



Update on Regulatory Review of Lecanemab for Early Alzheimer's Disease by the European Commission

TOKYO and CAMBRIDGE, Mass., April 1, 2025 – 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 an update on the ongoing regulatory review of the Marketing Authorization Application for lecanemab as a treatment for early AD (mild cognitive impairment and mild dementia due to Alzheimer's disease (AD)) by the European Commission (EC).

The final process for the EC decision on lecanemab's Marketing Authorisation Application (MAA) is underway, following the reconfirmation of the positive opinion for lecanemab's approval by the Committee for Medicinal Products for Human Use (CHMP) in February 2025¹. The EC announced that it has deliberated on the MAA in its Standing Committee and, based on the results of those deliberations, has referred the decision to the Appeal Committee in accordance with the EC review process.

Eisai serves as the lead for lecanemab's development and regulatory submissions globally with both 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. 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 1 (IgG1) monoclonal antibody directed against aggregated soluble (protofibril) and insoluble forms of amyloid-beta (Aβ).

Lecanemab has been approved in the U.S.,² Japan,³ China,⁴ South Korea,⁵ Hong Kong,⁶ Israel,⁷ the United Arab Emirates,⁸ the United Kingdom,⁹ Mexico,¹⁰ Macau, Oman and Taiwan, and is under regulatory review in 15 countries and regions including the EU. In January 2025, the supplemental Biologics License Application (sBLA) for intravenous (IV) maintenance dosing of the treatment was approved in the U.S. After an 18 months initiation phase with once every two weeks of dosing, a transition to the maintenance dosing regimen of 10 mg/kg once every four weeks or continuing 10 mg/kg once every two weeks may be considered. Additionally, the U.S. Food and Drug Administration (FDA) accepted Eisai's Biologics License Application (BLA) for the LEQEMBI subcutaneous autoinjector for weekly maintenance dosing in January 2025 and set a PDUFA action date for August 31, 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; 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.

References

- ¹ Committee for Medicinal Products for Human Use. 2024. Leqembi (Lecanemab). Overview. Available at: <https://www.ema.europa.eu/en/medicines/human/EPAR/leqembi#overview>. Last accessed: January 2025.
- ² U.S. Food and Drug Administration. 2023. FDA Converts Novel Alzheimer’s Disease Treatment to Traditional Approval. Last accessed: January 2025.
- ³ Reuters. 2023. Japan approves Alzheimer’s treatment Leqembi by Eisai and Biogen. Last accessed: January 2025.
- ⁴ The Pharma Letter. 2024. Brief - Alzheimer drug Leqembi now approved in China. Last accessed: January 2025.
- ⁵ Pharmaceutical Technology. 2024. South Korea’s MFDS approves Eisai-Biogen’s LEQEMBI for Alzheimer’s. Last accessed: January 2025.
- ⁶ Pharmaceutical Technology. 2024. Hong Kong approves Leqembi for Alzheimer’s treatment. Last accessed: January 2025.
- ⁷ Pharmaceutical Business Review. 2024. Leqembi gains approval for Alzheimer’s treatment in Israel. Last accessed: January 2025.
- ⁸ United Arab Emirates Ministry of Health & Prevention. 2024. Registered Medical Product Directory. Leqembi. Last accessed: January 2025.
- ⁹ Lecanemab United Kingdom Summary of Product Characteristics. Available at: <https://www.medicines.org.uk/emc/product/15908>. Last accessed: January 2025.
- ¹⁰ The Pharma Letter. 2024. BRIEF-Mexican approval for Alzheimer’s drug Leqembi. Available at: <https://www.thepharmaletter.com/brief-mexican-approval-for-alzheimers-drug-leqembi>. Last accessed: January 2025.