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Withdrawal of application for the marketing authorisation of Exkivity (mobocertinib)

Takeda Pharma A/S withdrew its application for a conditional marketing authorisation of Exkivity (mobocertinib) for the treatment of a certain type of lung cancer.

The company withdrew the application on 20 July 2022.

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

Exkivity was intended for use in adults with advanced non-small cell lung cancer (NSCLC) whose cancer cells have particular mutations (genetic changes). These mutations are in the gene for a protein that controls cell growth, the epidermal growth factor receptor (EGFR), and are known as 'EGFR exon 20 insertion mutations'. The medicine was to be given when cancer treatment with platinum-based chemotherapy had not worked well enough.

Exkivity contains the active substance mobocertinib and was to be available as tablets to be taken by mouth.

How does Exkivity work?

In NSCLC with EGFR exon 20 insertion mutations, the EGFR protein is overactive, causing uncontrolled growth of cancer cells.

The active substance in Exkivity, mobocertinib, is a type of medicine called a tyrosine kinase inhibitor that attaches to the overactive EGFR and blocks its effect, helping to slow down the growth of the cancer.

What did the company present to support its application?

The company presented the results of a main study which looked at the effects of Exkivity in 114 patients with advanced NSCLC with EGFR exon 20 insertion mutations and who previously had platinum-based chemotherapy. The study looked at the percentage of patients whose tumour shrank after treatment with Exkivity. Exkivity was not compared with other treatments in this study.

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How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the information from the company and prepared questions for the company.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 at the time of the withdrawal, the Agency had some concerns and its provisional opinion was that the results from the study could not have supported conditional marketing authorisation of Exkivity for the treatment of NSCLC with EGFR exon 20 insertion mutations.

In particular, the benefits of Exkivity could not be established as the percentage of patients who responded to the medicine was small and Exkivity had not been compared with other cancer medicines. Also, the results from the study did not show a major advantage of treatment with Exkivity versus other available treatments for lung cancer.

Although treatment with Exkivity was considered in principle an interesting option for these patients who often have a poor prognosis, and the safety of the medicine appears manageable, the available data were not sufficient to conclude on its benefit.

Therefore, at the time of the withdrawal, the Agency's opinion was that the benefits of Exkivity 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 acknowledged that the currently available data would not have been sufficient to address the Agency's concerns and support the conditional marketing authorisation of Exkivity.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no consequences for patients in clinical trials using Exkivity or for those currently accessing this medicine through compassionate use programmes.

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