments, and healthcare professional (HCP) implementation learnings in diverse U.S. clinical settings for patients with early Alzheimer's disease (AD). The study integrated deidentified chart and electronic medical record (EMR) data from 13 U.S. sites, HCP surveys and HCP interviews. This interim analysis included 432 patients with early AD who received at least seven LEQEMBI infusions as of May 2026.

Patient Characteristics at Baseline

- Mean age: 74 years
- Female Patients: 55.8%

Disease Stage at Baseline

- Mild cognitive impairment (MCI) due to AD: 63.9%
- Mild AD dementia: 36.1%.

Treatment

- The mean duration of LEQEMBI treatment was 520 days.
- The mean number of LEQEMBI doses was 26.
- Change in disease stage was defined as:
 - Stable: Patient remaining in the same disease stage (MCI due to AD or mild AD dementia) from baseline throughout the course of LEQEMBI treatment.
 - Improvement: Patient transitioning from mild AD dementia at baseline to MCI due to AD over the course of LEQEMBI treatment.
 - Progression: Patient advancing from MCI at baseline to mild/moderate AD dementia or from mild AD dementia at baseline to moderate AD dementia throughout the course of LEQEMBI treatment.

LEADER Study Key Findings

Real-World Evidence Shows Long-Term Benefit with Continuous LEQEMBI Treatment Across Sex, Race, Ethnicity and APOE Genotype

Overall Study Population Findings

- Of the 432 participants enrolled in the LEADER Study, disease stage could be evaluated in 427. Among these patients with early Alzheimer's disease, 82.5% remained stable or improved while receiving LEQEMBI, with consistent results across sex, race, ethnicity, and APOE genotype groups.
- 75.9% remained stable compared with baseline, meaning they remained in the same disease stage throughout treatment.
- 6.6% improved from baseline, moving from mild AD dementia to MCI due to AD.
- Nearly 87% of patients chose to remain on LEQEMBI treatment.
- In analyses by APOE $\epsilon 4$ status, clinician-evaluated stable or improved disease stage was observed in:
 - 81.7% of APOE $\epsilon 4$ heterozygotes (stable: 73.8%; improved: 7.9%)
 - 81.0% of APOE $\epsilon 4$ homozygotes (stable: 75.9%; improved: 5.2%).

Maintenance Dosing Population Findings

- Of the 432 participants in the LEADER Study, 155 transitioned to once-every-four-weeks intravenous (IV) maintenance treatment, and 14 transitioned to once-weekly subcutaneous (SC) maintenance treatment.
- Among the 155 participants who transitioned to IV maintenance therapy, nearly 81% remained stable (72.3%) or improved (8.4%).
- Of the 14 patients who transitioned to SC maintenance treatment, 12 (85.7%) maintained their disease stage.

Real-World Safety Consistent with U.S. FDA-Approved Label

Overall safety observations in this real-world study were consistent with the U.S. FDA-approved label.

- ARIA (amyloid-related imaging abnormalities)* was observed in 12.3% of patients overall; ARIA-E was observed in 6.3% and ARIA-H in 7.9% and isolated ARIA-H in 6.0%. Most ARIA cases were asymptomatic and mild in radiographic severity.
- No new ARIA-E events, macrohemorrhages or intracerebral hemorrhages greater than 1 cm were reported during once-every-four-weeks IV maintenance therapy.

APOE ϵ 4 status safety observations were consistent with the overall cohort and the U.S. FDA-approved label.

- ARIA-E was observed in 5.3% of APOE ϵ 4 noncarriers, 6.1% of APOE ϵ 4 heterozygotes and 10.3% of APOE ϵ 4 homozygotes.
- ARIA-H was observed in 12.1%, 4.8% and 12.1%, respectively.
- In APOE ϵ 4 homozygotes, no severe ARIA was reported, and all graded ARIA cases were mild to moderate in radiographic severity.

Antithrombotic therapy, including anticoagulants or antiplatelet medications, was used by 106 patients, representing 24.5% of the study population.

- Of these, 11 patients were receiving an anticoagulant, either alone or with an antiplatelet medication, and 95 patients were receiving antiplatelet therapy only.
- Among patients receiving antithrombotic therapy, the incidence of ARIA was not meaningfully different from that observed in patients not receiving antithrombotic therapy.

* ARIA refers to amyloid-related imaging abnormalities that can be observed with anti-amyloid beta antibody treatment and includes ARIA-E, which involves edema/effusion, and ARIA-H, which involves hemosiderin deposition, including cerebral microhemorrhage, cerebral macrohemorrhage and superficial siderosis, as observed on brain magnetic resonance imaging (MRI).

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

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Notes to Editors

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 (A β).

Lecanemab has been approved in 53 countries and regions including Japan, the United States, China, Europe, South Korea, Taiwan, and Saudi Arabia, and is under regulatory review in 6 countries. Following the initial phase with treatment every two weeks for 18 months, intravenous (IV) maintenance dosing with treatment every four weeks was approved in 8 countries including the U.S., China, the UK, and others, and applications have been filed in 12 countries and regions. The U.S. FDA approved LEQEMBI IQLIK, the subcutaneous autoinjector formulation of lecanemab, for use as maintenance treatment in August 2025 and as initiation treatment on July 13, 2026. In November 2025, an application for a subcutaneous injectable formulation in Japan was submitted. In January 2026, the Biologics License Application (BLA) for the subcutaneous formulation was accepted in China. Since December 2025, lecanemab (IV) has been included in the "Commercial Insurance Innovative Drug List", recently introduced by the National Healthcare Security Administration (NHSA) of China.

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.

About Protofibrils

Protofibrils are thought to be the most toxic A β 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 A β 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

Limitations of Real-World Studies

Retrospective real-world studies can be valuable in providing additional information to complement clinical trial data; however, there are potential limitations to consider, including: potential for biases, data completeness and consistency, lack of a control group, interpretation of data due to lack of placebo-controlled arms, and confounding variables, and data inconsistency. Data inconsistency may be mitigated by providing site access to standardized electronic case-report forms.

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.

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.

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](#).

About Biogen

Founded in 1978, Biogen is a leading biotechnology company that pioneers innovative science to deliver new medicines to transform patients' 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 including for lecanemab-irmb (LEQEMBI IQLIK); 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, which are available on the SEC's website at www.sec.gov.

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, 2025 and in our subsequent reports on Form 10-Q. 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.

Digital Media Disclosure

From time to time, we have used, or expect in the future to use, our investor relations website (investors.biogen.com), the Biogen LinkedIn account ([linkedin.com/company/biogen-](https://www.linkedin.com/company/biogen/)) and the Biogen X account (<https://x.com/biogen>) as a means of disclosing information to the public in a broad, non-exclusionary manner, including for purposes of the SEC's Regulation Fair Disclosure (Reg FD). Accordingly, investors should monitor our investor relations website and these social media channels in addition to our press releases, SEC filings, public conference calls and websites, as the information posted on them could be material to investors.

References

1. Amin L, Harris DA. A β 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.