Donanemab receives positive opinion from the Committee for Medicinal Products for Human Use (CHMP) in early symptomatic Alzheimer's disease

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The opinion will now be referred to the European Commission for final regulatory decision on donanemab

INDIANAPOLIS, July 25, 2025 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending donanemab for the treatment of early symptomatic Alzheimer's disease in adults with confirmed amyloid pathology who are apolipoprotein E ε4 (ApoE4) heterozygotes or non-carriers. The European Commission is expected to make a regulatory decision on donanemab in the coming months.

"This positive opinion marks a significant milestone in our efforts to bring donanemab to eligible patients across Europe," said Patrik Jonsson, executive vice president and president of Lilly International. "Donanemab has the potential to make a meaningful difference for people living with early symptomatic Alzheimer's disease, and Lilly remains committed to advancing the science through ongoing clinical trials and programs."

Alzheimer's disease currently affects as many as 6.9 million people in Europe, with this figure expected to almost double by 2050 as aging populations continue to increase.[1-2] Approximately one-third of individuals with mild cognitive impairment or mild dementia due to Alzheimer's disease progress to the next clinical stage of disease in one year.[3]

The positive opinion was primarily based on clinical trial data from the TRAILBLAZER-ALZ 2 clinical trial demonstrating that donanemab significantly slowed cognitive and functional decline and reduced the risk of progressing to the next clinical stage of disease, as well as the TRAILBLAZER-ALZ 6 clinical trial which evaluated a modified titration dosing schedule.[4] In the TRAILBLAZER-ALZ 6 study, the modified titration schedule significantly lowered the incidence of amyloid-related imaging abnormalities with edema/effusion (ARIA-E) versus the dosing schedule used in TRAILBLAZER-ALZ 2 at 24 and 52 weeks, while still achieving similar levels of amyloid plaque removal and P-tau217 reduction.

Amyloid-related imaging abnormalities (ARIA) with edema/effusion (ARIA-E) and with hemorrhage/ hemosiderosis (ARIA-H) are side effects within the class of therapies that do not usually cause any symptoms, but serious and life-threatening symptoms can occur. ARIA can be fatal. Carriers of one or two copies of the ApoE4 gene may be at higher risk of developing Alzheimer's disease and experiencing ARIA. Patients should discuss any safety concerns with their healthcare providers.

About Kisunla
Donanemab, a monthly infusion, is currently marketed as Kisunla in the United States and other countries, including Japan, China, United Kingdom, UAE, Qatar, Kuwait, Bahrain, Singapore*, Taiwan, Brazil, Mexico and Australia. In the United States, Japan, China and many other countries, donanemab is approved for patients regardless of ApoE4 status. Donanemab is the first and only amyloid plaque-targeting therapy with evidence to support stopping therapy when amyloid plaques are removed, which can result in lower treatment costs and fewer infusions.[5-8]

*Donanemab is branded as Lormalzi in Singapore.

U.S. INDICATION AND SAFETY SUMMARY WITH WARNINGS

Kisunla™ (kih-SUHN-lah)s used to treat adults with early symptomatic Alzheimer's disease (AD), which includes mild cognitive impairment (MCI) or mild dementia stage of disease.

Warnings - Kisunla can cause Amyloid-Related Imaging Abnormalities or "ARIA." This is a common side effect that does not usually cause any symptoms, but serious symptoms can occur. ARIA can be fatal. ARIA is most commonly seen as temporary swelling in an area or areas of the brain that usually goes away over time. Some people may also have spots of bleeding on the surface of or in the brain and infrequently, larger areas of bleeding in the brain can occur. Although most people do not have symptoms, some people have headaches, dizziness, nausea, difficulty walking, confusion, vision changes and seizures.

Some people have a genetic risk factor (homozygous apolipoprotein E ε4 gene carriers) that may cause an increased risk for ARIA. Talk to your healthcare provider about testing to see if you have this risk factor.

You may be at higher risk of developing bleeding in the brain if you take medicines to reduce blood clots from forming (antithrombotic medicines) while receiving Kisunla. **Talk to your healthcare provider to see if you are on any medicines that increase this risk.**

Your healthcare provider will do magnetic resonance imaging (MRI) brain scans before and during your treatment with Kisunla to check you for ARIA. You should carry information that you are receiving Kisunla, which can cause ARIA, and that ARIA symptoms can look like stroke symptoms. **Call your healthcare provider or go to the nearest hospital emergency room right away if you have any of the symptoms listed above.**

There are registries that collect information on treatments for Alzheimer's disease. Your healthcare provider can help you become enrolled in these registries.

Warnings - Kisunla can cause serious allergic and infusion-related reactions. Do not receive Kisunla if you have serious allergic reactions to donanemab-azbt or any of the ingredients in Kisunla. Symptoms may include swelling of the face, lips, mouth, or eyelids, problems breathing, hives, chills, irritation of skin, nausea, vomiting, sweating, headache, or chest pain. You will be monitored for at least 30 minutes after you receive Kisunla for any reaction. **Tell your healthcare provider right away if you have these symptoms or any reaction during or after a Kisunla infusion.**

Other common side effects

- Headache

Tell your healthcare provider right away if you have any side effects. These are not all of the possible side effects of Kisunla. **You can report side effects at 1-800-FDA-1088 or www.fda.gov/medwatch**.

Before you receive Kisunla, tell your healthcare provider:

- About all medicines you take, including prescription and over-the-counter medicines, as well as vitamins and herbal supplements. Especially tell your healthcare provider if you have medicines to reduce blood clots from forming (antithrombotic medicines, including aspirin).
- About all of your medical conditions including if you are pregnant, breastfeeding, or plan to become pregnant or breastfeed. Kisunla has not been studied in people who were pregnant or breastfeeding. It is not known if Kisunla could harm your unborn or breastfeeding baby.

How to receive Kisunla
Kisunla is a prescription medicine given through an intravenous (IV) infusion using a needle inserted into a vein in your arm. Kisunla is given once every 4 weeks. Each infusion will last about 30 minutes.

Learn more
For more information about Kisunla, call 1-800-LillyRx (1-800-545-5979) or go to **kisunla.lilly.com**.

This summary provides basic information about Kisunla. It does not include all information known about this medicine. Read the information given to you about Kisunla. This information does not take the place of talking with your healthcare provider. Be sure to talk to your healthcare provider about Kisunla. Your healthcare provider is the best person to help you decide if Kisunla is right for you.

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Please see full Prescribing Information including boxed warning for ARIA and Medication Guide for Kisunla.

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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 tens of millions of 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 Kisunla (donanemab-azbt) as a potential treatment for people with early symptomatic Alzheimer's disease, and regulatory approval and other milestones relating to Kisunla and reflects Lilly's current beliefs and expectations. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of drug research, development, and commercialization. Among other things, there is no guarantee that planned or ongoing studies will be completed as planned, that future study results will be consistent with study findings to date, that Kisunla will receive additional regulatory approvals or that Kisunla will be commercially successful. 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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