U.S. Food and Drug Administration to Convene Advisory Committee Meeting to Discuss the TRAILBLAZER-ALZ 2 Study of Donanemab

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INDIANAPOLIS, March 8, 2024 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that the U.S. Food and Drug Administration (FDA) expects to convene a meeting of the Peripheral and Central Nervous System Drugs Advisory Committee (PCNS) to discuss the Phase 3 TRAILBLAZER-ALZ 2 trial, which evaluated the efficacy and safety of donanemab in early symptomatic Alzheimer's disease.

The FDA has informed Lilly it wants to further understand topics related to evaluating the safety and efficacy of donanemab, including the safety results in donanemab-treated patients and the efficacy implications of the unique trial design of the TRAILBLAZER-ALZ 2 study, including its limited-duration dosing regimen that allowed patients to complete treatment based on an assessment of amyloid plaque and the inclusion of participants based on tau levels.

The date of the advisory committee meeting for donanemab has yet to be set by the FDA, and, as a result, the timing of expected FDA action on donanemab will be delayed beyond the first quarter of 2024. While it is unusual for an advisory committee to occur after the anticipated FDA action date, the advisory committee meeting for donanemab follows similar meetings for the two other amyloid plaque-targeting therapies the FDA has approved.

"We are confident in donanemab's potential to offer very meaningful benefits to people with early symptomatic Alzheimer's disease. It was unexpected to learn the FDA will convene an advisory committee at this stage in the review process, but we look forward to the opportunity to further present the TRAILBLAZER-ALZ 2 results and put donanemab's strong efficacy in the context of safety. We will work with the FDA and the stakeholders in the community to make that presentation and answer all questions," said Anne White, executive vice president of Eli Lilly and Company, and president of Lilly Neuroscience.

TRAILBLAZER-ALZ 2 is a Phase 3, double-blind, placebo-controlled study to evaluate the safety and efficacy of donanemab in participants ages 60-85 years with early symptomatic Alzheimer's disease (MCI or mild dementia due to Alzheimer's disease) with the presence of confirmed Alzheimer's disease neuropathology. Alzheimer's disease is a progressive and fatal disease that in its early symptomatic stages affects 6-7.5 million Americans. The trial enrolled 1,736 participants, across eight countries, selected based on cognitive assessments in conjunction with amyloid plaque imaging and tau staging by positron emission tomography (PET) imaging.

Compared to participants in similar trials of other amyloid plaque-targeting therapies, the TRAILBLAZER-ALZ 2 participants were more progressed in their disease. All groups of trial participants, regardless of tau level, benefited from treatment with donanemab, with patients in earlier stages of the disease experiencing the strongest results. Donanemab also demonstrated clinical benefits using a limited-duration treatment regimen, with nearly half of clinical trial participants completing their course of treatment in six or 12 months. The key risk associated with donanemab is amyloid related imaging abnormalities, or ARIA, which can be serious and life-threatening. Other most commonly reported risks include infusion-related reactions, headache and nausea.

The Phase 3 TRAILBLAZER-ALZ 2 study results were published in the *Journal of the American Medical Association* (JAMA). Lilly continues to study donanemab in multiple clinical trials.

This action does not result in a change to Lilly's 2024 financial guidance.

About Lilly
Lilly is a medicine company turning science into healing to make life better for people around the world. We've been pioneering life-changing discoveries for nearly 150 years, and today our medicines help more than 51 million people across the globe. Harnessing the power of biotechnology, chemistry and genetic medicine, our scientists are urgently advancing new discoveries to solve some of the world's most significant health challenges: redefining diabetes care; treating obesity and curtailing its most devastating long-term effects; advancing the fight against Alzheimer's disease; providing solutions to some of the most debilitating immune system disorders; and transforming the most difficult-to-treat cancers into manageable diseases. With each step toward a healthier world, we're motivated by one thing: making life better for millions more people. That includes delivering innovative clinical trials that reflect the diversity of our world and working to ensure our medicines are accessible and affordable. To learn more, visit Lilly.com and Lilly.com/news, or follow us on Facebook, Instagram and LinkedIn. P-LLY

Cautionary Statement Regarding Forward-Looking Statements
This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about donanemab as a potential treatment for people with early symptomatic Alzheimer's disease and reflects Lilly's current beliefs and expectations. However, as with any such undertaking, there are substantial risks and uncertainties in the process of drug research, development, and commercialization. Among other things, there is no guarantee that future study results will be consistent with study findings to date, that donanemab will prove to be a safe and effective treatment, or that donanemab will receive regulatory approval. For further discussion of these and other risks and uncertainties, see Lilly's Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

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