Drugs

PEER-REVIEWED FEATURE

Lecanemab: Adis Evaluation

Key Points

- A humanized IgG1 monoclonal antibody being developed by Eisai, under a global licence from BioArctic, and in collaboration with Biogen, for the treatment of Alzheimer's disease
- Received its first approval on 6 January 2023 in the USA under the Accelerated Approval Pathway
- Approved for the treatment of Alzheimer’s disease. Therapy should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, and a confirmed presence of amyloid beta pathology (the population in which treatment was initiated in clinical trials)

Summary

Lecanemab (lecanemab-irmb; LEQEMBI™) is a humanized immunoglobulin gamma 1 (IgG1) against aggregated soluble and insoluble forms of amyloid-β peptide.

It is being developed by Eisai, under a global licence from BioArctic (formerly BioArctic Neuroscience), and in collaboration with Biogen, for the treatment of Alzheimer's disease, and received its first approval for this indication on 6 January 2023 in the USA under the Accelerated Approval Pathway.

According to the US prescribing information, treatment should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, and a confirmed presence of amyloid beta pathology (i.e. the population in which treatment was initiated in clinical trials). There are no effectiveness or safety data on initiating treatment at earlier or later stages of the disease than were studied.

Lecanemab is undergoing regulatory review in the EU, Japan and China, with clinical development underway in several other countries worldwide.

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