# Lilly's Kisunla™ (donanemab-azbt) Receives Marketing Authorization in Great Britain for the Treatment of Mild Cognitive Impairment and Mild Dementia Due to Alzheimer's Disease in Adult Patients Who Are Apolipoprotein E E4 Heterozygotes or Non-Carriers

October 23, 2024

*Great Britain is the third major market where donanemab has received approval*

*Donanemab was first approved in the United States in July 2024 and then approved in Japan in September 2024*

INDIANAPOLIS, Oct. 23, 2024 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that the Medicines and Healthcare products Regulatory Agency (MHRA) has granted marketing authorization for donanemab, an injection for intravenous infusion every four weeks to treat mild cognitive impairment and mild dementia due to Alzheimer's disease in eligible adults in Great Britain. Eligible patients are limited to apolipoprotein E ε4 (ApoE ε4) heterozygotes or non-carriers, which is a requirement for the class of currently approved amyloid-targeting therapies in Great Britain. Donanemab is the only amyloid plaque-targeting therapy with evidence to support stopping therapy when amyloid plaques are removed. Great Britain is the third major market to approve donanemab, marketed as Kisunla.

"People around the world want and deserve access to treatment options for this disease. This approval in Great Britain is another significant step to ensure patients with Alzheimer's disease can receive treatment with this new class of amyloid targeting therapies, which could give them more time in the early symptomatic stage of the disease to do what matters most to them," said Ilya Yuffa, executive vice president and president of Lilly International, Eli Lilly and Company. "Donanemab demonstrated meaningful results for people with early symptomatic Alzheimer's disease by significantly slowing cognitive and functional decline in our TRAILBLAZER-ALZ 2 study."

Currently, there are 982,000 people estimated to be living with dementia in the United Kingdom (UK)[1], with 50-75% of cases attributable to Alzheimer's disease.[2] It is the leading cause of death[3] in the UK and an economic cost to society. The total cost of dementia on patients, families and the public sector is estimated to be £42 billion in 2024. Unpaid care is the largest component, with costs per person increasing threefold from mild to severe dementia.[4]

Amyloid is a protein produced naturally in the body that can clump together to create amyloid plaques. The excessive buildup of amyloid plaques in the brain may lead to memory and thinking issues associated with Alzheimer's disease. Donanemab can help the body remove the excessive buildup of amyloid plaques and slow the cognitive and functional decline that may diminish people's ability to remember information, make meals, manage finances, and maintain independence.

"I believe we can improve the standard of care for people living with Alzheimer's disease. Despite years of medical research, until recently, there has been little progress in treatment options for this disease. The authorisation of donanemab for eligible adults is welcome news. Great Britain now needs to rapidly increase National Health Service (NHS) capacity and expertise in diagnostics and treatment facilities to enhance the management of Alzheimer's disease for the benefit of people today and tomorrow," said Professor Cath Mummery, Consultant Neurologist at University College London Hospitals NHS Foundation Trust and Chair of the NIHR Dementia Translational Research Collaboration.

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

**About TRAILBLAZER-ALZ 2 Study and the TRAILBLAZER-ALZ program**
TRAILBLAZER-ALZ 2 (NCT04437511) is 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).

Lilly continues to study donanemab in multiple clinical trials, including TRAILBLAZER-ALZ 3, which is focused on reducing risk of progression to symptomatic Alzheimer's disease in participants with preclinical AD; TRAILBLAZER-ALZ 5, a registration trial for early symptomatic AD currently enrolling in China and Korea; and TRAILBLAZER-ALZ 6, which is focused on expanding our understanding of ARIA through novel MRI sequences, blood-based biomarkers, and different dosing regimens of donanemab.

**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.**

**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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**Refer to:** Aaron Fobes; aaron.fobes@lilly.com; 463-230-2378 (Media)
Joe Fletcher; jfletcher@lilly.com; 317-296-2884 (Investors)

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