14 November 2024
EMA/77657/2025
Committee for Medicinal Products for Human Use (CHMP)

Update as of 27 February 2025:

As part of its decision-making process, the European Commission asked the CHMP to consider information on the safety of Leqembi that became available after the adoption of the CHMP opinion in November 2024 and whether this would require an update of the opinion. The Commission also asked the CHMP to consider whether the wording of the risk minimisation measures in Annex II of the opinion was clear enough to ensure correct implementation.

The CHMP has now considered this request and concluded that its November opinion recommending the marketing authorisation of Leqembi does not need to be updated. EMA has provided a response to the European Commission which will now resume the decision-making process for Leqembi's marketing authorisation.

Summary of opinion[1] (initial authorisation)

Leqembi

lecanemab

On 14 November 2024, 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 Leqembi, intended for the treatment of early Alzheimer's disease in apolipoprotein E ε4 (ApoE ε4) non-carriers or heterozygotes. The applicant for this medicinal product is Eisai GmbH.

Leqembi will be available as a 100 mg/ml concentrate for solution for infusion. The active substance of Leqembi is lecanemab, a monoclonal antibody (ATC code: N06DX04) that binds to aggregated soluble and insoluble forms of amyloid beta and, by doing so, reduces beta plaques.

The benefit of Leqembi is a reduced progression of the cognitive and functional deficits associated with Alzheimer's disease. The most common side effects are amyloid-related imaging abnormalities.

The full indication is:

[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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Leqembi 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 Alzheimer's disease) who are apolipoprotein E ε4 (ApoE ε4) non-carriers or heterozygotes with confirmed amyloid pathology (see section 4.4).

Treatment should be initiated and supervised by physicians experienced in the diagnosis and treatment of Alzheimer's disease with timely access to magnetic resonance imaging (MRI). Leqembi infusions should be administered by qualified healthcare professionals trained to monitor for, recognize and manage infusion-related reactions. Leqembi will only be prescribed in the context of controlled access programmes.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.