Lilly's Kisunla (donanemab) receives marketing authorization by European Commission for the treatment of early symptomatic Alzheimer's disease

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Approved for earliest symptomatic stages of disease, demonstrating significant slowing of cognitive and functional decline

Only therapy with evidence to support completing course of treatment once amyloid plaques are reduced to minimal levels

INDIANAPOLIS, Sept. 25, 2025 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that the European Commission (EC) has granted marketing authorization for Kisunla (donanemab) for the treatment of early symptomatic Alzheimer's disease (AD), in adults with mild cognitive impairment as well as those with mild dementia stages of AD with confirmed amyloid pathology who are apolipoprotein E (ApoE4) heterozygotes or non-carriers.

"Kisunla demonstrated meaningful results in people with early symptomatic Alzheimer's disease by significantly slowing cognitive and functional decline in our Phase 3 TRAILBLAZER-ALZ 2 study," said Patrik Jonsson, executive vice president and president of Lilly International. "The data shows that the earlier patients are identified, diagnosed, and treated with Kisunla, the greater the response to treatment. This authorization brings a new option to patients in Europe—offering hope and the potential for more time to focus on what matters most."

Amyloid is a protein produced naturally in the body that can clump together to create amyloid plaques.[1,2] The excessive buildup of amyloid plaques in the brain may lead to memory and thinking issues associated with Alzheimer's disease. Kisunla can help the body remove the excessive buildup of amyloid plaques and slow the decline that may diminish people's ability to: remember new information, important dates and appointments; plan and organize; make meals; use household appliances; manage finances; and be left alone.[1-3]

Kisunla is the only once-monthly amyloid plaque-targeting therapy with evidence supporting completing course of treatment once amyloid is reduced to minimal levels. This may reduce infusion burden and treatment costs. Treatment with Kisunla slows disease progression which may help preserve cognitive function and independence longer.[4-7] Data has also shown that Kisunla can significantly reduce the risk of progressing to the next clinical stage of disease over 18 months.[4,8]

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.[9,10] Alzheimer's disease progresses in stages that increase in severity over time, resulting in loss of independence and ability to care for oneself. There is an urgent need for detection, referral to specialists, diagnosis and treatment at the earliest stages of Alzheimer's disease as approximately one-third of individuals in early symptomatic stages of the disease will progress to more advanced clinical stages within one year.[11]

The Kisunla marketing authorization in the European Union is based on the TRAILBLAZER-ALZ 2 and the TRAILBLAZER-ALZ 6 clinical trials. The Phase 3 TRAILBLAZER-ALZ 2 study demonstrated Kisunla significantly slowed cognitive and functional decline.[4,8] Cognitive and functional decline involves greater memory and thinking problems, affecting daily activities and needing more caregiver support.[4,12]

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.

The dosing schedule is based on the Phase 3b TRAILBLAZER-ALZ 6 study, which demonstrated that the incidence of ARIA-E was significantly lowered at 24 and 52 weeks using a more gradual titration dosing schedule versus the dosing schedule used in TRAILBLAZER-ALZ 2. This gradual dosing increase still achieved similar levels of amyloid plaque removal and P-tau217 reduction.[8]

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. In the European Union, Kisunla is approved for patients who are ApoE4 heterozygotes or non-carriers. Donanemab is the first and only amyloid plaque-targeting therapy with evidence supporting completing the course of treatment when amyloid plaques are removed to minimal levels, which can result in lower treatment costs and fewer infusions.

**Donanemab is branded as Lormalzi in Singapore*

About TRAILBLAZER-ALZ 2
TRAILBLAZER-ALZ 2 (NCT04437511) was a Phase 3, double-blind, placebo-controlled study to evaluate the safety and efficacy of donanemab over 18 months in participants 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. The trial enrolled 1,736 participants, across 8 countries, selected based on cognitive assessments in conjunction with evidence of Alzheimer's disease pathology. The Phase 3 TRAILBLAZER-ALZ 2 study results were published in the Journal of the American Medical Association (JAMA).

About TRAILBLAZER-ALZ 6 study and the TRAILBLAZER-ALZ program
TRAILBLAZER-ALZ 6 (NCT05738486) was a Phase 3b, multicenter, randomized, double-blind study to investigate different dosing regimens and their effect on ARIA-E in adults with early symptomatic Alzheimer's disease. The trial enrolled 843 participants ages 60-85 selected based on cognitive

assessments in conjunction with amyloid plaque imaging by PET scan. The primary endpoint results were published in *Alzheimer's and Dementia*.

Lilly continues to study donanemab in multiple clinical trials, including TRAILBLAZER-ALZ 3, which is evaluating the safety and efficacy of donanemab in patients with preclinical Alzheimer's disease (Stage 1 and 2) to determine if it reduces risk of progression to symptomatic Alzheimer's disease. TRAILBLAZER-ALZ 5 is a registration trial for early symptomatic Alzheimer's disease currently enrolling in China, Korea, Taiwan, and other geographies.

U.S. INDICATION AND SAFETY SUMMARY WITH WARNINGS

Kisunla (donanemab-azbt), pronounced kih-SUHN-lah, is 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.

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 treatment for people with early symptomatic Alzheimer's disease, the supply and commercialization of Kisunla, and future readouts, presentations, 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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