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Withdrawal of application to change the marketing authorisation for Amyvid (florbetapir (^{18}F))

Eli Lilly Nederland B.V. withdrew its application for the use of Amyvid in adults to monitor their response to treatments that reduce beta amyloid plaques. These plaques are abnormal clumps of protein that build up in the brain of people with Alzheimer's disease, leading to problems with brain function.

The company withdrew the application on 26 February 2025.

What is Amyvid and what is it used for?

Amyvid is a diagnostic medicine used with a type of brain scan called positron emission tomography (PET) to check for the presence of beta amyloid plaques in the brain.

Amyvid is used with a PET scan in adults with cognitive impairment (problems affecting the memory or ability to think) who are being evaluated for Alzheimer's disease, and other diseases that cause cognitive impairment. A negative scan indicates few or no beta amyloid plaques, meaning a patient is unlikely to have Alzheimer's disease. Doctors use the results of these scans along with a clinical evaluation to make a diagnosis as a positive scan on its own is not sufficient.

Amyvid contains the active substance florbetapir (^{18}F) and is available as a solution for injection. It has been authorised in the EU since January 2013.

Further information on Amyvid's current uses can be found on the Agency's website: ema.europa.eu/en/medicines/human/EPAR/amyvid

What change had the company applied for?

The company applied to extend the use of Amyvid in adults to monitor their response to treatments to reduce beta amyloid plaques.

How does Amyvid work?

The active substance in Amyvid, florbetapir (^{18}F), is a radiopharmaceutical that emits low amounts of radiation. It works by targeting and attaching to beta amyloid plaques in the brain. When florbetapir

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(^{18}F) attaches to these plaques, the radiation it emits is seen on a PET scan, allowing doctors to determine if significant amounts of plaques are present.

What did the company present to support its application?

The company presented data from the medical literature about studies in which PET scans were used to monitor the response to treatments intended to reduce beta-amyloid plaques. During the assessment, the company submitted additional data, including those from studies with a medicine developed to reduce beta amyloid plaques in people with Alzheimer's disease.

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

The application was withdrawn after the European Medicines Agency had evaluated the information from the company and had prepared questions for the company. After the Agency had assessed the company's responses to the questions, there were still some unresolved issues.

What did the Agency recommend at that time?

Based on the review of the information and the company's response to the Agency's questions, at the time of the withdrawal, the Agency had some concerns, and its provisional opinion was that Amyvid could not have been authorised to monitor treatment response.

The Agency considered that a study is needed to evaluate how well Amyvid PET scans perform when used to monitor treatment response and, to prove this is consistent with the performance of Amyvid PET scans when used to diagnose Alzheimer's disease. The Agency also considered that the method for interpreting Amyvid PET scans may require modification, and the modified method should be validated (formally tested to check suitability).

Therefore, at the time of the withdrawal, the Agency's opinion was that the company had not provided enough information to support the application for a change to the marketing authorisation of Amyvid.

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 they could not fully address the Agency's request for additional data within the timeframe set for this evaluation.

Does this withdrawal affect patients in clinical trials or compassionate use programmes?

The company informed the Agency that there are no consequences for patients in clinical trials or in compassionate use programmes using Amyvid.

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

What is happening with the authorised uses of Amyvid?

The withdrawal does not impact the authorised uses of Amyvid.