New Five-Year Lecanemab Data from Clarity AD Study Long-Term Extension Presented at CTAD 2026

November 16, 2026

Benefits of continuous lecanemab treatment in early Alzheimer's disease accrue over time

Lecanemab reduced the relative risk of progression to the next stage of disease by 36% vs. ADNI

62% of patients with low tau showed improvement in cognitive function and activities of daily living (CDR-SB) at five years

TOKYO and CAMBRIDGE, Mass., Nov. 16, 2026 (GLOBE NEWSWIRE) -- Eisai Co., Ltd. and Biogen Inc. (Nasdaq: BIIB) 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, were presented at the 19th Clinical Trials on Alzheimer's Disease (CTAD) conference, being held in Boston and online.

Figure 1

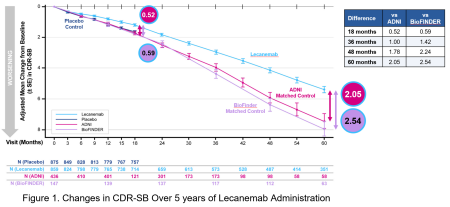


Figure 1. Changes in CDR-SB Over 5 years of Lecanemab Administration

Changes in CDR-SB Over 5 years of Lecanemab Administration

Figure 2

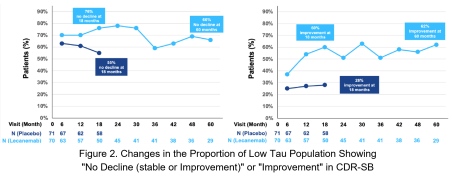


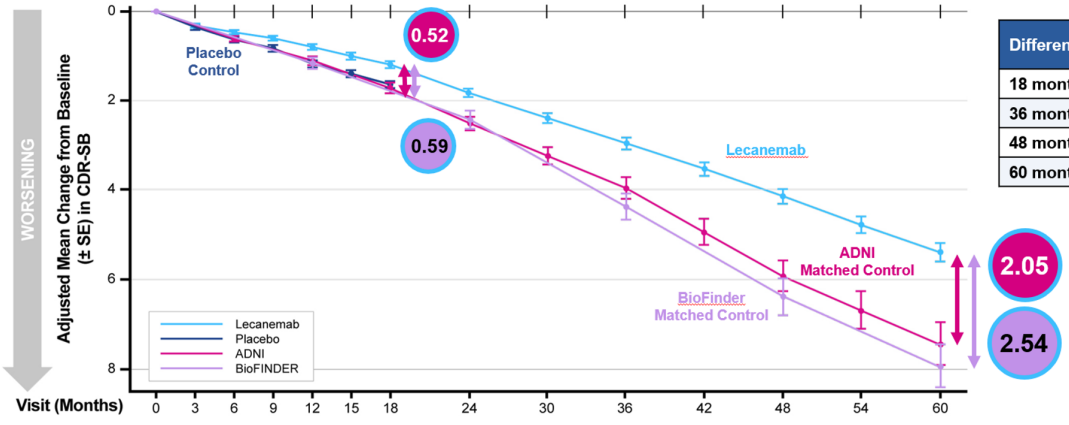
Figure 2. Changes in the Proportion of Low Tau Population Showing "No Decline (stable or Improvement)" or "Improvement" in CDR-SB

Changes in the Proportion of Low Tau Population Showing "No Decline (stable or Improvement)" or "Improvement" in CDR-SB.

Five Years of Continuous Lecanemab Treatment Extended the Time Patients Remained in the Early Stages of AD Compared with the Natural History of AD, with Benefit Continuing to Accrue Over Time

Clarity AD is a global Phase 3, placebo-controlled, double-blind, parallel-group, randomized study involving 1,795 patients with early Alzheimer's disease (AD) (898 in the lecanemab group, treated with 10 mg/kg by intravenous infusion every two weeks; and 897 in the placebo group). Of the patients who completed the 18-month core study, 95% chose to participate in the long-term extension (LTE) study that followed the core study, and 351 patients received five years of continuous treatment.

Among patients who received five years of continuous treatment through the core study and LTE, the difference in mean change from baseline in CDR-SB compared with the decline in AD based on data from the Alzheimer's Disease Neuroimaging Initiative (ADNI)* was −1.00 points at three years, −1.78 points at four years and −2.05 points at five years, with the benefit continuing to accrue over time. Compared with the decline in AD based on BioFINDER** data, the difference was −1.42 points at three years, −2.24 points at four years, and −2.54 points at five years, with the benefit continuing to accrue over time (Figure 1). In an assessment based on CDR-SB scores,*** lecanemab reduced the relative risk of progressing to the next stage of disease by 36% relative to ADNI; 61.9% of patients in the lecanemab group progressed from mild cognitive impairment (MCI) to mild AD dementia or from mild AD dementia to moderate dementia by five years, compared with 77.5% in the ADNI data. Similarly, lecanemab reduced the relative risk of progression from early AD to moderate or severe AD by 49% relative to ADNI; 31% of patients in the lecanemab group progressed to moderate or severe AD dementia, compared with 48.7% in the ADNI data.



