22 April 2002
EMA/225498/2022
EMEA/H/C/005558

Withdrawal of application for the marketing authorisation of Aduhelm (aducanumab)

Biogen Netherlands B.V. withdrew its application for a marketing authorisation of Aduhelm for the treatment of Alzheimer's disease.

The company withdrew the application on 20 April 2022.

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 was expected to help remove the plaques from the brain and delay the worsening of the disease.

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 dementia rating scale known as CDR-SB.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

How far into the evaluation was the application when it was withdrawn?

The evaluation had finished and the European Medicines Agency had recommended refusing marketing authorisation in December 2021. The company had requested a re-examination of the Agency's recommendation, but it withdrew the application before this re-examination had finished.

What did the Agency recommend at that time?

Based on the review of the data and the company's response to the Agency's questions, at the time of the withdrawal, the Agency had recommended refusing marketing authorisation for Aduhelm for the treatment of Alzheimer's disease.

The Agency considered 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 convincingly show 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 (amyloid-related imaging abnormalities) suggestive of swelling or bleeding in the brain, which could potentially cause harm. Furthermore, it is not clear that the abnormalities can be properly managed in clinical practice.

At the time of the withdrawal, while the re-examination was ongoing, the Agency was still of the opinion that the benefits of Aduhelm did not outweigh its risks.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of application, the company stated that it withdrew because the agency's scientific committee CHMP indicated that the data provided thus far would not be sufficient to support a positive opinion on the marketing authorisation of Aduhelm (aducanumab).

Does this withdrawal affect patients in clinical trials?

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