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Gavreto (*pralsetinib*)

An overview of Gavreto and why it is authorised in the EU

What is Gavreto and what is it used for?

Gavreto is a cancer medicine for treating 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 contains the active substance pralsetinib.

How is Gavreto used?

Gavreto is available as capsules. Patients are recommended to take 400 mg per day with a glass of water on an empty stomach. The medicine can only be obtained with a prescription.

For more information about using Gavreto, see the package leaflet or contact your doctor or pharmacist.

How does Gavreto work?

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 an abnormal protein called RET fusion protein, which is made by the body due to a change in the *RET* gene. In NSCLC cells, RET fusion proteins can lead to uncontrolled cell growth and cancer. By blocking RET fusion proteins, pralsetinib helps to reduce the growth and spread of the cancer.

What benefits of Gavreto have been shown in studies?

In one main study, Gavreto was effective at reducing tumour size in patients with RET fusion-positive NSCLC who had not been treated before as well as in those previously treated with platinum-based chemotherapy. In the study, Gavreto was not compared with any other treatment or placebo (dummy treatment).

Response to treatment was assessed using body scans, with a complete response being when the patient had no remaining signs of cancer. In previously untreated patients, around 72% (54 out of 75) responded completely or partially to treatment with Gavreto. In patients receiving Gavreto after being

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treated with platinum-based chemotherapy, around 59% (80 out of 136) responded completely or partially to treatment with Gavreto.

What are the risks associated with Gavreto?

The most common side effects with Gavreto (which may affect more than 3 in 10 people) are anaemia (low levels of red blood cells), neutropenia (low levels of neutrophils, a type of white blood cell), constipation, bone or muscle pain, tiredness, leukopenia (low levels of white blood cells), an increased amount of aminotransferases (liver enzymes), and increased blood pressure. The most common serious side effects are pneumonia (lung infections), pneumonitis (lung inflammation) and severe anaemia. Other common side effects include haemorrhage (bleeding) (more than 1 in 10 people) and QT prolongation (a change in the heart's electrical activity) (more than 1 in 100 people).

For the full list of side effects and restrictions, see the package leaflet.

Why is Gavreto authorised in the EU?

One main study showed that Gavreto is effective at shrinking tumours in patients with RET fusion-positive NLCSC. Regarding safety, the side effects seen to date are considered manageable. Given the seriousness of the condition and the lack of existing treatments, the European Medicines Agency decided that Gavreto's benefits are greater than its risk and it can be authorised for use in the EU.

Gavreto has been given 'conditional authorisation'. This means that there is more evidence to come about the medicine, which the company is required to provide. Every year, the European Medicines Agency will review any new information that becomes available and this overview will be updated as necessary.

What information is still awaited for Gavreto?

Since Gavreto has been given conditional authorisation, the company that markets Gavreto will submit further results from the ongoing main study for data on the long-term effectiveness and safety of Gavreto and provide results from another study that compares Gavreto with the current standard of care.

What measures are being taken to ensure the safe and effective use of Gavreto?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Gavreto have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Gavreto are continuously monitored. Suspected side effects reported with Gavreto are carefully evaluated and any necessary action taken to protect patients.

Other information about Gavreto

Gavreto received a conditional marketing authorisation valid throughout the EU on 18 November 2021

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

This overview was last updated in 11-2021.