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"Eisai is deeply concerned by the NICE decision announced today and very upset by what it means for people with Alzheimer's disease and their families in England, now and in the future. We call for urgent Government action on NHS readiness to tackle this condition and an immediate overhaul of the NICE appraisal process for early Alzheimer's disease medicines."

The National Institute for Health and Care Excellence (NICE) has announced that Leqembi®▼ (lecanemab) has not been recommended for use in the National Health Service (NHS) in England and those devolved nations that follow such decisions†[1]

Serious flaws in the NICE process have led to this decision by tipping the balance so heavily towards costs and away from treatment benefits. The assumptions that NICE has chosen to use for their assessment mean that even if Eisai provided lecanemab to the NHS for free, it would still not meet NICE's threshold for approval[1]

Eisai will appeal against this decision and categorically stands by the clinical and cost effectiveness of lecanemab in its licensed indication.[2] We remain committed to achieving equitable access to lecanemab for eligible patients in the UK

In August 2024, lecanemab became the first treatment that targets an underlying cause of Alzheimer's disease to be approved in the UK.[2,3] It is authorised for the treatment of mild cognitive impairment and mild dementia due to Alzheimer's disease in adult patients who are apolipoprotein E ε4 (ApoE ε4) heterozygotes or non-carriers in the UK[2]*

HATFIELD, HERTFORDSHIRE, UNITED KINGDOM (UK), and MAIDENHEAD, UK, 19 JUNE, 2025 — Responding to today's announcement by the National Institute of Health and Care Excellence (NICE) that it has not recommended Leqembi® (lecanemab) for use in its UK licensed indication in the National Health Service (NHS) in England and those devolved nations that follow such decisions,[1] senior Eisai executives and expert Alzheimer's doctors have issued the following statements.

Gary Hendler, Regional Chairman and CEO, Eisai EMEA, Senior Vice President & Global Corporate Officer, Eisai Co. Ltd, Tokyo, said,

"We are dismayed by today's decision and very upset about what it means for people with Alzheimer's disease and their families in England and those devolved nations that follow such decisions, both now and in the future. Alzheimer's disease is the biggest killer in the UK,[4] and the costs of managing it are set to double to £90 billion per year by 2040.[5] Tackling Alzheimer's disease is the biggest healthcare challenge in the world, and to do so successfully, all aspects of diagnosis and management, including focusing on the early stages of the disease, must be addressed.[6]"

"This decision protects a health service that is not yet ready to identify and manage patients in the early stages of their illness. On top of this, this outcome demonstrates that NICE's appraisal process is simply not fit to evaluate medicines for early Alzheimer's disease. There are currently over 130 new drugs in development for Alzheimer's around the world.[7] With 60% of those focused on the early stages of the disease,[7] we feel it is our duty to sound the alarm today that this appraisal process needs an immediate overhaul so that future medicines may be more appropriately assessed, and patients and their families can have hope regarding future treatments."

He added, "For the necessary change to happen in the management of Alzheimer's disease in the UK, there needs to be genuine conviction to take real steps to achieve this across the whole healthcare system. As such, we call on the UK Government to meet with us and other stakeholders

urgently to begin a robust national conversation about Alzheimer's and agree the significant changes required if we are to provide people with early Alzheimer's disease the care they need."

Nick Burgin, President and COO President Global Value & Access, Eisai EMEA, said,

"The science and economics have been telling healthcare systems around the world for a decade or more that to address the challenge of Alzheimer's disease, we must focus on early disease.[8,9] Unfortunately, we believe the NHS is not ready for this challenge, and worryingly, NHS England has so far failed to outline how, and how quickly, the service must adapt to become ready. Despite commitments and promises by successive different governments that they were preparing for a new era of managing Alzheimer's disease, not enough has changed. There must be a real commitment to drive this change and it is clear that this is simply not a priority at the moment."

