



Eisai Submits New Drug Application for Subcutaneous Formulation of “LEQEMBI®” for the Treatment of Early Alzheimer’s Disease in Japan

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If approved, lecanemab would be the first and only anti-amyloid treatment in Japan to offer an at-home injection from the initiation of treatment for this progressive, relentless disease

TOKYO and CAMBRIDGE, Mass., Nov. 27, 2025 (GLOBE NEWSWIRE) -- Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, “Eisai”) and Biogen Inc. (Nasdaq: BIIB, Corporate headquarters: Cambridge, Massachusetts, CEO: Christopher A. Viehbacher, “Biogen”) announced today that Eisai has filed a new drug application for “LEQEMBI®” (brand name, generic name: lecanemab) seeking approval for a subcutaneous formulation (subcutaneous autoinjector: SC-AI) as a new route of administration to Japan’s Pharmaceuticals and Medical Devices Agency (PMDA).

The application is based on data from multiple subcutaneous (SC) administration sub-studies of lecanemab conducted as part of the Phase 3 Clarity AD open-label extension (OLE), following the 18-month core study in individuals with Mild Cognitive Impairment (MCI) due to Alzheimer’s disease (AD) or mild stage of AD dementia (collectively referred to as early AD). It was confirmed that the once-weekly administration of SC-AI 500mg resulted in equivalent exposure to once every two weeks intravenous (IV) administration and similar clinical and biomarker benefits. Subcutaneous administration demonstrated a safety profile similar to IV administration, with less than 2% incidence of systemic injection/infusion-related reactions.

If approved, the SC-AI of 500 mg (two 250 mg injections) could be used to administer a once-weekly dose at home from the initiation of treatment, as an alternative to the current IV administration every two weeks dose in the hospital setting. The potential approval of SC-AI would expand the option for patients and care partners to receive LEQEMBI treatment at home. The injection time for each autoinjector (250mg injection) is approximately 15 seconds. The SC formulation also has the potential to reduce healthcare resources associated with IV dosing, such as preparation for infusion and nurse monitoring, while streamlining the overall AD treatment care pathway.

AD is a progressive, relentless disease with amyloid beta (A β) 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, which can impact tau downstream.

LEQEMBI is currently approved in 51 countries and regions and is under regulatory review in 9 countries.

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.

*Protofibrils are believed to contribute to the brain injury that occurs with AD and are considered to be the most toxic form of A β , 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 A β 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

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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 (A β).

Lecanemab has been approved in 51 countries and regions including Japan, the United States, Europe, China, South Korea, Taiwan, and Saudi Arabia, and is under regulatory review in 9 countries. Leqembi received manufacturing and marketing approval in Japan on September, 2023 for the indication of a treatment for slowing progression of mild cognitive impairment (MCI) and mild dementia due to Alzheimer's disease (AD). Following the initial phase with treatment every two weeks for 18 months, intravenous (IV) maintenance dosing with treatment every four weeks was approved in the U.S., China, the United Kingdom, and others, and applications have been filed in 4 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 rolling Supplemental Biologics License Application (sBLA) for initiation treatment was initiated under Fast Track status in September 2025, and completed in November 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 including for LEQEMBI (lecanemab) subcutaneous autoinjector (SC-AI); the potential to streamline the Alzheimer's disease treatment pathway; 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," "outlook," "plan," "possible," "potential," "predict," "project," "prospect," "should," "target," "will," "would" or the negative of these words or 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 differ materially from those stated or implied in this document, including, among others, uncertainty of our long-term success in developing, licensing, or acquiring other product candidates or additional indications for existing products; expectations, plans, prospects and timing of actions relating to product approvals, approvals of additional indications for our existing products, sales, pricing, growth, reimbursement and launch of our marketed and pipeline products; the potential impact of increased product competition in the biopharmaceutical and healthcare industry, as well as any other markets in which we compete, including increased competition from new originator therapies, generics, prodrugs and biosimilars of existing products and products approved under abbreviated regulatory pathways; our ability to effectively implement our corporate strategy; difficulties in obtaining and maintaining adequate coverage, pricing, and reimbursement for our products; the drivers for growing our business, including our dependence on collaborators and other third parties for the development, regulatory approval, and commercialization of products and other aspects of our business, which are outside of our full control; risks related to commercialization of biosimilars, which is subject to such risks related to our reliance on third-parties, intellectual property, competitive and market challenges and regulatory compliance; 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; and 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, 2024, 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.
3. Hampel H, Hardy J, Blennow K, et al. The amyloid pathway in Alzheimer's disease. *Mol Psychiatry.* 2021;26(10):5481-5503.