Update on Regulatory Review of Lecanemab for Early Alzheimer's Disease in the European Union

TOKYO and CAMBRIDGE, Mass., January 31, 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 due to Alzheimer's disease (AD) and mild AD) in the European Union.

In November 2024, a positive opinion was received from the Committee for Medicinal Products for Human Use (CHMP) recommending approval of lecanemab.[1] As part of its decision-making process, the European Commission (EC) has asked the CHMP to consider information on the safety of lecanemab that became available after the adoption of the CHMP opinion in November 2024 and whether this may require an update of the opinion, and to consider whether the wording of the risk minimization measures in the opinion is clear enough to ensure correct implementation. These will be discussed at the CHMP meeting in February 2025.

The safety profile of lecanemab reported in clinical practice in the United States, Japan and other countries after launch is consistent with that in the approved labels, and no new safety signals are identified. We believe that the EC's requests can be addressed with existing information and will be evaluated by the CHMP because of the clear and sufficient information available. We will continue to work closely with the authorities toward approval in the EU.

We will continue to make every effort to deliver lecanemab to patients with early AD in EU countries as soon as possible.

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.

MEDIA CONTACTS

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

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

Biogen Inc.
Jack Cox
+ 1-781-464-3260
public.affairs@biogen.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 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] and Macau, and is under regulatory review in 17 countries including the EU. In January 2025, the U.S. Food and Drug Administration (FDA) has approved the Supplemental Biologics License Application (sBLA) for once every four weeks maintenance dosing. In January 2025, the submission of a Biologics License Application (BLA) for maintenance dosing of a subcutaneous injection formulation, which is being developed to enhance convenience for patients, was accepted in the U.S.

   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 statements may be identified by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "possible," "potential," "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 studies may not be indicative of full results or results from later stage or larger scale clinical studies and do not ensure regulatory approval. You should not place undue reliance on these statements.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including without limitation unexpected concerns that may arise from additional data, analysis or results obtained during clinical studies; the occurrence of adverse safety events; risks of unexpected costs or delays; the risk of other unexpected hurdles; regulatory submissions may take longer or be more difficult to complete than expected; regulatory authorities may require additional information or further studies, or may fail or refuse to approve or may delay approval of Biogen's drug candidates, including lecanemab; actual timing and content of submissions to and decisions made by the regulatory authorities regarding lecanemab; uncertainty of success in the development and potential commercialization of lecanemab; failure to protect and enforce Biogen's data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; product liability claims; and third party collaboration risks, results of operations and financial condition. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from Biogen's expectations in any forward-looking statement. Investors should consider this cautionary statement as well as the risk factors identified in Biogen's most recent annual or quarterly report and in other reports Biogen has filed with the U.S. Securities and Exchange Commission. These statements speak only as of the date of this news release. Biogen does not undertake any obligation to publicly update any forward-looking statements.

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.