Difference	vs ADNI	vs BioFINDER
18 months	0.52	0.59
36 months	1.00	1.42
48 months	1.78	2.24
60 months	2.05	2.54

Figure 1. Changes in CDR-SB Over 5 years of Lecanemab Administration

More than 60% of Patients Who Started Lecanemab Treatment in the Earlier Stages of AD (Low Tau) Showed No Decline and Improvement in Clinical Scores (CDR-SB) at Five Years

The Clarity AD study included an optional tau PET substudy to identify patients with low levels of tau accumulation in the brain ("low tau"). As tau

accumulates in the brain, cognitive and daily living function declines; therefore, patients with low tau are considered to be at an earlier stage of AD.

After five years of lecanemab treatment, 66% of patients with low tau showed no decline (stable or Improvement) on the CDR-SB, and 62% showed improvement, indicating that many patients continued to benefit through 60 months (Figure 2). On the ADAS-Cog14, a scale that primarily assesses cognition, 55% of patients showed no decline (stable or Improvement) and 52% showed improvement. On the ADCS MCI-ADL, a scale that assesses activities of daily living, 69% of patients showed no decline (stable or Improvement) and 62% showed improvement. These findings suggest that initiating and continuing lecanemab treatment in the earlier biological stages of early AD may help slow clinical decline and provide sustained long-term benefit.

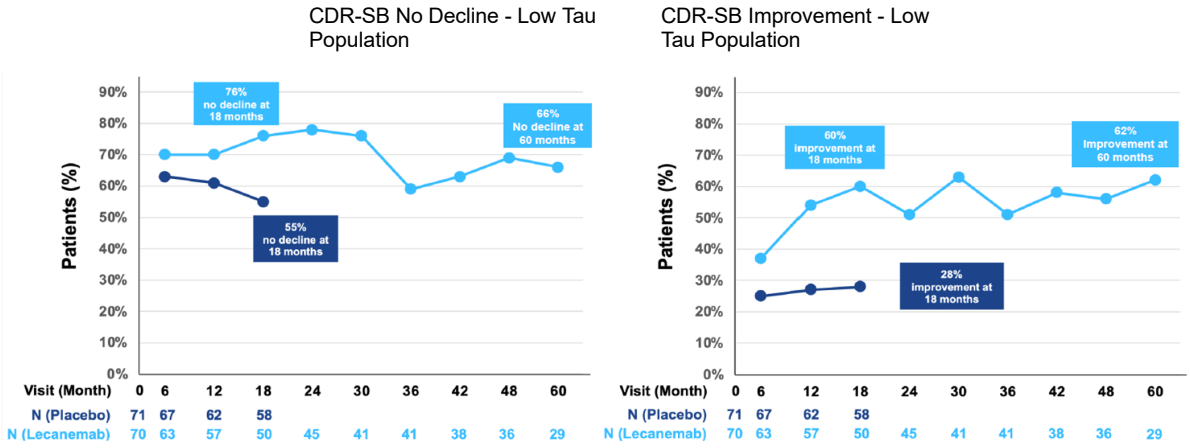


Figure 2. Changes in the Proportion of Low Tau Population Showing "No Decline (stable or Improvement)" or "Improvement" in CDR-SB

Consistent Safety Profile Observed Over Five Years of Lecanemab Treatment
No new safety findings were observed during five years of continuous lecanemab treatment. Amyloid-related imaging abnormalities with edema/effusion (ARIA-E) occurred most frequently within the first six months of treatment. When results were grouped into 12-month treatment intervals, the incidence of ARIA-E was 13.5% during the first 12 months, followed by 3.6%, 1.1%, 1.3%, and 0.6% in subsequent intervals compared with 1.7% in the placebo group over 18 months.

AD is a progressive, relentless disease with Aβ and tau as hallmarks that is caused by a continuous underlying neurotoxic process driven by protofibrils that begins before amyloid plaque accumulation and continues after plaque removal.[1,2,3] Only LEQEMBI fights AD in two ways – targeting both protofibrils and amyloid plaque.

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.

* 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).

*** Disease-stage progression was assessed using CDR-SB rather than the global CDR to capture changes in disease stage in greater detail, because assessments were conducted at relatively long intervals and control-group data were used to impute missing values. Based on CDR-SB scores, progression was defined as a transition from MCI (0.5–4.0) to mild AD dementia (4.5–9.0) or moderate AD dementia (9.5–15.5). Progression to moderate or severe dementia was defined as a transition to moderate dementia (9.5–15.5) or severe dementia (16.0–18.0), based on the CDR-SB staging criteria.

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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. **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.

4. **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.

5. **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 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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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.
3. Hampel H, Hardy J, Blennow K, et al. The amyloid pathway in Alzheimer's disease. *Mol Psychiatry.* 2021;26(10):5481-5503.

Photos accompanying this announcement are available at:
https://www.globenewswire.com/NewsRoom/AttachmentNg/b284d23e-1e93-464c-97d9-ce18abfe3e25
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