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Withdrawal of application to change the marketing authorisation for Gavreto (pralsetinib)

Roche Registration GmbH withdrew its application for the use of Gavreto in certain types of thyroid cancer.

The company withdrew the application on 3 November 2022.

What is Gavreto and what is it used for?

Gavreto is a cancer medicine used to treat adults with advanced non-small cell lung cancer caused by changes in a gene called *RET* (known as RET fusion-positive NSCLC) and who have not been treated with a RET inhibitor.

Gavreto has been authorised in the EU since November 2021.

It contains the active substance pralsetinib and is available as capsules.

Further information on Gavreto's current uses can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/gavreto

What change had the company applied for?

The company applied to extend the use of Gavreto to treat patients from 12 years of age who have thyroid cancer caused by a change in RET (RET-mutant medullary thyroid cancer or RET fusion-positive thyroid cancer). It was intended for patients who had received previous treatments but not with a RET inhibitor, and whose cancer was advanced or had spread to other parts of the body.

How does Gavreto work?

In thyroid cancer caused by changes in the RET protein, Gavreto is expected to work in the same way as it does in its existing indication. The active substance in Gavreto, pralsetinib, is a RET inhibitor, which belongs to a broader class of cancer medicines known as tyrosine kinase inhibitors. It blocks the activity of the abnormal RET protein, which causes uncontrolled cell growth and cancer. By blocking the abnormal RET, pralsetinib helps to reduce the growth and spread of the cancer.

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What did the company present to support its application?

The company presented the results from a trial including 172 patients with RET-mutant medullary thyroid cancer or RET fusion-positive thyroid cancer who all received Gavreto. The main measure of effectiveness was the proportion of patients whose cancer responded to treatment.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the information from the company and had prepared questions for the company. After the Agency had assessed the company's responses to the questions, there were still some unresolved issues.

What did the Agency recommend at that time?

Based on the review of the information and the company's response to the Agency's questions, at the time of the withdrawal, the Agency had some concerns and its provisional opinion was that Gavreto could not have been authorised for the treatment of patients from 12 years of age with RET-mutant medullary thyroid cancer or RET fusion-positive thyroid cancer. The Agency considered that the company did not provide adequate data to support the use of Gavreto in adolescents.

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 withdrew its application because of a change in its strategy.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no consequences for patients in clinical trials using Gavreto.

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

What is happening with Gavreto for the treatment of NSCLC

There are no consequences on the use of Gavreto in NSCLC.