LEQEMBI® Subcutaneous Autoinjector Clinical Data Supports Similar Efficacy and Safety to IV Formulation in Early Alzheimer's Disease Presented at the Alzheimer's Association International Conference® (AAIC®) 2026

New clinical and real-world data support a subcutaneous treatment pathway from initiation through maintenance treatment, offering dosing convenience for patients and care partners

TOKYO and CAMBRIDGE, Mass., July 13, 2026 – Eisai Co., Ltd. and Biogen Inc. (Nasdaq: BIIB) announced today that new data presented at the Alzheimer's Association International Conference® (AAIC®) 2026 in London support that the LEQEMBI® (lecanemab) subcutaneous autoinjector (SC-AI) formulation offers efficacy and safety comparable to intravenous (IV) administration for people with early Alzheimer's disease (AD). The data was featured during the "Lecanemab Subcutaneous Formulation in Early Alzheimer's Disease: Emerging Clinical Evidence and Practical Use Considerations" Developing Topics Session #1-32-FRS-C.

AD is a chronic, progressive disease that requires ongoing treatment. LEQEMBI is an early AD treatment that targets the underlying pathology of the disease, helping to slow cognitive decline and loss of daily functioning. The lecanemab subcutaneous auto-injector (SC-AI) was developed to provide a more convenient alternative to intravenous (IV) dosing from the initiation of treatment.

Key Findings

This session presented data from the lecanemab SC-AI development program in early Alzheimer's disease, including pharmacokinetic (PK), pharmacodynamic (PD), efficacy, safety and real-world patient and care partner experience findings. Results showed that once-weekly 500 mg SC-AI achieved drug exposure similar to the approved intravenous (IV) initiation regimen (10 mg/kg every two weeks), supporting the expectation of similar clinical efficacy and safety, independent of the route of administration.

The subcutaneous dosing option may offer a convenient at-home alternative to IV infusion which could support access and delivery of care across healthcare settings.

Data Showed

- Bioequivalence Achieved: Once-weekly 500 mg SC-AI demonstrated bioequivalence to the IV initiation regimen (10 mg/kg every two weeks), with an exposure ratio of 104% (90% confidence interval [CI]: 99.1%–109%). Exposure remained consistent across body weight quartiles, demonstrating a stable pharmacokinetic profile in a broad patient population.
- Efficacy Driven by Exposure, Not Route of Administration: Amyloid removal measured by amyloid PET, clinical efficacy measured by CDR-SB, and the incidence of ARIA-E were driven by lecanemab exposure rather than route of administration. The 500 mg SC-AI initiation regimen achieved exposure comparable to the IV initiation regimen, supporting the expectation of a comparable efficacy and safety profile despite the different route of administration.
- Consistent Results Across Patient Populations: The 500 mg SC-AI initiation regimen demonstrated consistent exposure, amyloid clearance as measured by amyloid PET, clinical efficacy and safety across body weight groups. In addition, amyloid clearance and clinical outcomes were not meaningfully affected by body weight, supporting the appropriateness of a fixed-dose regimen.
- Flexible switching between IV and SC administration: Patients may also switch from IV to SC administration, or vice versa, and if a dose is missed patients can take it the next day or up to day six providing greater convenience and flexibility in LEQEMBI administration.

Safety Profile Aligned of SC LEQEMBI

- Overall safety profile of SC-AI was generally consistent with that observed for the IV formulation.
- Incidence of ARIA-E with the 500 mg SC-AI initiation regimen was predicted to be similar to that observed with the IV initiation regimen.

- Injection-related reactions were observed with subcutaneous LEQEMBI, most of which were localized, while systemic reactions were less frequently observed.
- The incidence of anti-drug antibodies (ADA) was low, at 1.4% in the 500 mg SC-AI group. No neutralizing antibodies were observed, confirming that the low immunogenicity profile was maintained with the SC-AI formulation.

Clinical Trial Perspectives and Real-World Evidence: Sustained Clinical Benefit with SC-AI

- Data from two U.S. Alzheimer's treatment centers (Alzheimer's Research and Treatment Center, and First Choice Neurology and Visionary Investigators Network) provide early insight into clinical trial and real-world use of subcutaneous LEQEMBI:
    - At Alzheimer's Research and Treatment Center, 28 patients receiving SC administration demonstrated slower cognitive decline as measured by CDR-SB over 36 months relative to a matched Alzheimer's Disease Neuroimaging Initiative (ADNI) natural history cohort. The cohort included 25 patients newly initiated on SC administration and 3 patients who transitioned from IV administration.
    - In a separate case series from First Choice Neurology and Visionary Investigators Network, 10 of 11 evaluable patients (91%) showed improvement or remained stable on MMSE compared with baseline before maintenance therapy. At this center, patients who had received maintenance therapy with SC administration for at least 6 months were included in the analysis.
    - Patient and care partner surveys in these two sites demonstrated high satisfaction with subcutaneous LEQEMBI administration, with satisfaction rates ranging from 75% to 97%, convenience ratings from 83% to 97%, and willingness to recommend treatment ranging from 92% to 100%.

  Results presented in this session further reinforce the importance of early and continuous treatment, highlighting how LEQEMBI SC initiation and maintenance administration provides greater optionality for long-term disease management.

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 (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 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 Eisai's Biologics License Application (BLA) for subcutaneous maintenance dosing with LEQEMBI IQLIK in August 2025. A Supplemental Biologics License Application (sBLA) for initiation treatment was accepted in January 2026 and granted Priority Review. The sBLA has been assigned an extended Prescription Drug User Fee Act (PDUFA) action date of August 24, 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. In 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 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]

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.

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 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 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-) 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

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