FDA Approves LEQEMBI IQLIK® (lecanemab-irmb) Subcutaneous Injection as an Initiation Dose for Early Alzheimer's Disease

LEQEMBI IQLIK is a first-of-its-kind anti-amyloid treatment worldwide, offering at-home dosing for initiation and maintenance (approved in the U.S.)

U.S. launch of LEQEMBI IQLIK as an initiation dose planned for late August 2026

TOKYO and CAMBRIDGE, Mass., July 14, 2026 — Eisai Co., Ltd. and Biogen Inc. (Nasdaq: BIIB), announced that the U.S. Food and Drug Administration (FDA) has approved a supplemental Biologics License Application (sBLA) for a once-weekly lecanemab-irmb subcutaneous injection (U.S. brand name: LEQEMBI IQLIK®) as an initiation dose for the treatment of early Alzheimer's disease.

LEQEMBI IQLIK is administered via an autoinjector, introducing a convenient alternative to intravenous (IV) dosing from the start of treatment. For initiation, the approved regimen is 500 mg given once weekly as two 250 mg injections, each delivered in approximately 15 seconds. LEQEMBI IQLIK may also be used for maintenance dosing at 360 mg once weekly after 18 months of IV or subcutaneous treatment. Throughout the entire treatment course - from initiation through maintenance - patients may receive LEQEMBI either as IV infusion or as subcutaneous (SC) injection with LEQEMBI IQLIK. Patients may also switch from IV to SC administration, or vice versa, providing greater convenience and flexibility in LEQEMBI administration.

LEQEMBI is indicated in the United States for adults with mild cognitive impairment (MCI) or mild dementia due to Alzheimer's disease, collectively referred to as early Alzheimer's disease. MCI due to AD is the earliest symptomatic stage of Alzheimer's disease and can appear with subtle symptoms such as forgetfulness, confusion, or feeling at a loss for words.

Clinical Data Supporting FDA Approval of Subcutaneous Initiation Dosing

The FDA approval of LEQEMBI IQLIK as an initiation dose is supported by a comprehensive clinical data package evaluating SC administration of lecanemab across multiple studies and a range of dosing regimens. Sub-studies within the Phase 3 Clarity AD long-term extension (LTE), following the 18-month core study in individuals with early Alzheimer's disease, showed:

- Once-weekly subcutaneous administration achieved exposure equivalent to intravenous dosing, supporting similar clinical (efficacy) and biomarker (amyloid removal) benefits.
- The rate of exposure-related adverse events such as ARIA-E with SC administration is expected to be comparable with IV administration. There was no increase in isolated ARIA-H (i.e., ARIA-H in patients who did not also experience ARIA-E) for LEQEMBI compared to placebo.
- The overall safety profile of SC administration was generally similar to intravenous administration. Injection-related reactions were observed with subcutaneous LEQEMBI, most of which were localized, while systemic reactions were less frequently observed.

“The approval of LEQEMBI IQLIK for initiation dosing marks a new era of Alzheimer's treatments," said Howard Fillit, MD, Co-Founder and Chief Science Officer Emeritus of the Alzheimer's Drug Discovery Foundation (ADDF). "For the first time, patients and their care partners have meaningful choice in how anti-amyloid treatment is delivered. As treatment approaches continue to expand, innovations in drug delivery will play a critical role in improving access to therapies, supporting the investigation of potential combination treatments, and advancing a precision medicine approach to Alzheimer’s care.”

Expanding Treatment Flexibility Across the Alzheimer’s Disease Care Pathway

The approval of LEQEMBI IQLIK as a subcutaneous initiation dose provides patients and care partners with the only at-home administration option throughout the Alzheimer’s disease treatment journey which could support access and delivery of care across healthcare settings. Subcutaneous administration may:

- Reduce the burden of clinic visits for patients and care partners
- Reduce reliance on infusion and associated healthcare resources
- Decrease treatment preparation and administration time, and nursing monitoring requirements
- Preserve infusion capacity for patients who prefer or require intravenous therapy

Insights from an autoinjector acceptability study indicated that 94% of patients with early Alzheimer’s disease and their care partners, found the LEQEMBI IQLIK device easy to use, with high levels of satisfaction and confidence in using it in an at-home setting.*

Support for Patients

The LEQEMBI Companion™ program offers help with understanding insurance coverage and potential out-of-pocket costs, and identifying financial support programs, including the LEQEMBI Copay Assistance Program for eligible patients.

