FOR EUROPEAN TRADE AND MEDICAL MEDIA

Leqembi®▼ (lecanemab) is the First Medicine that Slows Progression of Early Alzheimer's Disease to be Authorised in the European Union

In the European Union (EU), lecanemab is indicated for the treatment of adult patients with a clinical diagnosis of mild cognitive impairment (MCI) and mild dementia due to Alzheimer's disease (AD) (early AD) who are apolipoprotein E ε4 (ApoE ε4) non-carriers or heterozygotes with confirmed amyloid pathology[1]*

Lecanemab is the first therapy that targets an underlying cause of the disease to be authorised in the EU for eligible people with early AD[1,2]

Authorisation is primarily based on data from the global Phase 3 clinical trial, Clarity AD, which demonstrated that lecanemab slowed disease progression in early AD vs placebo at 18 months[1,2]

The European Commission's decision brings access to lecanemab one step closer for eligible people with early AD in the EU[3]

HATFIELD, HERTFORDSHIRE, UNITED KINGDOM, and CAMBRIDGE, Mass., 16 April, 2025 – Eisai Europe Ltd. and Biogen Inc. announced today that the European Commission (EC) has granted Leqembi® (lecanemab) Marketing Authorisation (MA) in the European Union (EU).[1] This makes the medicine the first therapy that targets an underlying cause of Alzheimer's disease (AD) to be granted a MA in the EU.[1,2]

Lecanemab is indicated for the treatment of adult patients with a clinical diagnosis of mild cognitive impairment (MCI) and mild dementia due to AD (early AD) who are apolipoprotein E ε4 (ApoE ε4*) non-carriers or heterozygotes with confirmed amyloid pathology.[1] Early AD is usually the first stage of the disease, where symptoms become noticeable.[4] Today's MA applies to all 27 EU Member States as well as Iceland, Liechtenstein and Norway.[5]

Lecanemab is an amyloid-beta (Aβ) monoclonal antibody that preferentially binds and clears toxic protofibrils** (soluble Aβ aggregates), in addition to targeting and reducing Aβ plaques (insoluble Aβ aggregates).[1,2,6-10] Aβ protofibrils are a key toxic form of Aβ that accumulate in the brain and cause neuronal injury.[7,11,12]

AD is a neurodegenerative disease that progresses in stages and increases in severity over time, and each stage of the disease presents different challenges for those living with AD and their care partners.[13,14] Early symptoms can include forgetting recent events or conversations.[15] As AD progresses, everyday activities, hobbies and social engagements become more challenging, and independence is lost.[4,15] Early detection and diagnosis of AD can provide opportunities for interventions and support to be put in place for those in the early stages of the disease.[1,13,16]

"Today's decision makes lecanemab the first treatment option in the European Union that can slow the progression of early Alzheimer's disease and is a key step to making the medicine available to eligible patients. This is important news for those in the clinical and research Alzheimer's community who are dedicated to improving the management of a disease which poses a significant burden to healthcare systems and society," said Gary Hendler, Regional Chairman and CEO, Eisai EMEA, Senior Vice President & Global Corporate Officer, Eisai Co. Ltd, Tokyo. "We are proud that our heritage of over 40 years in dementia has led to this milestone, as we aim to be part of the solution for a better future for those impacted by this disease."

"The European Commission's authorisation of lecanemab represents a significant milestone in addressing this progressive disease," said Wolfram Schmidt, President and Head of Europe at Biogen. "We are proud there is now an approved treatment in the European Union that can slow the progression of early Alzheimer's disease. Our team at Biogen remains dedicated to standing with the Alzheimer's community, working collectively to achieve meaningful advancements in patient care."

"Eisai will work collaboratively with national reimbursement authorities and healthcare providers to support access for eligible patients in European Union countries as soon as possible," said Nick Burgin, President & COO, President Global Value & Access, Eisai EMEA. "Achieving optimal outcomes for people treated with the medicine is of paramount importance. To help achieve this, we are working with the European Medicines Agency and relevant national organisations to put measures in place to support the appropriate use of lecanemab as soon as it is introduced into each European Union country."

The EC authorisation was primarily based on Phase 3 data from Eisai's global, placebo-controlled, double-blind, parallel-group, randomised Clarity AD clinical trial, in which the medicine met its primary endpoint (change from baseline in the Clinical Dementia Rating Sum of Boxes [CDR-SB]† at 18 months), demonstrating that lecanemab slowed disease progression in early AD vs placebo, and all key secondary endpoints.[2]

In the indicated population in the Clarity AD clinical trial, the most common adverse events in the treatment group (n=757) were infusion-related reaction, amyloid-related imaging abnormalities with haemorrhage (small spots of bleeding) (ARIA-H)‡, headache and amyloid-related imaging abnormalities with cerebral oedema (build-up of fluid) (ARIA-E)‡‡.[1,17]

Eisai serves as the lead for lecanemab's development and regulatory submissions globally with both Eisai and Biogen co-commercialising 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 MA Holder. In the Nordic countries, Eisai and BioArctic will co-promote the medicine, with Eisai distributing the product as the MA Holder.

