LEQEMBI® Pen (Subcutaneous Formulation of LEQEMBI®) Now Available in Japan for Patients with Early Alzheimer's Disease

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The First and Only Anti-Amyloid Treatment in Japan that Enables At-Home Administration

TOKYO and CAMBRIDGE, Mass., Nov. 12, 2026 (GLOBE NEWSWIRE) -- Eisai Co., Ltd. and Biogen Inc. (Nasdaq: BIIB) announced today that "LEQEMBI® Pen", the subcutaneous (SC) formulation of "LEQEMBI®" (generic name: lecanemab) has been launched in Japan.

LEQEMBI Pen was approved as a new route of administration in Japan on September 16, 2026, and was published in Japan's National Health Insurance (NHI) Drug Price List today. Following the United States, Japan is the second country where LEQEMBI's subcutaneous formulation has been launched.

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LEQEMBI Pen is an autoinjector formulation that enables either patient self-administration, or administration by a care partner, using two pens (500 mg total) once weekly. With this launch, LEQEMBI treatment now offers a new option of once-weekly SC administration, in addition to intravenous (IV) administration every two weeks in a medical facility.

LEQEMBI Pen may reduce the time required for anti-amyloid therapy administration compared with IV infusions (approximate injection time of 15 seconds per injection). In addition to administration at a medical facility, the possibility of self-administration at home or while traveling may reduce the burden of clinic visits for patients and their care partners and provide greater flexibility in treatment, allowing patients to make treatment choices that better fit their lifestyles, including fewer constraints on going out and traveling. These features are expected to lower barriers to initiating and continuing treatment with LEQEMBI. LEQEMBI Pen also may reduce healthcare resources associated with IV administration, such as nurse monitoring and infusion capacity, contributing to a more streamlined Alzheimer's disease (AD) treatment pathway. For amyloid-related imaging abnormalities (ARIA) monitoring, as with IV administration, brain magnetic resonance imaging (MRI) is performed prior to initiating treatment and at specified time points after treatment initiation.

The following points are stipulated to be observed when self-administering.

- When initiating administration, treatment must be administered by a physician or under the direct supervision of a physician at a medical facility.
- With regard to the applicability of self-administration, the appropriateness thereof shall be carefully considered, and only after providing thorough education and training, and confirming that the patient or family member/caregiver understands the risks associated with administration of this drug and how to respond to them, and that the patient or family member/caregiver is able to reliably administer it themselves, shall self-administration be implemented under the management and guidance of a physician.

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 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. **Product Outline**
   Product name: LEQEMBI® Pen
   Generic name: Lecanemab (recombinant)
   Indication for use: Slowing progression of mild cognitive impairment (MCI) and mild dementia due to Alzheimer's disease.
   Dosage and administration: The usual dose of lecanemab (recombinant) is 500 mg injected subcutaneously once weekly.
   National Health Insurance (NHI) Drug Price: 27,141 JPY per pen
   Packaging: LEQEMBI® Pen 1.25mL x 2 pens
2. **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 U.S., China, Canada, Europe, South Korea, Taiwan, and Saudi Arabia, and is under regulatory review in 6 countries. In September 2023, Eisai received approval in Japan for lecanemab as a treatment for slowing progression of mild cognitive impairment (MCI) and mild dementia due to AD. Following the initial phase with treatment every two weeks for 18 months, intravenous (IV) maintenance dosing with treatment every four weeks is approved in 9 countries and regions 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 (360 mg) with LEQEMBI IQLIK in August 2025. For subcutaneous initiation treatment (500 mg), approval was obtained in the U.S. in July 2026 and China in September 2026, and applications are under review in 4 countries.

   The approval in Japan is based on the integrated results of data and associated modeling and simulation from the 18-month core study of the Phase 3 Clarity AD study of LEQEMBI in patients with mild cognitive impairment (MCI) due to AD or mild AD dementia (collectively referred to as early AD), as well as multiple SC administration sub-studies in its subsequent long-term extension study (LTE). In this sub-study, once-weekly administration of SC formulation 500 mg demonstrated similar exposure to IV administration once every two weeks and supported the expectation that the SC formulation provides efficacy comparable to that of the IV formulation. The overall safety profile of SC administration was generally similar to that of IV administration, while systemic injection/infusion-related reactions were observed less frequently with SC administration (1.4%)* than with IV administration.

   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.

   * Incidence in participants newly initiated on lecanemab treatment via SC administration, based on clinical data obtained from once-weekly subcutaneous administration of lecanemab 720 mg using vial formulations.

3. **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]
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 lecanemab 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 Pen to increase flexibility in treatment options and reduce use of healthcare resources and the time required for and burden of clinical visits; 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 complying with our obligations under 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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A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/156b9abe-3a78-43e0-95d3-1f7892106375