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Withdrawal of application for the marketing authorisation of Rilonacept FGK Representative Service GmbH (rilonacept)

FGK Representative Service GmbH withdrew its application for a marketing authorisation of Rilonacept FGK Representative Service GmbH for the treatment of adults and children from 12 years of age with idiopathic pericarditis (inflammation of the membrane around the heart) which keeps coming back. Idiopathic means that the cause of the disease is not known.

The company withdrew the application on 12 February 2025.

What is Rilonacept FGK Representative Service GmbH and what was it intended to be used for?

Rilonacept FGK Representative Service GmbH was developed as a medicine for the treatment of adults and children from 12 years of age with idiopathic pericarditis which keeps coming back. This medicine was also intended to reduce the risk of pericarditis coming back.

Rilonacept FGK Representative Service GmbH contains the active substance rilonacept and was developed as a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance, but there are certain differences between the two. The reference medicine, Rilonacept Regeneron, was authorised for a condition called cryopyrin-associated periodic syndrome (CAPS), while Rilonacept FGK Representative Service GmbH was intended for the treatment of idiopathic pericarditis. The marketing authorisation for Rilonacept Regeneron was withdrawn in October 2012 due to commercial reasons.

Rilonacept was designated an 'orphan medicine' (a medicine used in rare diseases) on 6 January 2021 for idiopathic pericarditis. Further information on the orphan designation can be found on the Agency's website.

How does Rilonacept FGK Representative Service GmbH work?

The active substance in Rilonacept FGK Representative Service GmbH, rilonacept, is an interleukin inhibitor. It works by attaching to and blocking the activity of chemical messengers in the body called

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interleukin-1 alpha and interleukin-1 beta, which are involved in causing inflammation. By blocking interleukin-1 alpha and interleukin-1 beta, the medicine was expected to reduce inflammation in patients with idiopathic pericarditis, thereby relieving symptoms of the condition and preventing the disease from coming back.

What did the company present to support its application?

The company provided data from one main study involving 61 adults and children from 12 years of age with pericarditis that keeps coming back. The study compared Rilonacept FGK Representative Service GmbH with placebo (a dummy treatment), and the main measure of effectiveness was the time until pericarditis came back.

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

The application was withdrawn after the European Medicines Agency had evaluated the initial information from the company and had prepared questions for the company. The company had not responded to the questions at the time of the withdrawal.

What did the Agency recommend at that time?

Based on the review of the data, at the time of the withdrawal, the Agency had some concerns and its provisional opinion was that Rilonacept FGK Representative Service GmbH could not have been authorised for the treatment of adults and children with idiopathic pericarditis.

The Agency's concerns related to the proposed indication for use, which did not fully reflect the patients recruited in the main study. The Agency noted that the majority of patients in the main study were at high risk of pericarditis coming back despite a combination of therapies. Therefore, the Agency had a question on whether use of the medicine should be limited to patients with a high risk of pericarditis coming back. Furthermore, the Agency considered that the data in children from 12 to 17 years of age were not sufficient to assess the safety and effectiveness of the medicine in this age group. The Agency also noted that the pharmaceutical form of the medicine was not consistently described in the submitted documentation.

Therefore, at the time of the withdrawal, the Agency's opinion was that the company had not provided enough data to support the application for Rilonacept FGK Representative Service GmbH.

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 the withdrawal is based on business reasons.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no consequences for patients in clinical trials using Rilonacept FGK Representative Service GmbH.

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