



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

July 26, 2024

TOKYO and CAMBRIDGE, Mass., July 26, 2024 (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 Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a negative opinion on the Marketing Authorization Approval (MAA) for the humanized anti-soluble aggregated amyloid-beta (A $\beta$ ) monoclonal antibody lecanemab as treatment for early AD (mild cognitive impairment due to Alzheimer's disease (AD) and mild AD).<sup>1</sup>

"We are extremely disappointed by the CHMP's negative opinion and understand that this may also be disappointing for the wider Alzheimer's disease (AD) community. AD is an irreversible, neurodegenerative disease that poses significant challenges to those living with AD, their care partners and society," said Lynn Kramer, M.D., Chief Clinical Officer at Eisai. "There is a significant unmet need for new innovative treatment options that target an underlying cause of disease progression. We remain focused on making a meaningful difference to those living with early AD and those closest to them."

Eisai will seek re-examination of the CHMP opinion and work with the relevant authorities to ensure this treatment is available for eligible people living with early AD in the European Union (EU) as soon as possible.

Lecanemab is already approved in the United States, Japan, China, South Korea, Hong Kong and Israel, and is being marketed in the U.S., Japan and China.

AD currently affects 6.9 million people in Europe,<sup>2</sup> and this figure is expected to nearly double by 2050 as aging populations increase.<sup>3</sup>

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 (A $\beta$ ).

Lecanemab is approved in the U.S., Japan, China, South Korea, Hong Kong and Israel for the treatment of MCI due to AD and mild AD dementia. Lecanemab'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.<sup>4,5</sup> The primary endpoint was the global cognitive and functional scale, Clinical Dementia Rating Sum of Boxes (CDR-SB). In the Clarity AD clinical trial, treatment with lecanemab reduced clinical decline on CDR-SB by 27% at 18 months compared to placebo.<sup>4</sup> The mean CDR-SB score at baseline was approximately 3.2 in both groups. The adjusted least-squares mean change from baseline at 18 months was 1.21 with lecanemab and 1.66 with placebo (difference, -0.45; 95% confidence interval [CI], -0.67 to -0.23; P<0.001).<sup>4</sup> In addition, the secondary endpoint from the AD Cooperative Study-Activities of Daily Living Scale for Mild Cognitive Impairment (ADCS-MCI-ADL), which measures information provided by people caring for patients with AD, noted a statistically significant benefit of 37% compared to placebo.<sup>4</sup> The adjusted mean change from

baseline at 18 months in the ADCS-MCI-ADL score was -3.5 in the lecanemab group and -5.5 in the placebo group (difference, 2.0; 95% CI, 1.2 to 2.8; P<0.001).<sup>4</sup> The ADCS MCI-ADL assesses the ability of patients to function independently, including being able to dress, feed themselves and participate in community activities. The most common adverse events (>10%) in the lecanemab group were infusion reactions, ARIA-H (combined cerebral microhemorrhages, cerebral macrohemorrhages, and superficial siderosis), ARIA-E (edema/effusion), headache, and fall.<sup>4</sup>

Eisai has submitted applications for approval of lecanemab in 12 countries and regions, including the European Union (EU). A supplemental Biologics License Application (sBLA) for intravenous maintenance dosing was submitted to the U.S. Food and Drug Administration (FDA) in March 2024, which was accepted in June 2024. The rolling 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 initiated in the U.S. under Fast Track status in May 2024.

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](http://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](http://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](http://www.biogen.com). Follow Biogen on social media – [Facebook](#), [LinkedIn](#), [X](#), [YouTube](#). The website and social media channels are intended for audiences outside of the UK and Europe.

### Biogen Safe Harbor

This news release contains forward-looking statements, 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

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<sup>1</sup> Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 22-25 July 2024 <https://www.ema.europa.eu/en/news/meeting-highlights-committee-medicinal-products-human-use-chmp-22-25-july-2024>.

<sup>2</sup> Gustavsson, A., et al. Global estimates on the number of persons across the Alzheimer's disease continuum. *Alzheimer's & Dementia*. 2023;19:658-670. <https://alz-journals.onlinelibrary.wiley.com/doi/full/10.1002/alz.12694>.

<sup>3</sup> Alzheimer Europe. Prevalence of dementia in Europe. Available at: <https://www.alzheimer-europe.org/dementia/prevalence-dementia-europe>.

<sup>4</sup> van Dyck, H., et al. Lecanemab in Early Alzheimer's Disease. *New England Journal of Medicine*. 2023;388:9-21. <https://www.nejm.org/doi/full/10.1056/NEJMoa2212948>.

<sup>5</sup> Eisai Global. 2023. Eisai Presents Full Results of Lecanemab Phase 3 Confirmatory Clarity AD Study for early Alzheimer's Disease at Clinical Trials on Alzheimer's Disease (CTAD) Conference. Available at: <https://www.eisai.com/news/2022/news202285.html>. Last accessed: July 2024.