To further support access to LEQEMBI for certain patients who need help paying for their medicines, Eisai’s Patient Assistance Program (PAP) will provide LEQEMBI and LEQEMBI IQLIK at no cost, for eligible uninsured patients, who meet financial need and other program criteria.

LEQEMBI IQLIK for initiation dosing is expected to be available in late August 2026 in the U.S. Patients will receive LEQEMBI IQLIK from a specialty pharmacy.

Eisai serves as the lead for lecanemab’s development and regulatory submissions globally with Eisai and Biogen co-commercializing and co-promoting the product and Eisai having final decision-making authority.

*Based on in-person interviews of 50 patients with early AD and 50 care partners currently assisting people with early AD. Participants were given the opportunity to interact with a training autoinjector device (containing no needles or medication) and an injection pad, then asked to answer computer-based surveys about their experience, including “How difficult or easy was it to use the self-injection device?”

INDICATION

LEQEMBI® is indicated for the treatment of Alzheimer's disease (AD). Treatment with LEQEMBI should be initiated in patients with mild cognitive impairment (MCI) or mild dementia stage of disease, the population in which treatment was initiated in clinical trials.

IMPORTANT SAFETY INFORMATION

WARNING: AMYLOID-RELATED IMAGING ABNORMALITIES (ARIA)

- **Monoclonal antibodies directed against aggregated forms of beta amyloid, including LEQEMBI, can cause ARIA, characterized as ARIA with edema (ARIA-E) and ARIA with hemosiderin deposition (ARIA-H). Incidence and timing of ARIA vary among treatments. ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events, including seizure and status epilepticus, can occur. ARIA can be fatal. Serious intracerebral hemorrhages (ICH) >1 cm, some of which have been fatal, have been observed with this class of medications. Because ARIA-E can cause focal neurologic deficits that can mimic an ischemic stroke, consider whether such symptoms could be due to ARIA-E before giving thrombolytic therapy to a patient being treated with LEQEMBI.**
  - **Apolipoprotein E ε4 (ApoE ε4) Homozygotes: Patients who are ApoE ε4 homozygotes (~15% of patients with AD) treated with this class of medications have a higher incidence of ARIA, including symptomatic, serious, and severe radiographic ARIA, compared to heterozygotes and noncarriers. Testing for ApoE ε4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA. Prior to testing, prescribers should discuss with patients the risk of ARIA across genotypes and the implications of genetic testing results. Prescribers should inform patients that if genotype testing is not performed, they can still be treated with LEQEMBI; however, it cannot be determined if they are ApoE ε4 homozygotes and at higher risk for ARIA.**
- **Consider the benefit of LEQEMBI for the treatment of AD and the potential risk of serious ARIA events when deciding to initiate treatment with LEQEMBI.**

CONTRAINDICATION

Contraindicated in patients with serious hypersensitivity to lecanemab-irmb or to any of the excipients. Reactions have included angioedema and anaphylaxis.

WARNINGS AND PRECAUTIONS

AMYLOID-RELATED IMAGING ABNORMALITIES

Medications in this class, including LEQEMBI, can cause ARIA-E, which can be observed on MRI as brain edema or sulcal effusions, and ARIA-H, which includes microhemorrhage and superficial siderosis. ARIA can occur spontaneously in patients with AD, particularly in patients with MRI findings suggestive of cerebral amyloid angiopathy (CAA), such as pretreatment microhemorrhage or superficial siderosis. ARIA-H generally occurs with ARIA-E. Reported ARIA symptoms may include headache, confusion, visual changes, dizziness, nausea, and gait difficulty. Focal neurologic deficits may also occur. Symptoms usually resolve over time.

Incidence of ARIA

Symptomatic ARIA occurred in 3% and serious ARIA symptoms in 0.7% with LEQEMBI. Clinical ARIA symptoms resolved in 79% of patients during the period of observation. ARIA, including asymptomatic radiographic events, was observed: LEQEMBI, 21%; placebo, 9%. ARIA-E was observed: LEQEMBI, 13%; placebo, 2%. ARIA-H was observed: LEQEMBI, 17%; placebo, 9%. No increase in isolated ARIA-H was observed for LEQEMBI vs placebo.

