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EPAR summary for the public

Tagrisso

osimertinib

This is a summary of the European public assessment report (EPAR) for Tagrisso. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Tagrisso.

For practical information about using Tagrisso, patients should read the package leaflet or contact their doctor or pharmacist.

What is Tagrisso and what is it used for?

Tagrisso is a cancer medicine used to treat adults with a type of lung cancer called non-small cell lung cancer (NSCLC).

Tagrisso is used in patients whose cancer is advanced or has spread and who have the T790M mutation, a particular change in the gene for a protein called epidermal growth factor receptor (EGFR).

It contains the active substance osimertinib.

How is Tagrisso used?

Treatment with Tagrisso should be started and supervised by a doctor who is experienced in the use of cancer medicines. Before starting treatment, doctors must confirm that their patients have the T790M mutation by genetic testing in an appropriate laboratory.

Tagrisso is available as tablets (40 and 80 mg) to be taken by mouth. The recommended dose is 80 mg once a day. Treatment with Tagrisso may continue 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 further information, see the package leaflet.

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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 division of cancer cells. By blocking EGFR, osimertinib helps to reduce the growth and spread of the cancer.

Unlike most other tyrosine kinase inhibitors, Tagrisso is active against cancer cells with the T790M mutation in the EGFR gene.

What benefits of Tagrisso have been shown in studies?

Tagrisso has been shown to be effective at shrinking tumors in patients with the T790M mutation and at slowing down the worsening of the cancer.

In two studies involving 411 patients, 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 patients 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.

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), pruritus (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 all restrictions and side effects with Tagrisso, see the package leaflet.

Why is Tagrisso approved?

Patients with the T790M mutation 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 this mutation 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 Agency's Committee for Medicinal Products for Human Use (CHMP) therefore concluded that Tagrisso's benefits are greater than its risks and recommended that it be approved 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.

Other information about Tagrisso

The European Commission granted a conditional marketing authorisation valid throughout the European Union for Tagrisso on 2 February 2016. This was switched to a full marketing authorisation on 24 April 2017.

The full EPAR for Tagrisso can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Tagrisso, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 04-2017.