Biologics License Application for Subcutaneous Formulation of “LEQEMBI®” (lecanemab) for the Treatment of Early Alzheimer’s Disease Designated for Priority Review in China

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TOKYO and CAMBRIDGE, Mass., Feb. 08, 2026 (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 the Biologics License Application (BLA) for the subcutaneous formulation (subcutaneous autoinjector: SC-AI) of “LEQEMBI®” (brand name in China: “乐意保®”, generic name: lecanemab), an anti-amyloid beta (Aβ) protofibril antibody, which was accepted in January 2026, has been designated for Priority Review by the National Medical Products Administration (NMPA) of China.

The Priority Review and Approval Procedure was implemented by the NMPA with the aim of accelerating research, development and launch of new medicines that have significant clinical value. Under this Procedure, the assessment period is expected to be shortened.

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 in a 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 (250 mg 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.

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 with the aging of the population.

LEQEMBI was launched in China in June 2024 and has been delivered in the private market. Furthermore, LEQEMBI has been included in the newly introduced “Commercial Insurance Innovative Drug List” (Chinese: 商业健康保险创新药品目录), which took effect in January 2026, under new Chinese government policies that support the development of and access to innovative medicines. Based on the Commercial Insurance Innovative Drug List, Commercial insurance companies will develop insurance products covering LEQEMBI.

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. In China, Eisai will distribute the product and conduct information provision activities through specialized Medical Representatives.

MEDIA CONTACTS

Eisai Co., Ltd.
Public Relations Department
TEL: +81 (0)3-3817-5120

Biogen Inc.
Madeleine Shin
+1-781-464-3260
public.affairs@biogen.com

Eisai Europe, Ltd.
EMEA Communications Department
+44 (0) 797 487 9419
Emea-comms@eisai.net

Eisai Inc. (U.S.)
Libby Holman
+1-201-753-1945
Libby_Holman@Eisai.com

INVESTOR CONTACTS

Eisai Co., Ltd.
Investor Relations Department
TEL: +81 (0) 3-3817-5122

Biogen Inc.
Tim Power
+ 1-781-464-2442
IR@biogen.com

Notes to Editors

1. About LEQEMBI (generic name: lecanemab, Chinese brand name: 乐意保)
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 7 countries including the U.S., China, the UK, and others, and applications have been filed in 7 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. The sBLA has been granted Priority Review, with a Prescription Drug User Fee Act (PDUFA) action date of May 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.

2. About Protofibril
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 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 about the potential clinical effects of lecanemab (marketed as 乐意保 in China); 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 expand options and reduce healthcare resources by treating Alzheimer's disease at home; 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-) 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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