FOR UNITED KINGDOM AND EUROPEAN TRADE AND MEDICAL MEDIA

Leqembi®▼ (lecanemab) proposed Marketing Authorisation Variation for monthly intravenous maintenance dosing for the treatment of early Alzheimer's disease in the UK is validated for evaluation by the MHRA

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

The variation application will be evaluated by the Medicines and Healthcare products Regulatory Agency, which will decide whether to approve or reject the proposal

HATFIELD, HERTFORDSHIRE, UNITED KINGDOM (UK), and MAIDENHEAD, UK, 30 APRIL, 2025 – Eisai Europe Ltd. and Biogen Idec Ltd. announced today that the Medicines and Healthcare products Regulatory Agency (MHRA) has validated a proposed Marketing Authorisation Variation for monthly lecanemab dosing for eligible adult patients with early Alzheimer's disease (AD) in the UK, after an initial 18 months of treatment at the currently approved dosing regimen. The variation application will now be evaluated by the MHRA to decide whether to approve or reject the proposal.

Currently, lecanemab is licenced as an intravenous (IV) infusion once every two weeks (10 mg/kg).[1] If approved, this application may enable the dosing frequency to decrease to once every four weeks, after eligible patients have completed the initial 18 months of treatment every two weeks.

The submission is part of Eisai and Biogen's ongoing commitment to addressing the unmet needs of people living with AD, healthcare systems and wider society. Maintenance dosing is an important step forward in providing flexibility to eligible patients and healthcare professionals in managing this chronic, progressive disease.[2,3]

AD is a chronic disease which progresses in stages and increases in severity over time.[2] AD is the leading cause of death in the UK,[4] with early AD usually being the first stage of the disease where symptoms become noticeable, such as forgetting recent events or conversations.[5,6] As AD progresses, everyday activities, hobbies and social engagements become more challenging, and independence is lost.[5,6]

Eisai serves as the lead of lecanemab 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 UK, Eisai and Biogen co-promote the medicine, with Eisai distributing the product as the Marketing Authorisation Holder.

▼: 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 Yellow Card Scheme at www.mhra.gov.uk/yellowcard 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.

Media Contacts:

Eisai Europe, Ltd.
Communications Department
+44 (0) 7974 879 419
EMEA-comms@eisai.net

Biogen Idec Ltd.
UK External Affairs Team
+44 (0) 7753 136 948
ukicommunications@biogen.com

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.[1] The medicine is authorised in the U.S.,[7] Japan,[8] China,[9] South Korea,[10] Hong Kong,[11] Israel,[12] the United Arab Emirates,[13] the UK,[1] Mexico,[14] Macau,[15] Oman,[16] Taiwan,[16] the European Union,[17] and is under regulatory review in 13 countries.

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,” “assume,” “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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