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Tagrisso (*osimertinib*)

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

What is Tagrisso and what is it used for?

Tagrisso is medicine for treating a lung cancer called non-small cell lung cancer (NSCLC) when the cancer is advanced or has spread.

It is used in patients who have mutations (changes) in a gene for a protein called EGFR. If a patient has mutations known as an 'activating mutations', Tagrisso is given as the first treatment. In patients with T790 mutation, the medicine may be given after other treatments.

It contains the active substance osimertinib.

How is Tagrisso used?

Before starting treatment, doctors should use a genetic test to confirm that the patient has an EGFR mutation.

Tagrisso is available as 40 and 80 mg tablets. The patient should take 80 mg once a day for as long as the disease improves or remains stable and the side effects are tolerable. If certain side effects develop the doctor may decide to reduce the dose or stop treatment. For more information about using Tagrisso, see the package leaflet or contact your doctor or pharmacist.

Treatment with Tagrisso should be started and supervised by a doctor who is experienced in the use of cancer medicines.

How does Tagrisso work?

The active substance in Tagrisso, osimertinib, is a type of cancer medicine called tyrosine kinase inhibitor. It blocks the activity of EGFR, which normally controls growth and division of cells. In lung cancer cells, EGFR is often overactive, causing uncontrolled growth of cancer cells. By blocking EGFR, osimertinib helps to reduce the growth and spread of the cancer.

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What benefits of Tagrisso have been shown in studies?

Tagrisso has been shown to be effective at shrinking tumours in patients with NSCLC and at slowing down the worsening of the cancer.

In two studies involving 411 previously treated patients who had T790 mutations, the overall response rates (the proportion of patients whose tumours shrank) with Tagrisso was 66% and the average length of time the response lasted was 12.5 months. In these studies, Tagrisso was not compared with any other treatment.

A third study in 419 previously treated patients with T790 mutations looked mainly at how effective Tagrisso was at preventing the cancer from worsening, comparing it with a platinum-based chemotherapy (the standard treatment for NSCLC). In patients taking Tagrisso, the cancer did not get worse for around 10.1 months compared with 4.4 months in patients on chemotherapy.

Finally, in a study of 556 patients with activating mutations, patients taking Tagrisso as a first treatment lived for 18.9 months without their disease getting worse compared with 10.2 months in patients receiving treatment with other medicines (either erlotinib or gefitinib).

What are the risks associated with Tagrisso?

The most common side effects with Tagrisso (which may affect more than 1 in 10 people) are diarrhoea, rash, dry skin, paronychia (nail bed infection), itching, stomatitis (inflammation of the lining of the mouth) and a decrease in the levels of white blood cells and platelets.

Tagrisso must not be used together with St. John's wort (a herbal preparation used to treat depression). For the full list of restrictions and side effects with Tagrisso, see the package leaflet.

Why is Tagrisso authorised in the EU?

Patients with EGFR mutations have a poor prognosis and limited treatment options; therefore there is a high unmet medical need. Tagrisso has been shown in studies to be effective at shrinking tumors in patients with these mutations and at slowing down the worsening of the cancer. Regarding safety, the adverse effects with Tagrisso are similar to other medicines of the same class and are considered acceptable.

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

Tagrisso was originally given 'conditional approval' because there was more evidence to come about the medicine. As the company has supplied the additional information necessary, the authorisation has been switched from conditional to full approval.

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

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

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

Other information about Tagrisso

Tagrisso received a conditional marketing authorisation valid throughout the EU on on 2 February 2016. This was switched to a full marketing authorisation on 24 April 2017.

Further information on Tagrisso can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

This overview was last updated in 06-2018.