New Three-Year Real-World LEQEMBI® Data Presented at CTAD 2026

November 18, 2026

Largest analysis of LEQEMBI LEADER study reported to date includes findings on amyloid clearance in routine clinical practice, delayed progression to moderate or severe AD, expanded subcutaneous maintenance experience, and additional sex-based outcomes

TOKYO and CAMBRIDGE, Mass., Nov. 18, 2026 (GLOBE NEWSWIRE) -- Eisai Co., Ltd. and Biogen Inc. (Nasdaq: BIIB) today announced new three-year real-world findings of 560 patients across 13 U.S. clinical sites from the largest analysis of the ongoing Lecanemab in Early Alzheimer's Disease (LEADER) study* reported to date. New LEADER findings from a pre-specified analysis show a 76% lower rate of progression to moderate or severe Alzheimer's disease dementia with LEQEMBI ® compared to a matched natural history cohort. The data were presented alongside an additional international real-world meta-analysis of approximately 5,000 patients at the 19th Clinical Trials on Alzheimer's Disease (CTAD) Conference in Boston.

"As Alzheimer's disease progresses, patients and families can experience increasing challenges that affect cognition and function," said Brent Berry, M.D., Ph.D., Minneapolis Clinic of Neurology. "The LEADER study is helping us understand how the benefits of continued LEQEMBI treatment seen in the Clarity AD clinical trial carry over into routine clinical practice. These real-world findings from sites across the U.S. suggest that continued treatment with LEQEMBI may help keep patients in the early stages of Alzheimer's disease for longer. They also add to our understanding of treatment persistence, subcutaneous maintenance therapy and safety across diverse clinical settings, which can help inform treatment decisions with patients and families."

Key Findings from the LEADER Study

LEADER Patients Showed Slower Progression Compared to ADNI Control**

- In a pre-specified comparison of LEADER (N=504) and an ADNI-weighted external control cohort (N=573) through 36 months, LEQEMBI patients in the study had a 76% lower rate of progression to moderate or severe AD dementia (HR 0.24; 95% CI, 0.15-0.39).

More Than 8 in 10 Patients Remained Stable or Improved***

- Among the 546 people with early AD whose change in disease stage could be assessed after an average of approximately 18 months of treatment, 81.1% of patients were reported as stable (75.8%) or improved (5.3%) compared with baseline.
- Results were generally consistent across groups defined by sex, race, ethnicity, APOE genotype and concomitant antithrombotic-use groups.
- Among all 560 patients, 87.5% remained on LEQEMBI treatment at the time of chart extraction, with an average treatment duration of approximately 19 months.

Most Patients Estimated to Remain in Early AD Through Three Years

- Among all 560 patients receiving LEQEMBI in the overall study, 95.0% were estimated to remain in the early stages of AD through three years (36 months) of treatment, based on statistical modeling of observed real-world patient data.

New Real-World Evidence Shows Complete Amyloid Clearance

- At sites performing both baseline and follow up amyloid PET data, 77% of patients (N=33 of 43 across 6 sites) became amyloid-negative at a median follow up of 18.1 months (IQR 16.4–18.7 months).

Expanding Experience with LEQEMBI Maintenance Therapy

- Of the patients who reached 18 months of treatment, 91.7% remained on LEQEMBI treatment. A total of 218 patients transitioned to once-every-four-weeks intravenous (IV) maintenance therapy and, following its subsequent approval, 64 patients transitioned to once-weekly subcutaneous (SC) maintenance therapy.
- 71.1% of patients on monthly IV maintenance treatment and 76.6% on weekly SC maintenance treatment remained stable after an average of 26 months and 25.1 months following treatment initiation, respectively.
- All 64 patients receiving SC maintenance therapy remained on therapy at the time of chart extraction.
- No ARIA**** events were reported during the subcutaneous maintenance period and there were no other safety events of significance. There was a 0.5% incidence of isolated ARIA-H reported during the IV maintenance period.