*Apolipoprotein E is a protein involved in the metabolism of lipids in humans. It is implicated in AD.[2]

**Protofibrils are believed to contribute to brain injury that occurs with AD and are considered to be a key toxic form of Aβ, having a primary role in the cognitive decline of this progressive, debilitating condition.[11] Protofibrils can cause injury to neurons in the brain which, in turn, can negatively impact cognitive function via multiple mechanisms,[11] 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.[12] It is believed the reduction of protofibrils may slow the progression of AD by reducing damage to neurons in the brain and cognitive dysfunction.[12]

†CDR-SB is a disease staging tool used in clinical trials, which can help to stage dementia due to AD.[15] It 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.[15]

‡ARIA-H: amyloid-related imaging abnormalities with haemorrhage (cerebral microhaemorrhages and superficial siderosis).

‡‡ARIA-E: amyloid-related imaging abnormalities with oedema (oedema/effusion).

▼: This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. If you get any side effects, talk to your healthcare professional. This includes any possible side effects not listed in the package leaflet. In the UK you can also report side effects directly via Yellow Card Scheme at www.mhra.gov.uk/yellowcard, for EU, via your EU national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

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Notes to editors:

1. About lecanemab

Lecanemab is the result of a strategic research alliance between Eisai and BioArctic. It is a humanised immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble (protofibril) and insoluble forms of amyloid-beta (Aβ).[2] The medicine is authorised in the U.S.,[18] Japan,[19] China,[20] South Korea,[21] Hong Kong,[22] Israel,[23] the United Arab Emirates,[24] the United Kingdom,[10] Mexico,[25] Macau,[26] Oman,[27] Taiwan,[27] and the EU,[1] and is under regulatory review in 14 countries and regions.

The EC's authorisation was primarily based on Phase 3 data from Eisai's global Clarity AD clinical trial, in which the medicine met its primary endpoint and all key secondary endpoints.[1,2] Clarity AD was a Phase 3 global, placebo-controlled, double-blind, parallel-group, randomised 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 randomised, 1,521 were in the EU indicated population (ApoE ε4 heterozygotes or non-carriers).[1,2] 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 heterozygotes or non-carriers, measured by controlled-based multiple imputation††), reduced clinical decline on CDR-SB by 31% at 18 months compared to placebo (n=764).[1,17] The mean CDR-SB score at baseline was approximately 3.2 in both groups.[1,2] 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).[1,17] 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.[15]

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).[1,17] The ADCS-MCI-ADL assesses the ability of patients to function independently, including being able to dress, feed themselves and participate in community activities.[28]

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%).[1,17]

††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.[17] This methodology differs from that used in the Clarity AD primary analysis which used mixed-model repeat measures (MMRM) with missing at random assumption.[2,17]

2. About the Collaboration between Eisai and Biogen for AD

Eisai and Biogen have been collaborating on the joint development and commercialisation of AD treatments since 2014. Eisai serves as the lead of lecanemab development and regulatory submissions globally with both companies co-commercialising 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 commercialisation 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 commercialisation agreement on the antibody back-up was signed in May 2015.

4. About Eisai EMEA

At Eisai, we give our first thought to patients, their care partners and to society, to increase the benefits health care provides them – we call this *human health care* (*hhc*). We focus beyond the realm of health to the value we bring to society. Through the power of collaboration and by using insights to guide our

work, we can make a meaningful contribution to people and society, and to improve outcomes and services for all.

In EMEA, we are the European hub of Tokyo-based Eisai Co. Ltd., forming part of a multinational team working across a global network of R&D facilities, manufacturing sites and marketing subsidiaries.

Our collective passion and dedication to patient care is the driving force behind our efforts to discover and develop innovative medicines in a variety of therapeutic areas where a high unmet medical need remains, including oncology and neurology.

Our mission is clear; we strive to make a significant long-lasting contribution to society in an ethical, compliant, and sustainable way by embodying *hhc* in everything we do.

For more information about Eisai in the EMEA region please visit www.eisai.eu.

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 with aspirations 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.

Biogen routinely post information that may be important to investors on its website.

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 AD; the anticipated benefits and potential of Biogen's collaboration arrangements with Eisai; the potential of Biogen's commercial business and pipeline programmes, including lecanemab; and risks and uncertainties associated with drug development and commercialisation. These forward-looking statements may be accompanied by such words as "aim," "anticipate," "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 commercialisation involve a high degree of risk, and only a small number of research and development programmes result in commercialisation 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 realised 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 materialise 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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