Health Canada Grants Authorization for “LEQEMBI®” (lecanemab) for the Treatment of Early Alzheimer’s Disease

October 26, 2025

In Canada, lecanemab is indicated for the treatment of adult patients with a clinical diagnosis of mild cognitive impairment or mild dementia due to Alzheimer’s disease (early AD) who are apolipoprotein E ε4 (ApoE ε4*) non-carriers or heterozygotes and who have confirmed amyloid pathology

TOKYO and CAMBRIDGE, Mass., Oct. 26, 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 Health Canada has issued a Notice of Compliance with Conditions (NOC/c) for humanized anti-soluble aggregated amyloid-beta (Aβ) monoclonal antibody “LEQEMBI®” (lecanemab) for the treatment of adult patients with a clinical diagnosis of mild cognitive impairment or mild dementia due to Alzheimer’s disease (early AD) who are apolipoprotein E ε4 (ApoE ε4*) non-carriers or heterozygotes and who have confirmed amyloid pathology. LEQEMBI is the first treatment for early AD that targets an underlying cause of the disease, to be authorized in Canada.

LEQEMBI selectively binds to soluble Aβ aggregates (protofibrils**), as well as insoluble Aβ aggregates (fibrils) which are a major component of Aβ plaques, thereby reducing both Aβ protofibrils and Aβ plaques in the brain. LEQEMBI is the first approved treatment shown to reduce the rate of disease progression and to slow cognitive and functional decline in adults with AD. LEQEMBI is also approved in 51 countries and regions including Japan,[1] the United States,[2] Europe,[3] China,[4] South Korea,[5] Taiwan,[6] and SaudiArabia,[7] and applications have been filed in 9 countries.

The approval of LEQEMBI is based on the large global Phase 3 Clarity AD study. In the Clarity AD study, LEQEMBI met its primary endpoint and all key secondary endpoints with statistically significant results.[8,9] LEQEMBI has been issued market authorization with conditions, pending the results of trials to verify its clinical benefit. Eisai plans to submit clinical assessment data captured from participants in real-world clinical practice.

AD is the most common form of dementia, accounting for 60 to 80% of all cases.[10] As of January 1, 2025, it is estimated there are more than 771,000 patients with dementia in Canada, which is expected to increase to approximately 1 million in 2030 and over 1.7 million in 2050.[11] In addition, annual care provided by family and friends for those with dementia is equivalent to 290,000 full-time jobs, which is expected to increase to 690,000 full-time jobs in 2050.[11]

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. In Canada, Eisai Limited will distribute the product and conduct information provision activities. Eisai and Biogen are committed to working together with healthcare professionals and other stakeholders towards the early treatment of AD.

* 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).[12]
** Protofibrils are believed to contribute to the brain injury that occurs with AD and are considered to be the most toxic form of Aβ, having a primary role in the cognitive decline associated with this progressive, debilitating condition.[13] 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.[14]

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 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 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).

LEQEMBI’s approvals in these countries was 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.[8,9] 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 LEQEMBI reduced clinical decline on CDR-SB by 27% at 18 months compared to placebo. 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 LEQEMBI and 1.66 with placebo (difference, −0.45; 95% confidence interval [CI], −0.67 to −0.23; P<0.001). 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. The adjusted mean change from baseline at 18 months in the ADCS-MCI-ADL score was −3.5 in the LEQEMBI group and −5.5 in the placebo group (difference, 2.0; 95% CI, 1.2 to 2.8; P<0.001). 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 LEQEMBI group were infusion reactions, ARIA-H (combined cerebral microhemorrhages, cerebral macrohemorrhages, and superficial siderosis), ARIA-E (edema/effusion), headache, and fall.

LEQEMBI is approved in 51 countries and regions including Japan,[1] the United States,[2] Europe,[3] China,[4] South Korea,[5] Taiwan,[6] and SaudiArabia,[7] and applications have been filed 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 U.S. and China, and others, and applications have been filed in 5 countries and regions.

LEQEMBI's approvals in these countries was 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).[8,12] 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 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.

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