Incidence of ICH

ICH >1 cm in diameter was reported in 0.7% with LEQEMBI vs 0.1% with placebo. Fatal events of ICH in patients taking LEQEMBI have been observed.

Risk Factors of ARIA and ICH

ApoE ε4 Carrier Status

Of the patients taking LEQEMBI, 16% were ApoE ε4 homozygotes, 53% were heterozygotes, and 31% were noncarriers. With LEQEMBI, ARIA was higher in ApoE ε4 homozygotes (LEQEMBI: 45%; placebo: 22%) than in heterozygotes (LEQEMBI: 19%; placebo: 9%) and noncarriers (LEQEMBI: 13%; placebo: 4%). Symptomatic ARIA-E occurred in 9% of ApoE ε4 homozygotes vs 2% of heterozygotes and 1% of noncarriers. Serious ARIA events occurred in 3% of ApoE ε4 homozygotes and in ~1% of heterozygotes and noncarriers. The recommendations on management of ARIA do not differ between ApoE ε4 carriers and noncarriers.

Radiographic Findings of CAA

Neuroimaging findings that may indicate CAA include evidence of prior ICH, cerebral microhemorrhage, and cortical superficial siderosis. CAA has an increased risk for ICH. The presence of an ApoE ε4 allele is also associated with CAA.

The baseline presence of at least 2 microhemorrhages or the presence of at least 1 area of superficial siderosis on MRI, which may be suggestive of CAA, have been identified as risk factors for ARIA. Patients were excluded from Clarity AD for the presence of >4 microhemorrhages and additional findings suggestive of CAA (prior cerebral hemorrhage >1 cm in greatest diameter, superficial siderosis, vasogenic edema) or other lesions (aneurysm, vascular malformation) that could potentially increase the risk of ICH.

Concomitant Antithrombotic or Thrombolytic Medication

In Clarity AD, baseline use of antithrombotic medication (aspirin, other antiplatelets, or anticoagulants) was allowed if the patient was on a stable dose. Most exposures were to aspirin. Antithrombotic medications did not increase the risk of ARIA with LEQEMBI. The incidence of ICH: 0.9% in patients taking LEQEMBI with a concomitant antithrombotic medication vs 0.6% with no antithrombotic and 2.5% in patients taking LEQEMBI with an anticoagulant alone or with antiplatelet medication such as aspirin vs none in patients receiving placebo.

Fatal cerebral hemorrhage has occurred in 1 patient taking an anti-amyloid monoclonal antibody in the setting of focal neurologic symptoms of ARIA and the use of a thrombolytic agent.

Additional caution should be exercised when considering the administration of antithrombotics or a thrombolytic agent (e.g., tissue plasminogen activator) to a patient already being treated with LEQEMBI. Because ARIA-E can cause focal neurologic deficits that can mimic an ischemic stroke, treating clinicians should consider whether such symptoms could be due to ARIA-E before giving thrombolytic therapy in a patient being treated with LEQEMBI.

Caution should be exercised when considering the use of LEQEMBI in patients with factors that indicate an increased risk for ICH and, in particular, patients who need to be on anticoagulant therapy or patients with findings on MRI that are suggestive of CAA.

Radiographic Severity With LEQEMBI

Most ARIA-E radiographic events occurred within the first 7 doses, although ARIA can occur at any time, and patients can have >1 episode. Maximum radiographic severity of ARIA-E with LEQEMBI was mild in 4%, moderate in 7%, and severe in 1% of patients. Resolution on MRI occurred in 52% of ARIA-E patients by 12 weeks, 81% by 17 weeks, and 100% overall after detection. Maximum radiographic severity of ARIA-H microhemorrhage with LEQEMBI was mild in 9%, moderate in 2%, and severe in 3% of patients; superficial siderosis was mild in 4%, moderate in 1%, and severe in 0.4% of patients. With LEQEMBI, the rate of severe

radiographic ARIA-E was highest in ApoE ε4 homozygotes (5%) vs heterozygotes (0.4%) or noncarriers (0%). With LEQEMBI, the rate of severe radiographic ARIA-H was highest in ApoE ε4 homozygotes (13.5%) vs heterozygotes (2.1%) or noncarriers (1.1%).

