FOR EUROPEAN AND UNITED KINGDOM TRADE AND MEDICAL MEDIA

Eisai submits Marketing Authorisation Variation to the European Medicines Agency (EMA) for monthly intravenous dosing of Leqembi®▼ (lecanemab) for the treatment of early Alzheimer's disease in the European Union (EU)

Proposed intravenous maintenance dosing application to reduce lecanemab infusion frequency from every two weeks to every four weeks for eligible adult EU patients after initial 18 months of treatment

The submission of the application reflects the continued progress Eisai and Biogen are making to help patients, care partners and health systems manage this progressive, relentless disease

HATFIELD, HERTFORDSHIRE, UNITED KINGDOM (UK), and CAMBRIDGE, Mass, 26 JANUARY, 2026 – Eisai Europe Ltd. and Biogen Inc. announced today the submission of a proposed Marketing Authorisation Variation to the European Medicines Agency (EMA) for lecanemab monthly intravenous (IV) infusion maintenance dosing for the treatment of adult patients in the European Union (EU) 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 currently licenced as an IV infusion with a dosing regimen of once every two weeks (10 mg/kg).[1] Eisai's submission states that following the initial dosing regimen of once every two weeks, after 18 months, patients will be transitioned to the maintenance dosing regimen of once every four weeks. Treatment with lecanemab should be discontinued once the patient progresses to moderate AD.[1]

AD is a relentless, neurodegenerative disease that negatively impacts patients' memory, independence and dignity.[2,3,4] Anti-amyloid treatments like lecanemab target an underlying cause of the disease and have been proven to slow the progression of early AD for some patients before the more severe symptoms of the disease have developed.[5] The more severe symptoms that can occur at the moderate stage of the disease can include memory and information recall challenges, social withdrawal, confusion about days and dates, bladder and bowel control, changes in sleep patterns, and personality and behaviour changes.[6,7]

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 and United Kingdom (UK) (excluding Nordic countries), Eisai and Biogen co-promote the medicine, with Eisai distributing the product as the Marketing Authorisation (MA) Holder. In the Nordic countries, Eisai and BioArctic co-promote the medicine, with Eisai distributing the product as the MA Holder.

*Apolipoprotein E is a protein involved in the metabolism of fats in humans. It is implicated in, and is a major risk factor for, AD.[8]

▼: This medicine is subject to additional monitoring. This will allow quick identification of new safety information. If you have any side effects, talk to your healthcare professional. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play and Apple App store. 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 Aβ.[1,5] The medicine is authorised in 53 countries and is under regulatory review in 7 countries and regions.[1,9]

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).[5] Of the total number of patients randomised, 1,521 were in the EU indicated population (ApoE ε4 heterozygotes or non-carriers).[1,10] 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.[5]

The primary endpoint was the global cognitive and functional scale, Clinical Dementia Rating-Sum Of Boxes (CDR-SB†).[5] In the Clarity AD clinical trial, treatment with lecanemab (n=757), in the EU indicated population (ApoE ε4 heterozygotes or non-carriers, measured by control-based multiple imputation‡), reduced clinical decline on CDR-SB by 31% at 18 months compared to placebo (n=764). The mean CDR-SB score at baseline was approximately 3.2 in both groups.[1,10] 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; p=0.00001).[1,10] CDR-SB is a global cognitive and functional scale that measures six domains, including Memory, Orientation, Judgement and Problem Solving, Community Affairs, Home and Hobbies, and Personal Care.[11,12]

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.[1,10] 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; p=0.00002).[1,10] The ADCS-MCI-ADL assesses the ability of patients to function independently, including being able to participate in community activities, dress and feed themselves.[13]

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%).[1,10]

†CDR-SB is a disease staging tool used in clinical trials, which can help to stage dementia due to AD.[11] It is a global cognitive and functional scale that measures six domains, including memory, orientation, judgement and problem solving, community affairs, home and hobbies and personal care.[11,12]

‡As requested by the regulatory authority, efficacy analyses were conducted for ApoE ε4 non-carriers or heterozygote participants using a control-based multiple imputation method, in which all missing values were imputed with copy-increments (change between visits) using the actual value in the placebo group.[10] This methodology differs from that used in the Clarity AD primary analysis which used mixed-model repeat measures (MMRM) with missing at random assumption.[5,10]

§ARIA-H: amyloid-related imaging abnormalities with haemosiderin deposition (cerebral microhaemorrhages and superficial siderosis).

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

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 posts 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.

Digital Media Disclosures

From time to time, we have used, or expect in the future to use, our investor relations website, the Biogen LinkedIn account and the Biogen X account, as a means of disclosing information to the public in a broad, non-exclusionary manner, including for purposes of the SEC’s Regulation Fair Disclosure (Reg FD). Accordingly, investors should monitor our investor relations website and these social media channels in addition to our press releases, SEC filings, public conference calls and websites, as the information posted on them could be material to investors.

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