24 July 2025
EMADOC-628903358-125940
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Kisunla

donanemab

On 24 July 2025, the Committee for Medicinal Products for Human Use (CHMP), following a re-examination procedure, adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Kisunla, intended for the treatment of early symptomatic Alzheimer's disease in adults who are apolipoprotein E ε4 (ApoE ε4) non-carriers or heterozygotes. The applicant for this medicinal product is Eli Lilly Nederland B.V.

Kisunla will be available as a 350 mg concentrate for solution for infusion. The active substance of Kisunla is donanemab, a monoclonal antibody (ATC code: N06DX05) that binds to amyloid plaques and thus aids removal of plaques through microglial-mediated phagocytosis.

The benefit of Kisunla is a reduced progression of cognitive and functional deficits associated with Alzheimer's disease. The most common side effects include amyloid-related imaging abnormalities (ARIA) and headache.

The full indication is:

> Donanemab is indicated for the treatment of adult patients with a clinical diagnosis of mild cognitive impairment and mild dementia due to Alzheimer's disease (Early symptomatic Alzheimer's disease) who are apolipoprotein E ε4 (ApoE ε4) heterozygotes or non-carriers with confirmed amyloid pathology (see section 4.4).

Treatment with Kisunla should be initiated by physicians experienced in the diagnosis and treatment of Alzheimer's disease with timely access to magnetic resonance imaging. Donanemab should be administered under the supervision of a multidisciplinary team trained in detection, monitoring and management of ARIA and experienced in detecting and managing infusion related reactions. Initiation of treatment with Kisunla will be through a central registration system implemented as part of a controlled access programme.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.