Regarding the NICE appraisal process specifically, he commented,

"Eisai has participated in this process fully and in good faith for over two years, providing all the information requested, answering all questions and working with NICE to enable appropriate NHS patients to access this treatment. We will appeal against this decision and categorically stand by the clinical and cost effectiveness of lecanemab in its licensed indication.[2]"

"However, with patient need so great and so many other potential medicines in development for early Alzheimer's disease, we now also have a duty to call out what we believe are serious flaws of the NICE appraisal process. These include a failure to appropriately reflect the impact of the illness on family caregivers as well as the use of costs for giving the medicine to each patient that do not reflect the true cost of the resource required for this activity. For example, the EQ-5D assessment was used to assess health-related quality of life, however it undervalues the complex psychological, social and emotional toll of caring for someone with Alzheimer's disease.[10,11] These and other flaws have led to this decision by tipping the balance so heavily towards costs and away from treatment benefits. The assumptions that NICE has chosen to use for their assessment mean that even if Eisai provided lecanemab to the NHS for free, it would still not meet NICE's threshold for approval. This outcome demonstrates that the process is not fit for purpose and must be urgently reviewed so that other future medicines may be more appropriately assessed and have a realistic chance of benefiting patients and their families."

Shaeed Chowdhury, Medical Director, Eisai UK and Ireland, said,

"This decision is a heavy blow for the Alzheimer's disease community - not just for the patients and families but for all the healthcare professionals and researchers involved in Alzheimer's disease. In 2023, lecanemab was granted the Medicines & Healthcare products Regulatory Agency's Innovation Passport status under the UK's Innovative Licensing and Access Pathway (ILAP) framework.[12] ILAP was designed to accelerate access to groundbreaking treatments for the most urgent, unmet needs.[13] Yet today's decision moves us further from that promise."

"Patient groups have called for a managed access agreement which would allow some patients to use the new medicine via the NHS,[14] to support the generation of experience and evidence that is needed to assess the full benefits of new dementia treatments. We feel that it is extraordinary to come out of a two-year NICE appraisal process for an ILAP-designated product without even a managed access agreement. It is even more extraordinary when the Innovative Medicines Fund, the managed access fund designed to specifically support the introduction of innovative non-cancer treatments, has so far only been used for a handful of medicines.[15]"

"Whilst these new treatments are not a cure, they are a beginning. Alzheimer's disease progressively robs people of their memory, their independence and ultimately their dignity.[16] For families already carrying the emotional and/or financial weight of Alzheimer's disease, this is a frustrating setback."

"At Eisai, we firmly believe that each day without real change in the management of Alzheimer's disease incurs a greater financial and emotional cost for patients and their families, as well as imposing increased strain and pressure on the NHS and society."

"We cannot afford to wait for a cure. Because, while we wait, Alzheimer's doesn't."

Dr Elizabeth Coulthard, Professor of Cognitive Neurology, Bristol Medical School (Translational Health Sciences), said,

"We are still working hard to help people live well for longer by delaying symptoms of dementia. It is now really important that we find a way to deliver treatments equitably to people who will benefit most. I really hope a collaborative approach between the NHS, the pharmaceutical industry, charities and the public will eventually benefit the people I see in clinic every week who are experiencing the effects of early Alzheimer's disease."

Professor Sir John Hardy, UK Dementia Research Institute London, said,

"It's a shame that UK patients will not be able to access the treatment via the NHS in England, and I hope this decision can be revisited in the future. This is particularly the case given that the research which led to the development of anti-amyloid treatments was originally funded by the UK Government. It is important that patients in the UK and many other countries are able to feel the benefit of this research. We anticipate that real-world clinical data from countries where lecanemab has already launched will become available in the near future, so the role of the medicine in practice can be even better understood."

*Apolipoprotein E is a protein involved in the metabolism of fats in humans. It is implicated in AD.[17]

† Devolved nations which closely monitor and informally reference NICE outcomes in decision-making e.g. Wales and Northern Ireland.

▼: 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 doctor, pharmacist or nurse. 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.

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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 UK,[2] Mexico,[25] Macau, Oman, Taiwan,[26] the European Union,[27] Qatar and Singapore, and is under regulatory review in 12 countries and regions.[26]

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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