Clinical Outcomes Consistent Between Women and Men

- 79.3% of women (N=300) and 83.3% of men (N=246) in the study were reported as stable or improved.***

- Treatment duration and persistence were similar across sexes, with 86.0% of females and 88.9% of males remaining on therapy at time of chart extraction.
- ARIA incidence and severity were generally consistent between female and male patients: any ARIA (14.7% females vs. 17.0% males), ARIA-E (7.5% females vs. 5.5% males), ARIA-H (9.8% females vs. 12.6% males), isolated ARIA-H (7.2% females vs. 11.5% males).

LEADER Safety Findings Consistent with ALZ-NET Real-World Experience
Overall safety findings in LEADER were consistent with the independent ALZ-NET registry and U.S. prescribing information for LEQEMBI.

- ALZ-NET is a North American voluntary health care provider-enrolled patient network that collects longitudinal clinical, imaging, and safety data in patients treated with FDA-approved AD therapies. Over 1,700 patients taking LEQEMBI were included in ALZ-NET at the time of data extraction.
- ARIA-E was observed in 6.6% of patients in LEADER, compared with 6.3% in ALZ-NET, while ARIA-H was observed in 11.1% of patients in LEADER, compared with 10.1% of patients in ALZ-NET.
- Observed ARIA rates were generally consistent regardless of APOE ε4 status, concomitant antithrombotic use, race and ethnicity.

Additional International Real-World Meta-Analysis Evaluates Approximately 5,000 Patients***
A separate post hoc-exploratory analysis presented at CTAD evaluated 16 published real-world LEQEMBI cohorts across six countries, representing approximately 5,000 patients treated in routine clinical practice.

Key findings include:

- Rates of ARIA were lower than those reported in Clarity AD. Across the 16 real-world studies, the pooled average total ARIA rate was 12.4% compared to 21.5% in Clarity AD, ARIA-E rate was 4.0% compared to 12.6% in Clarity AD, and the ARIA-H rate was 9.4% compared to 17.3% in Clarity AD.
- Symptomatic ARIA was 0.8% compared to 2.8% in Clarity AD.
- Treatment discontinuation due to adverse events was 3.2%.

*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 AD. The study integrated deidentified chart and electronic medical record (EMR) data from 13 U.S. sites, HCP surveys and HCP interviews. This updated analysis included 560 patients with early AD who, as of September 2026, received at least seven LEQEMBI initiation infusions. The maintenance therapy analysis included patients who received biweekly IV initiation treatment for 18 months, followed by at least three months of IV or SC maintenance therapy.

**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.

***Change in clinical disease stage was defined as:

- Stable: Patient remaining in the same clinical 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.

****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).

*****The meta-analysis on ARIA rates and safety profiles in clinical practice included centers located in the U.S., China, South Korea, Japan, Italy and Israel. Patients were treated between 2023 and 2026 and received at least six months of LEQEMBI treatment

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

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).

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 9 countries including the U.S., China, the UK, and others, and applications have been filed in 11 countries and regions. The U.S. FDA approved Eisai's Biologics License Application (BLA) for subcutaneous maintenance dosing (360mg) with LEQEMBI IQLIK in August 2025. For subcutaneous initiation treatment (500 mg), approval was obtained in the U.S. in July 2026 and China and Japan in September 2026, and applications are under review in 4 countries.

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 Protofibrils**

Protofibrils are believed to contribute to the brain injury that occurs with AD and are considered to be the most toxic form of soluble 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]

3. **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.

4. **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.

5. **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.

6. **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.

7. **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 those about the potential clinical effects of LEQEMBI (lecanemab); the potential benefits, safety and efficacy of LEQEMBI; the potential for LEQEMBI to slow clinical decline and provide sustained long-term benefit; 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, 2025 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.

Digital Media Disclosure
We use, and expect in the future to use, our investor relations website (investors.biogen.com), the Biogen LinkedIn account (linkedin.com/company/biogen-) and the Biogen X account (https://x.com/biogen) as a means of disclosing material nonpublic 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

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