LEQEMBI® (lecanemab) Subcutaneous Formulation as an Initiation Treatment for Early Alzheimer's Disease Approved in China

The First and Only Anti-Amyloid Therapy in China that Enables At-Home Administration for Alzheimer's Disease, a Progressive Neurodegenerative Disease

TOKYO and CAMBRIDGE, Mass., September 3, 2026 — Eisai Co., Ltd. and Biogen Inc. (Nasdaq: BIIB) announced today that the National Medical Products Administration (NMPA) of China has approved the subcutaneous formulation (subcutaneous autoinjector: SC-AI), the anti-amyloid beta (Aβ) protofibril antibody LEQEMBI® (Chinese trademark: 乐意保®; generic name: lecanemab) as an initiation treatment for mild cognitive impairment (MCI) due to Alzheimer's disease（AD) or mild AD dementia (collectively referred to as early AD）. The application was accepted by the NMPA in January 2026 and was subsequently granted Priority Review designation. Launch is planned during Eisai's FY 2026, ending March 31, 2027.

LEQEMBI SC-AI is a self-administered autoinjector formulation. The approved regimen is 500 mg given once weekly as two consecutive 250 mg injections. With this approval, LEQEMBI treatment now offers a new option of once-weekly SC administration at home, in addition to intravenous (IV) administration every two weeks in a hospital setting. Patients may also switch from IV to SC administration, or vice versa, during treatment.

LEQEMBI SC-AI may significantly reduce the time required compared with IV infusions (approximate injection time of 15 seconds per injection). In addition, at-home administration may reduce the burden of clinic visits for patients and their care partners and enable treatment options that better fit their lifestyles, providing greater flexibility for going out and traveling. The improved convenience and flexibility of treatment with LEQEMBI is expected to lower barriers to initiating and continuing treatment with LEQEMBI. Furthermore, LEQEMBI SC-AI also has the potential to reduce healthcare resources associated with IV dosing, such as nurse monitoring, as well as maintaining infusion capacity. These features are expected to contribute to further streamlining the overall AD treatment pathway. For ARIA (amyloid-related imaging abnormalities) monitoring, as with IV administration, brain magnetic resonance imaging (MRI) is performed prior to initiating treatment and at specified time points after treatment initiation.

AD is a relentless disease with Aβ and tau as hallmarks, 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.

This marks the second country globally to approve LEQEMBI SC-AI. This approval 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 early AD, as well as multiple subcutaneous (SC) administration sub-studies (including the Chinese cohort) in its subsequent long-term extension (LTE). Once-weekly administration of SC-AI 500mg demonstrated exposure equivalent to once every two weeks IV administration, with similar clinical and biomarker benefits. The overall safety profile of SC administration was generally similar to that of

IV administration. Injection-related reactions were observed with subcutaneous LEQEMBI, most of which were localized, while systemic reactions were less frequently observed.

Eisai estimates that there were 17 million patients with MCI or mild dementia due to AD in China in 2024, which is expected to increase as the population ages. LEQEMBI was launched in China in June 2024 and is leading the establishment of anti-amyloid therapy in AD management, expanding its contribution to patients with early AD.

Eisai serves as the lead of LEQEMBI development and regulatory submissions globally with Eisai and Biogen co-commercializing and co-promoting the product and Eisai having final decision-making authority. Eisai will distribute the product in China and will conduct information provision activities through specialized medical representatives.

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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 U.S., China, Canada, 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 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 with LEQEMBI IQLIK in August 2025. For subcutaneous initiation treatment (500 mg), approval was obtained in the United States in July 2026, and applications are under review in three countries, including Japan.

LEQEMBI's approvals in these countries were based on Phase 3 data from Eisai's global placebo-controlled, double-blind, parallel-group, randomized Clarity AD clinical trial, in which it met its primary endpoint and all key secondary endpoints with statistically significant results. The primary endpoint was the global cognitive and functional scale, Clinical Dementia Rating Sum of Boxes (CDR-SB). Clarity AD evaluated lecanemab 10 mg/kg bi-weekly IV treatment of early Alzheimer's disease, which involved 1,795 patients (treatment group: 898, placebo group: 897). 95% of patients who completed the core study (18 months) chose to continue in the long-term extension study (LTE), with 478 patients still receiving treatment for four years. In the Clarity AD core clinical study, data showed LEQEMBI IV significantly slowed disease progression at 18 months (27% vs placebo), and the mean change from baseline between the lecanemab treated group and the placebo group after 18 months was -0.45 (P=0.00005) on the primary endpoint of CDR-SB global cognitive and functional scale.

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 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.[2] 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.[3]

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 lecanemab 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.

6. 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 SC-AI (lecanemab subcutaneous formulation); the potential benefits, safety and efficacy of LEQEMBI SC-AI; the potential to reduce time receiving anti-amyloid therapy via IV infusions and healthcare resources associated with IV dosing; potential regulatory discussions, submissions and approvals and the timing thereof including for LEQEMBI SC-AI; 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, 2024 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

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

1. National Institute on Aging (NIA), National Institutes of Health. *What Is Mild Cognitive Impairment?* Available at: https://www.nia.nih.gov/health/memory-loss-and-forgetfulness/what-mild-cognitive-impairment. Accessed July 22, 2026.
2. Amin L, Harris DA. Aβ receptors specifically recognize molecular features displayed by fibril ends and neurotoxic oligomers. *Nat Commun*. 2021; 12:3451. doi:10.1038/s41467-021-23507-z.
3. 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.