Monitoring and Dose Management Guidelines

Baseline brain MRI and periodic monitoring with MRI are recommended. Enhanced clinical vigilance for ARIA is recommended during the first 14 weeks of treatment. Depending on ARIA-E and ARIA-H clinical symptoms and radiographic severity, use clinical judgment when considering whether to continue dosing or to temporarily or permanently discontinue LEQEMBI. If a patient experiences ARIA symptoms, clinical evaluation should be performed, including MRI if indicated. If ARIA is observed on MRI, careful clinical evaluation should be performed prior to continuing treatment.

HYPERSENSITIVITY REACTIONS

Hypersensitivity reactions, including angioedema, bronchospasm, and anaphylaxis, have occurred with LEQEMBI. Promptly discontinue the infusion upon the first observation of any signs or symptoms consistent with a hypersensitivity reaction and initiate appropriate therapy.

INFUSION-RELATED REACTIONS (IRRs)

IRRs were observed—LEQEMBI: 26%; placebo: 7%—and most cases with LEQEMBI (75%) occurred with the first infusion. IRRs were mostly mild (69%) or moderate (28%). Symptoms included fever and flu-like symptoms (chills, generalized aches, feeling shaky, and joint pain), nausea, vomiting, hypotension, hypertension, and oxygen desaturation.

IRRs can occur during or after the completion of infusion. In the event of an IRR during the infusion, the infusion rate may be reduced or discontinued, and appropriate therapy initiated as clinically indicated. Consider prophylactic treatment prior to future infusions with antihistamines, acetaminophen, nonsteroidal anti-inflammatory drugs, or corticosteroids.

ADVERSE REACTIONS

- The most common adverse reactions reported in ≥5% with LEQEMBI infusion every 2 weeks and ≥2% higher than placebo were IRRs (LEQEMBI: 26%; placebo: 7%), ARIA-H (LEQEMBI: 14%; placebo: 8%), ARIA-E (LEQEMBI: 13%; placebo: 2%), headache (LEQEMBI: 11%; placebo: 8%), superficial siderosis of central nervous system (LEQEMBI: 6%; placebo: 3%), rash (LEQEMBI: 6%; placebo: 4%), and nausea/vomiting (LEQEMBI: 6%; placebo: 4%)
- The safety profile of subcutaneous LEQEMBI was similar to intravenous infusion. Subcutaneous dosing was associated with mostly localized (erythema, induration, swelling, heat, pain, pruritus, rash, ecchymosis, nodule, and hematoma) and less frequent systemic (headache, chills, fever, and fatigue) injection-related reactions, majority at first dose when initiating therapy. Localized reactions that were recurrent and/or delayed were observed. Severe localized reactions and cases leading to dose discontinuation or interruption occurred.

LEQEMBI (lecanemab-irmb) is available:

- Intravenous infusion: 100 mg/mL
- Subcutaneous injection: 200 mg/mL

Please see full Prescribing Information for LEQEMBI, including Boxed WARNING.

Click **here** to access the LEQEMBI digital library with assets available for download.

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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 (IgG1) monoclonal antibody directed against aggregated soluble (protofibril) and insoluble forms of amyloid-beta (Aβ).

Lecanemab has been approved in 53 countries and regions including Japan, the United States, China, Europe, South Korea, Taiwan, and Saudi Arabia, and is under regulatory review in 6 countries. Following the initial phase with treatment every two weeks for 18 months, intravenous (IV) maintenance dosing with treatment every four weeks was approved in 8 countries including the U.S., China, the UK, and others, and applications have been filed in 12 countries and regions. The U.S. FDA approved Eisai's Biologics License Application (BLA) for subcutaneous maintenance dosing with LEQEMBI IQLIK in August 2025. In November 2025, an application for a subcutaneous injectable formulation in Japan was submitted. In January 2026, the Biologics License Application (BLA) for the subcutaneous formulation was accepted in China. In December 2025, lecanemab (IV) has been included in the “Commercial Insurance Innovative Drug List”, recently introduced by the National Healthcare Security Administration (NHSA) of China.

