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Withdrawal of application for the marketing authorisation of Xiidra (lifitegrast)

Novartis Europharm Ltd withdrew its application for a marketing authorisation of Xiidra for the treatment of dry eye disease.

The company withdrew the application on 18 June 2020.

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

Xiidra was to be used for the treatment of moderate to severe dry eye disease in adults for whom treatment with artificial tears has not been sufficient to improve the condition.

Xiidra contains the active substance lifitegrast and was to be available as eye drops.

How does Xiidra work?

T cells (cells in the immune system, the body's natural defences) are involved in the development of dry eye disease. The active substance in Xiidra, lifitegrast, was expected to work by preventing the interaction between two proteins, LFA-1 and ICAM-1, which play a role in the activity of T cells. By blocking this interaction, Xiidra was expected to reduce activation of the immune system and the inflammation that occur in dry eye disease.

What did the company present to support its application?

Two main studies involving a total of 1,429 adults with dry eye disease compared Xiidra with the vehicle (the same eye drop formula but without any active substance). The main measures of effectiveness were reduction in damage to the cornea and of the severity of symptoms, including eye dryness and discomfort.

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How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the information from the company and prepared questions for the company.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, including consultations with experts in the field of eye diseases 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 Xiidra could not have been authorised for the treatment of dry eye disease in adults for whom treatment with artificial tears has not been sufficient to improve the condition.

The Agency considered that the effectiveness of Xiidra was not demonstrated across different symptoms of dry eye disease. Although some effect was seen in the reduction of eye dryness, the improvement was not considered clinically significant. In addition, although Xiidra was intended to be used in patients with more severe disease in whom artificial tears had not been sufficient in improving the condition, the Agency had some concerns about how these patients were to be selected, and noted that the studies had compared Xiidra with the vehicle, and had not used artificial tears in an optimal way. The Agency also noted that there were no data on the effect of long-term treatment with Xiidra despite eye dryness being a chronic (long-lasting) disease.

Therefore, at the time of the withdrawal, the Agency's opinion was that, because effectiveness was not proven, the benefits of Xiidra 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 the application, the company stated that it withdrew its application because the Agency's concerns could not be addressed within the available timeframe.

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

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

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