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Withdrawal of application for the marketing authorisation of Kinharto (omecamtiv mecarbil)

On 7 May 2024, Cytokinetics (Ireland) Limited withdrew its application for a marketing authorisation of Kinharto for the treatment of chronic (long-term) heart failure.

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

Kinharto was developed as a medicine to treat adults with long-term heart failure who have symptoms of the disease and a reduced ejection fraction of less than 30%. Ejection fraction is a measure of how well the heart pumps blood.

Kinharto contains the active substance omecamtiv mecarbil and was to be available as prolonged-release tablets to be taken by mouth. Prolonged-release tablets release the active substance slowly over a few hours, allowing the medicine to be given less frequently.

How does Kinharto work?

The active substance in Kinharto, omecamtiv mecarbil, binds to a heart muscle protein called myosin, which is involved in the contraction of the heart. By binding to myosin, Kinharto was expected to help the heart muscle contract more strongly, which increases the heart's ability to pump blood around the body.

What did the company present to support its application?

The company presented data from a study involving over 8,200 people with symptomatic heart failure and reduced ejection fraction (35% or below) who were hospitalised at the time of the study or had recently been hospitalised or sought urgent medical attention due to heart failure and were receiving standard treatment. The study compared Kinharto with placebo (a dummy treatment) and the main measure of effectiveness was the time until patients experienced a worsening of their heart failure that required urgent medical care or died due to cardiovascular disease (disease of the heart or blood vessels).

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How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the information from the company and prepared questions for the company.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 concerns and its provisional opinion was that Kinharto could not be authorised for the treatment of chronic (long-term) heart failure.

Although the results from the main study showed that treatment with Kinharto increased the time until patients experienced worsening of their heart failure or died, the Agency considered that this main beneficial effect was modest and could not be supported by other results from the study. In addition, although the data appeared to suggest that patients with a more severely reduced ejection fraction (below 30%) would be more likely to benefit from Kinharto, there was not enough evidence to support limiting treatment to this subgroup, nor could other studies be found to back up this subgroup finding. Therefore, at the time of the withdrawal, the Agency's opinion was that the benefits of Kinharto 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 the withdrawal is based on feedback from EMA that the results from the main study were not sufficient to conclude that the benefits of Kinharto outweigh the risks.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no ongoing clinical trials with Kinharto.