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Retsevmo (*selpercatinib*)

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

What is Retsevmo and what is it used for?

Retsevmo is a cancer medicine for use in patients whose cancer is caused by certain changes in a gene called *RET*, leading to the production of abnormal RET proteins. It can be used for:

- advanced non-small cell lung cancer (NSCLC) in adults not previously treated with a RET inhibitor;
- advanced thyroid cancer in patients from 12 years of age in whom radioactive iodine (an element that is taken up by the thyroid gland and leads to thyroid cell death) has not worked or has stopped working;
- advanced medullary thyroid cancer in patients aged from 12 years;
- advanced solid tumours in adults in whom treatments not targeting the RET protein have not worked well enough or who have no other treatment option.

Retsevmo contains the active substance selpercatinib.

How is Retsevmo used?

The medicine can only be obtained with a prescription and treatment should be started and supervised by a doctor experienced in the use of cancer treatments.

Retsevmo is available as capsules to be taken by mouth twice daily. Treatment with Retsevmo can continue until it stops working or the patient has severe side effects.

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

How does Retsevmo work?

The active substance in Retsevmo, selpercatinib, is a RET inhibitor which belongs to a broader class of cancer medicines known as tyrosine kinase inhibitors. It blocks the activity of abnormal proteins, which are made by the body due to changes in the *RET* gene. In patients with such changes, these abnormal proteins can lead to uncontrolled cell growth and cancer. By blocking the proteins, selpercatinib helps to reduce the growth and spread of cancer cells.

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What benefits of Retsevmo have been shown in studies?

In one main study in patients with cancers caused by abnormalities in the *RET* gene, Retsevmo was effective at reducing tumour size. In this study, Retsevmo was not compared with other medicines or placebo (a dummy treatment).

Advanced NSCLC

In adults with NSCLC who had previously been treated with platinum-based chemotherapy, the cancer shrank in 64% (67 out of 105) of patients treated with Retsevmo. In previously untreated patients, 84% (58 out of 69) had a complete (no signs of cancer) or partial (shrinkage of the tumour) response to treatment with Retsevmo.

Solid tumours (other than NSCLC and thyroid cancer)

Retsevmo was tested in 52 adults with a solid tumour (mostly cancer of the pancreas or the colon, and 14 other types of cancer), the majority of whom had been treated before but none of whom had previously received a RET inhibitor. The results showed that around 44% of patients (23 out of 52) had a complete or partial response to treatment which lasted on average 37 months.

Advanced thyroid cancer

In 19 adults with thyroid cancer who had previously been treated with sorafenib or lenvatinib or both, the cancer shrank in 79% of patients.

In 24 adults with thyroid cancer who did not receive other treatments besides radioactive iodine, the cancer shrank in around 96% (23 out of 24) of these patients.

In a study in patients from 12 to 21 years of age who had been previously treated or could not receive available treatments, the cancer shrank in 60% (6 out of 10) of patients. Based on these data and because the medicine is distributed in, and removed from, the body of these patients in the same way as in adults, Retsevmo is expected to be effective in adolescents.

Advanced medullary thyroid cancer

In adults and adolescents from 15 years of age with medullary thyroid cancer, the cancer shrank in 73.5% (111 out of 151) of patients who had previously been treated with cabozantinib or vandetanib, and in 81% (115 out of 142) of patients who had not previously received treatment with cabozantinib or vandetanib.

Retsevmo is also expected to be effective in adolescents from 12 years of age with medullary thyroid cancer because the medicine is distributed in, and removed from, the body of these patients in the same way as in adults.

What are the risks associated with Retsevmo?

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

The most common serious side effects with Retsevmo (which may affect up to 1 in 10 people) include pneumonia (infection of the lung), headache, hypersensitivity (allergic reactions), high blood pressure, abdominal (belly) pain, diarrhoea, nausea (feeling sick), vomiting, fever, tiredness, bleeding, blood tests showing changes in liver enzymes (indicating stress on the liver), increased creatinine (indicating kidney problems) and chylothorax (a condition in which fluid leaks into the space between lungs and the chest wall).

Why is Retsevmo authorised in the EU?

Retsevmo has been found to be effective at treating NSCLC and certain thyroid cancers caused by changes to the *RET* gene, reducing the size of the cancer in most patients. Beneficial effects were also shown in patients with other solid tumours that have changes to the *RET* gene. Its side effects are considered manageable. At the time of the medicine's approval for these conditions, treatment options were limited and Retsevmo addressed an medical need for these patients.

There are uncertainties concerning the long-term safety and effectiveness of Retsevmo due to the small number of patients included in the studies and the limited duration of treatment. However, these will be addressed by studies conducted by the company that markets Retsevmo.

The European Medicines Agency decided that Retsevmo's benefits are greater than its risks and it can be authorised for use in the EU.

Retsevmo has been given 'conditional authorisation'. This means that it has been authorised on the basis of less comprehensive data than are normally required because it fulfils an unmet medical need. The Agency considers that the benefit of having the medicine available earlier outweighs any risks associated with using it while waiting for further evidence.

The company marketing Retsevmo must provide further data on the medicine. It must submit results of studies to confirm its effectiveness and safety, particularly in comparison with other medicines that are used for the cancers for which Retsevmo has been authorised.

Every year, the Agency will review any new information that becomes available.

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

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

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

Other information about Retsevmo

Retsevmo received a conditional marketing authorisation valid throughout the EU on 11 February 2021.

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

This overview was last updated in 04-2024.