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Withdrawal of application for the marketing authorisation of Febseltiq (infigratinib)

Helsinn Birex Pharmaceuticals Ltd withdrew its application for a marketing authorisation of Febseltiq for the treatment of cholangiocarcinoma (cancer of the bile ducts).

The company withdrew the application on 11 October 2022.

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

Febseltiq was developed as a medicine for treating adults with cholangiocarcinoma (cancer of the bile ducts) when the cancer cells have an abnormal form of a receptor (target) called FGFR on their surface.

It was intended for previously treated adults whose cancer could not be removed by surgery and was advanced or had spread to other parts of the body.

Febseltiq contains the active substance infigratinib and was to be available as capsules to be taken by mouth.

How does Febseltiq work?

The active substance in Febseltiq, infigratinib, belongs to a group of medicines called protein kinase inhibitors. It works by blocking the activity of FGFRs. Abnormal FGFRs are found on the surface of cancer cells and are involved in the growth and spread of the cancer. By blocking their activity, Febseltiq is expected to reduce the growth and spread of the cancer.

What did the company present to support its application?

The company presented results from a study involving 108 patients who had cholangiocarcinoma with abnormal forms of FGFR and who had previously received platinum-based chemotherapy. The study looked at the percentage of patients whose tumour shrank after treatment with Febseltiq. All of the patients took Febseltiq and the medicine was not compared with any other treatment.

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How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the initial information from the company and had prepared questions for the company.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 Febseltiq could not have been authorised for the treatment of cholangiocarcinoma.

The Agency noted that the company still needed to show that the medicine's benefits outweigh its risks. There was insufficient evidence that it works well against tumours, there were a number of severe side effects and there were questions about how the medicine passes through and is metabolised in the body.

As the company was seeking a conditional marketing authorisation, the Agency noted that the requirements for such an authorisation were not met. Finally, the Agency also had some questions about the manufacturing process for the medicine.

Therefore, at the time of the withdrawal, the Agency's opinion was that the benefits of Febseltiq 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 had decided to stop development of the medicine after it had reassessed its regulatory and business strategy.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that the ongoing clinical trial with this medicine will be stopped. If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.