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Questions and answers

Withdrawal of the marketing authorisation application for Xegafri (rociletinib)

On 3 May 2016, Clovis Oncology UK Ltd officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Xegafri, for the treatment of non-small cell lung cancer.

What is Xegafri?

Xegafri is a medicine that contains the active substance rociletinib. It was to be available as tablets (125 mg and 250 mg).

What was Xegafri expected to be used for?

Xegafri was to be used to treat a type of lung cancer called non-small cell lung cancer (NSCLC) in adults who have the T790M mutation (a particular change in the gene for a protein called epidermal growth factor receptor or EGFR) and who had already been treated with EGFR-targeted therapy.

How is Xegafri expected to work?

The active substance in Xegafri, rociletinib, is a tyrosine kinase inhibitor. This means that it blocks the activity of enzymes known as tyrosine kinases, particularly tyrosine kinases that are present in EGFRs. EGFR controls growth and division of cells. In lung cancer cells, EGFR is often overactive, causing uncontrolled division of cancer cells. By blocking the tyrosine kinase in EGFR, rociletinib is expected to help reduce the growth and spread of the cancer. Unlike most other tyrosine kinase inhibitors, rociletinib targets cancer cells with the T790M mutation in the EGFR gene.

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What did the company present to support its application?

Xegafri is being investigated in two studies in 457 NSCLC patients who have the T790M mutation and had already been treated with EGFR-targeted therapy. In these studies, Xegafri is not compared with any other treatment. The main measure of effectiveness is the number of patients who respond to treatment.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the CHMP had evaluated the initial documentation provided by the company and formulated a list of questions. The company had not yet responded to the questions at the time of the withdrawal.

What was the recommendation of the CHMP at that time?

Based on the review of the data, at the time of the withdrawal, the CHMP had had some concerns and was of the provisional opinion that Xegafri could not have been approved for the treatment of NSCLC patients who have the T790M mutation. The data provided were too limited to enable evaluation of the effectiveness of Xegafri at this time. In addition, QT prolongation (a change in the heart's electrical activity) and cases of serious heart problems presented a safety concern.

Therefore, at the time of the withdrawal, the CHMP was of the opinion that the benefits of Xegafri 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 application, the company stated that it was withdrawing its application because of a revised business strategy for the product.

The withdrawal letter is available here.

What consequences does this withdrawal have for patients in clinical trials or compassionate use programmes?

The company informed the CHMP that they will stop enrolling patients in the ongoing clinical trials. The company will continue to provide Xegafri to patients whose doctor recommend they should continue to take this medicine. In addition, patients currently receiving Xegafri through a compassionate use programme can continue to receive this medicine.

If you are in a clinical trial or compassionate use programme and need more information about your treatment, contact the doctor who is giving it to you.