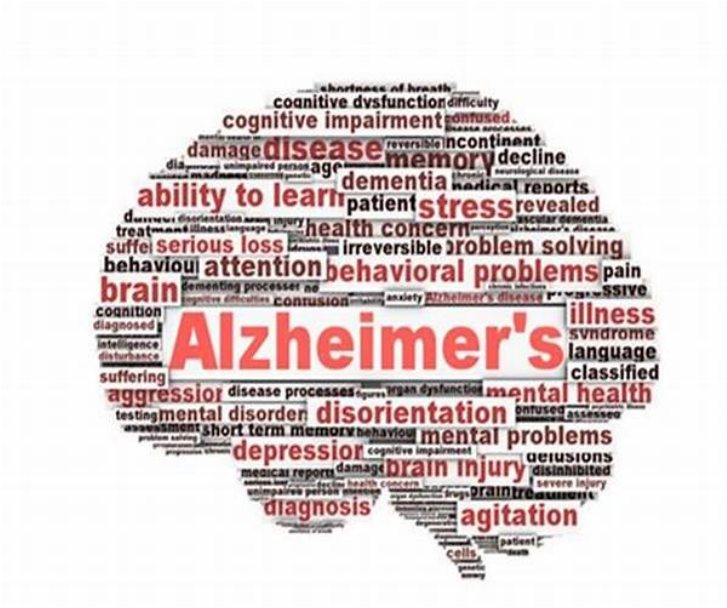
BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Lilly's Kisunla receives marketing authorisation in Australia for treatment of early symptomatic Alzheimer's disease

23 May 2025 | News

The authorization in Australia is for adult patients who are Apolipoprotein E-?4 heterozygotes or non-carriers



Eli Lilly and Company has announced 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* ?4 (*ApoE ?4)* 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's estimated that 600,000 Australians are currently living with Alzheimer's disease, 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. Alzheimer's disease is the third leading cause of death in Australia.

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.

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