Lilly's Kisunla (donanemab) receives marketing authorization in Australia for the treatment of early symptomatic Alzheimer's disease

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The authorization in Australia is for adult patients who are *Apolipoprotein E-ε4 heterozygotes or non-carriers*

INDIANAPOLIS, May 21, 2025 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that the Australian Therapeutic Goods Administration (TGA) has granted marketing authorization for Kisunla (donanemab), an injection for intravenous infusion every four weeks to treat mild cognitive impairment and mild dementia due to Alzheimer's disease in adults who are *Apolipoprotein E* ε4 (*ApoE ε4)* heterozygotes or non-carriers. Kisunla is the first amyloid-targeting therapy for people with Alzheimer's registered in Australia and the only amyloid plaque-targeting therapy with evidence to support stopping therapy when amyloid plaques are removed.

Amyloid is a protein produced naturally in the body that can clump together to create amyloid plaques. Kisunla can help remove the excessive buildup of amyloid plaques and help slow the cognitive and functional decline in patients with early symptomatic Alzheimer's disease.

"It is exciting to see Kisunla's marketing authorization in Australia, marking it as the 13th regulatory authorization. In our TRAILBLAZER-ALZ 2 Phase 3 study, results showed that Kisunla significantly slowed cognitive and functional decline in patients with early symptomatic Alzheimer's disease, which allowed them more time to do things that mattered most to them like remember information, make meals, manage finances, and maintain independence," said Ilya Yuffa, executive vice president and president of Lilly International, Eli Lilly and Company. "As our data showed, the earlier patients are identified, diagnosed, and treated with Kisunla, the greater their response to treatment."

It's estimated that 600,000 Australians are currently living with Alzheimer's disease,[1] with approximately 450,000 of these individuals in the early stages of the disease who could be assessed to determine eligibility for treatment with Kisunla.[4] Alzheimer's disease is the third leading cause of death in Australia.[1]

The registration of Kisunla in Australia was based on the TRAILBLAZER-ALZ 2 Phase 3 and TRAILBLAZER-ALZ 6 clinical trial data. The TRAILBLAZER-ALZ 2 study demonstrated that Kisunla significantly slowed cognitive and functional decline — characterized by more significant memory and thinking deficits, with related impacts on daily functioning and requiring higher levels of caregiver support—by up to 35% compared to placebo at 18 months and reduced the risk of progressing to the next clinical stage of disease by 39% over the same period.[3]

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 are usually asymptomatic, although serious and life-threatening events can rarely occur.[2] Because ARIA-E can cause focal neurologic deficits that can mimic ischemic stroke, the product information in Australia includes a boxed warning that notes treatment to dissolve blood clots should be carefully considered by the patient's doctor.

The titration schedule approved in Australia is based on TRAILBLAZER-ALZ 6, which demonstrated that the incidence of ARIA-E at 24 weeks was significantly lowered versus the original dosing schedule, while preserving Kisunla's ability to reduce amyloid plaque and plasma P-tau217.[2] The modified titration schedule has been submitted for regulatory review in other countries.

Donanemab is now approved in the United States, Japan, China, United Kingdom, UAE, Qatar, Kuwait, Bahrain, Singapore, Taiwan, Brazil, Mexico and Australia.

About Kisunla
In Australia, Kisunla is an amyloid-targeting treatment for people with mild cognitive impairment and mild dementia due to Alzheimer's disease in adult patients who are *ApoE* ε4 heterozygotes or non-carriers. Kisunla can cause serious side effects, including amyloid-related imaging abnormalities (ARIA), and infusion-related reactions. Donanemab is a prescription medicine administered intravenously every four weeks.

About TRAILBLAZER-ALZ 2 Study
TRAILBLAZER-ALZ 2 (NCT04437511) was a Phase 3, double-blind, placebo-controlled study to evaluate the safety and efficacy of donanemab 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, focused on reducing risk of progression to symptomatic AD in participants with preclinical Alzheimer's disease; and TRAILBLAZER-ALZ 5, a registration trial for early symptomatic

Alzheimer's disease currently enrolling in China, Korea, Taiwan, and other geographies.

INDICATION AND SAFETY SUMMARY WITH WARNINGS

Kisunla (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:

- Headache
- Dizziness
- Nausea
- Difficulty walking
- Confusion
- Vision changes
- 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.

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.

References

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