Lilly Statement on FDA Advisory Committee Meeting on Donanemab for Early Symptomatic Alzheimer’s Disease

May 7, 2024

The U.S. Food and Drug Administration (FDA) will convene an in-person meeting of the Peripheral and Central Nervous System Drugs Advisory Committee (PCNS) on Monday, June 10, 2024, to discuss donanemab, which Eli Lilly and Company (NYSE: LLY) has submitted for the treatment of early symptomatic Alzheimer’s disease. The open public hearing portion of the meeting will be conducted virtually.

The Phase 3 study submitted as part of this application, TRAILBLAZER-ALZ 2, is a 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 (mild cognitive impairment 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.

The 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, including TRAILBLAZER-ALZ-3, studying donanemab for the prevention of Alzheimer’s disease.

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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