



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Update as of 25 February 2022:

The applicant for Aduhelm has requested a re-examination of EMA's December 2021 opinion. Upon receipt of the grounds of the request, the Agency will re-examine its opinion and issue a final recommendation.

17 December 2021

Refusal of the marketing authorisation for Aduhelm (aducanumab)

The European Medicines Agency has recommended the refusal of the marketing authorisation for Aduhelm, a medicine intended for the treatment of Alzheimer's disease.

The Agency issued its opinion on 16 December 2021. The company that applied for authorisation, Biogen Netherlands B.V., may ask for re-examination within 15 days of receiving the opinion.

What is Aduhelm and what was it intended to be used for?

Aduhelm was developed as a medicine for treating adults with Alzheimer's disease.

It was intended for treating the early stages of the disease known as the mild cognitive impairment (MCI) stage and the mild dementia stage.

Aduhelm contains the active substance aducanumab and was to be available as a concentrate for solution for infusion (drip) into a vein.

How does Aduhelm work?

The active substance in Aduhelm, aducanumab, is a monoclonal antibody (a type of protein) that attaches to a substance called amyloid beta which forms plaques in the brains of people with Alzheimer's disease. By attaching to amyloid beta, the medicine is expected to help clear the plaques away and delay the worsening of the disease.

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What did the company present to support its application?

The company presented results of two main studies of over 3,000 patients with early stage Alzheimer's disease comparing the effects of a low- and high-dose of Aduhelm with the effects of placebo (a dummy treatment). The studies looked at how the patients' symptoms changed after 78 weeks of treatment using a standard scoring system known as CDR-SB.

What were the main reasons for refusing the marketing authorisation?

The European Medicines Agency noted that although Aduhelm reduces amyloid beta in the brain, the link between this effect and clinical improvement had not been established. Results from the main studies were conflicting and did not show overall that Aduhelm was effective at treating adults with early stage Alzheimer's disease.

In addition, the studies did not show that the medicine was sufficiently safe as images from brain scans of some patients showed abnormalities suggestive of swelling or bleeding, which could potentially cause harm. Furthermore, it is not clear that the abnormalities can be properly monitored and managed in clinical practice.

Therefore, the Agency's opinion was that the benefits of Aduhelm did not outweigh its risks and it recommended refusing marketing authorisation.

Does this refusal affect patients in clinical trials?

The company informed the Agency that there are no consequences for patients in clinical trials with Aduhelm.

If you are in a clinical trial and need more information about your treatment, speak with your doctor.