LEQEMBI's approvals in these countries were based on Phase 3 data from Eisai's global placebo-controlled, double-blind, parallel-group, randomized Clarity AD clinical trial, in which it met its primary endpoint and all key secondary endpoints with statistically significant results. The primary endpoint was the global cognitive and functional scale, Clinical Dementia Rating Sum of Boxes (CDR-SB). Clarity AD evaluated lecanemab 10 mg/kg bi-weekly IV treatment of early Alzheimer's disease, which involved 1,795 patients (treatment group: 898, placebo group: 897). 95% of patients who completed the core study (18 months) chose to continue in the long-term extension study (LTE), with 478 patients still receiving treatment for four years. In the Clarity AD core clinical study, data showed LEQEMBI IV significantly slowed disease progression at 18 months (27% vs placebo), and the mean change from baseline between the lecanemab treated group and the placebo group after 18 months was -0.45 (P=0.00005) on the primary endpoint of CDR-SB global cognitive and functional scale.

To provide context, a change from 0.5 to 1 on the Clinical Dementia Rating (CDR) score domains of Memory, Community Affairs and Home/Hobbies reflects a shift from mild impairment to loss of independence. This can affect a person's ability to be left alone safely, recall recent events, participate in daily activities, manage household tasks, and engage in hobbies and intellectual interests.

LEQEMBI also rapidly reduced plaque as early as three months (−59.1 CL difference vs placebo in amyloid level at 18 months; P<0.00001).* Additionally, LEQEMBI continued to show benefit over a four-year LTE treatment period; in a subgroup analysis, 81 percent of LEQEMBI patients who stayed on treatment remained in the early AD stages at four years.**

Over three years of treatment, including both the core study and the LTE, data showed lecanemab demonstrated a reduction in cognitive decline—measured by CDR-SB—of 1.01 points compared to the expected decline observed in the Alzheimer's Disease Neuroimaging Initiative (ADNI)** cohort. This benefit grew more pronounced after four years, with a reduction of 1.75 points. Similarly, when benchmarked against the expected decline in the BioFINDER cohort, lecanemab showed a reduction of 1.40 points at three years and an even greater reduction of 2.17 points at the four-year mark. In Clarity AD, the most common adverse events (>10%) in the lecanemab group were infusion reactions, ARIA-H (combined cerebral microhemorrhages, cerebral macrohemorrhages, and superficial siderosis), ARIA-E (edema/effusion), headache, and fall.

*The Centiloid scale is used for amyloid PET, where 0 CL is anchored as the average amyloid in young people without amyloid plaques, and 100 is anchored as the average amyloid level in moderate AD. The baseline centiloid level in CLARITY AD was approximately 78 CL. Plaque negativity is defined as conversion to amyloid PET negative (<30 centiloid, or CL).

**Prespecified subgroup analysis of reduced risk of progression: Progression was defined as CDR-SB score progressing to moderate or severe dementia (≥9.5), based on Kaplan-Meier plots.

2. About Protofibrils

Protofibrils are thought to be the most toxic Aβ species that contribute to brain damage in AD and play a major role in the cognitive decline of this progressive and devastating disease. Protofibrils can cause neuronal and synaptic damage in the brain, which can subsequently adversely affect cognitive function through multiple mechanisms.[18]The mechanism by which this occurs has been reported not only by increasing the formation of insoluble Aβ plaques, but also by directly damaging signaling between neurons and other cells. It is believed that reducing protofibrils may reduce neuronal damage and cognitive impairment, potentially preventing the progression of AD.[2]

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 lecanemab 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. The website and social media channels are intended for audiences outside of the UK and Europe. For audiences based in the UK and Europe, please visit www.eisai.eu and Eisai EMEA LinkedIn.

6. 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 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, 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 including for lecanemab-irmb (LEQEMBI IQLIK); 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 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 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 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 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 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.

Digital Media Disclosure

From time to time, we have used, or expect in the future to use, our investor relations website (investors.biogen.com), the Biogen LinkedIn account (linkedin.com/company/biogen-) and the Biogen X account (https://x.com/biogen) 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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