Austria and Germany to become the first markets in the European Union (EU) to launch LEQEMBI® (lecanemab)

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TOKYO and CAMBRIDGE, Mass., Aug. 25, 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 the anti-amyloid beta (Aβ) monoclonal antibody “LEQEMBI®” has been launched in Austria on August 25, 2025 and will be launched in Germany on September 1, 2025. LEQEMBI received the European Commission (EC) approval in April 2025 as the first therapy that targets an underlying cause of Alzheimer’s disease (AD). It is indicated for the treatment of adult patients with a clinical diagnosis of mild cognitive impairment (MCI) and mild dementia due to AD (collectively referred to as early AD) who are apolipoprotein E ε4 (ApoE ε4*) non-carriers or heterozygotes with confirmed amyloid pathology.[1] Germany and Austria will mark the first launches in the EU.

Following the EC approval, Eisai has been collaborating with the regional and local healthcare authorities to implement the mandatory authorisation requirements ahead of launch. The required controlled access program** is now in place in Austria and Germany, enabling the launch in these first two EU countries.

AD is a progressive, relentless disease with Aβ and tau as hallmarks. AD progresses in stages that increase in severity over time, and each stage of the disease presents different challenges for those living with AD and their care partners. There is a significant unmet need for new treatment options that slow the progression of AD by initiating therapy from its early stage and continuing it in order to reduce the overall burden on people affected by AD and society. Only LEQEMBI fights AD in two ways - targeting both amyloid plaque and protofibrils***, which can impact tau downstream.

In the Clarity AD clinical trial, the primary endpoint was the global cognitive and functional scale, Clinical Dementia Rating – Sum of Boxes (CDR-SB).[1] Treatment with lecanemab (n=757), in the EU indicated population (ApoE ε4 non-carriers or heterozygotes, measured by controlled-based multiple imputation†), reduced clinical decline on CDR-SB by 31% at 18 months compared to placebo (n=764).[1]

In the EU indicated population (ApoE ε4 non-carriers or heterozygotes) (n=757), the most common adverse reactions were infusion-related reaction (26%), ARIA-H (13%), headache (11%) and ARIA-E (9%). Symptomatic ARIA-E occurred in 2% of participants. Symptomatic ARIA-H occurred in 0.8% of patients.[1]

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 the EU (excluding the Nordic countries), Eisai and Biogen will co-promote the medicine, with Eisai distributing the product as the Marketing Authorization Holder.

* 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).[2] ARIA is a recognized important side effect with lecanemab that involves swelling and potential bleeding in the brain.[1, 2]

** Controlled access program is a system that restricts the use and distribution of certain medicines. It is designed to promote the appropriate use of medicines while ensuring patient safety. In line with the EC approval requirements, initiation of lecanemab treatment should be through a central registration system implemented as part of CAP.

*** 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.[3] 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.[3, 4]

† As requested by the regulatory authority, efficacy analyses were conducted for ApoE ε4 non-carriers or heterozygotes participants using control-based multiple imputation method, in which all missing values were imputed with copy-increments (change between visits) using the actual value in placebo group.[5] This methodology differs from that used in the Clarity AD primary analysis which used mixed-model repeat measures (MMRM) with missing at random assumption.[2]

Leqembi®▼ : This medicine is subject to additional monitoring. This allows for rapid identification of new findings on safety. Healthcare professionals are asked to report any suspected side effects.

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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).[1, 2]

   The EC's authorization was primarily 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.[1,2] Clarity AD was a Phase 3 global, placebo-controlled, double-blind, parallel-group, randomized study in 1,795 patients with early AD (MCI or mild dementia due to AD, with confirmed presence of amyloid pathology). Of the total number of patients randomized, 1,521 were in the EU indicated population (ApoE ε4 non-carriers or heterozygotes).[2] The treatment group was administered lecanemab 10 mg/kg bi-weekly, with participants allocated in a 1:1 ratio to receive either placebo or lecanemab for 18 months.[2]

   The primary endpoint was the global cognitive and functional scale, CDR-SB.[2] In the Clarity AD clinical trial, treatment with lecanemab (n=757), in the EU indicated population (ApoE ε4 non-carriers or heterozygotes, measured by controlled-based multiple imputation), reduced clinical decline on CDR-SB by 31% at 18 months compared to placebo (n=764).[1] The mean CDR-SB score at baseline was approximately 3.2 in both groups.[1] The adjusted least-squares mean change from baseline at 18 months was 1.217 with lecanemab and 1.752 with placebo (difference, −0.535; 95% confidence interval [CI], −0.778 to −0.293).[1] CDR-SB is a global cognitive and functional scale that measures six domains of functioning, including memory, orientation, judgement and problem solving, community affairs, home and hobbies, and personal care.[6]

   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 33% less decline compared to placebo at 18 months.[1] The adjusted mean change from baseline at 18 months in the ADCS MCI-ADL score was −3.873 in the lecanemab group and −5.809 in the placebo group (difference, 1.936; 95% CI, 1.029 to 2.844).[1] The ADCS MCI-ADL assesses the ability of patients to function independently, including being able to dress, feed themselves and participate in community activities.[7] Amyloid Positron Emission Tomography (PET) using Centiloids and ADAS-Cog14 also showed highly statistically significant results compared with placebo (P<0.001).[1]

   In the EU indicated population (ApoE ε4 non-carriers or heterozygotes) (n=757), the most common adverse reactions were infusion-related reaction (26%), ARIA-H (13%), headache (11%) and ARIA-E (9%). Symptomatic ARIA-E occurred in 2% of participants. Symptomatic ARIA-H occurred in 0.8% of patients.[1]

   Lecanemab has been approved in 48 countries and is under regulatory review in 10 countries. In January 2025, the supplemental Biologics License Application (sBLA) for intravenous (IV) maintenance dosing of the treatment was approved in the U.S., and application have been filed in 9 countries and regions. 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. **Application specifics[1]**
   To ensure the safe and effective use of lecanemab and to support its use in accordance with the approval, all prescribers and patients must be enrolled in a controlled access programme before starting treatment.
   Physicians should recommend that patients participate in the collection of data from clinical practice (e.g. in reg-istries) to further improve understanding of Alzheimer's disease and the effects of appropriate therapies.
   Patients will receive the Leqembi package leaflet and a patient card to carry with them at all times when they start treatment. They must be informed about the risks of lecanemab treatment, the necessary monitoring by MRI scans and the

signs or symptoms of ARIA, and should be encouraged to report these symptoms and signs urgently.

3. **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.

4. **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 back-up was signed in May 2015.

5. **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.

6. **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, 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 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 risks associated with third party collaborations; 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.

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