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Withdrawal of application for the marketing authorisation of Izelvay (avacincaptad pegol)

Astellas Pharma Europe B.V. withdrew its application for a marketing authorisation of Izelvay, a medicine intended for the treatment of geographic atrophy caused by age-related macular degeneration (AMD).

The company withdrew the application on 24 October 2024.

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

Izelvay was developed as a medicine to treat adults with geographic atrophy, an advanced form of AMD. AMD is a disease that affects the central part of the retina (called the macula) at the back of the eye. In patients with geographic atrophy, lesions (areas of cell death) gradually develop in the retina , leading to loss of vision.

Izelvay contains the active substance avacincaptad pegol and was to be available as a solution to be given as an injection into the eye.

How does Izelvay work?

The complement system is a set of proteins that is part of the immune system (the body's natural defences). In people with geographic atrophy, the complement system is overactive, causing inflammation and cell death.

The active substance in Izelvay, avacincaptad pegol, attaches to the C5 protein of the complement system. This blocks its action and prevents activation of the complement system, potentially protecting light-sensitive cells in the retina and slowing down vision loss.

What did the company present to support its application?

The company presented results from two main studies involving a total of 734 adults with geographic atrophy caused by AMD. The studies compared Izelvay injections into the eye with a sham procedure where no actual injection with an active substance was given. The main measure of effectiveness was the change in the size of geographic atrophy lesions in the eye over a 12-month period.

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How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the information from the company and prepared questions for the company.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

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 some concerns and its provisional opinion was that Izelvay could not have been authorised for the treatment of geographic atrophy.

Although the studies provided by the applicant showed that Izelvay slowed the growth of geographic atrophy lesions, the Agency considered that this effect did not lead to clinically meaningful improvements in visual function for patients. Because regular injections into the eye increase the risk of side effects, such as conjunctival haemorrhage (bleeding in the white of the eye), increased eye pressure and choroidal neovascularisation (abnormal development of new blood vessels behind the retina, worsening vision), the Agency concluded at the time of withdrawal that a positive balance of the medicine's benefits and risks could not be established for this medicine.

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

In its letter notifying the Agency of the withdrawal of the application, the company stated that it withdrew the application because of the Agency's concerns about the effectiveness of the medicine.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no consequences for patients in clinical trials using Izelvay. If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.