“LEQEMBI®” (lecanemab) IV Maintenance Dosing for the Treatment of Early Alzheimer’s Disease Approved in the United Kingdom

November 13, 2025

TOKYO and CAMBRIDGE, Mass., Nov. 13, 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 humanized anti- soluble aggregated amyloid-beta (Aβ) monoclonal antibody “LEQEMBI®” (generic name: lecanemab) has been approved for once every four weeks intravenous (IV) maintenance dosing by the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom.

In August 2024, LEQEMBI was approved for the treatment of mild cognitive impairment (MCI) and mild dementia due to Alzheimer’s disease (AD) in adult patients that are apolipoprotein E ε4 (ApoE ε4)* heterozygotes or non-carriers in the United Kingdom. With this latest approval for IV maintenance dosing, after 18 months of a dosing regimen of 10 mg/kg once every two weeks patients may be transitioned to the maintenance dosing regimen of 10 mg/kg once every four weeks, or the regimen of 10 mg/kg once every two weeks may be continued.

AD is a progressive, relentless disease characterized by formation of protein deposits known as plaques made of amyloid-beta aggregates and neurofibrillary tangles made of tau protein in the brains of people living with AD. It is caused by a continuous underlying neurotoxic process that begins before amyloid plaque accumulation and continues after plaque removal.[1,2] The data show that amyloid-beta protofibrils and tau tangles play roles in the neurodegeneration process,[2,3] and only LEQEMBI fights AD in two ways – targeting both amyloid plaque and protofibrils**, which can impact tau downstream. Due to the reaccumulation of AD biomarkers and return to placebo rate of decline after therapy is stopped,[3-5] continuing maintenance treatment after the initial 18-month therapy is essential to slow the progression of AD and extend the therapeutic benefits, helping patients maintain who they are for longer.

In the United Kingdom, it is estimated that 982,000 people are living with dementia,[6] and AD is the cause in 60-70% of people with dementia.[7] These numbers are expected to rise, as the population ages.[6,7]

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.

* Apolipoprotein E is a protein involved in the metabolism of lipid in humans. It is implicated in AD. People with only one (heterozygous) or no copy (non-carriers) of the ApoE ε4 gene are less likely to experience ARIA than people with two ApoE ε4 copies (homozygous).[8]
** 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.[3] 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 slowing the progression of AD.[4]

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Notes to Editors

1. **About LEQEMBI (generic name: lecanemab)**

   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 51 countries and is under regulatory review in 9 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 the United Kingdom, the U.S, China and others, and applications have been filed in 4 countries and regions.

   LEQEMBI's approvals in these countries were based on Phase 3 data from Eisai's, global 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).[1] The U.S. FDA approved Eisai’s Biologics License Application (BLA) for subcutaneous maintenance dosing with LEQEMBI IQLIK in August 2025. In September 2025, the rolling sBLA application to the U.S. FDA for the subcutaneous initiation dosing with LEQEMBI IQLIK was also initiated.

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 Eisai and Biogen 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.), us.eisai.com (for U.S. headquarters: Eisai, Inc.) or www.eisai.eu (for Europe, Middle East, Africa, Russia, Australia and New Zealand headquarters: Eisai Europe Ltd.), and connect with us on X (global and U.S), LinkedIn (for global, U.S. and EMEA) and Facebook (global).

5. About Biogen

Founded in 1978, Biogen is a leading biotechnology company that pioneers innovative science to deliver new medicines to transform patients' 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 (LEQEMBI); the potential benefits, safety and efficacy of LEQEMBI; 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," "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 commercialisation involve a high degree of risk, and only a small number of research and development programmes result in commercialisation 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 realised 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 materialise 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 Disclosures
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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