EMA/547447/2024
EMEA/H/C/004124

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 a cancer medicine used to treat non-small cell lung cancer (NSCLC). It is used in patients whose cancer cells have certain mutations (changes) in the gene for a protein called EGFR.

It is used on its own:

- in patients whose cancer cells have Ex19del or L858R mutations and whose cancer has not spread to other organs and has been completely removed by surgery; the medicine is then given to help prevent the cancer from coming back (adjuvant therapy);
- in patients whose cancer cells have Ex19del or L858R mutations whose cancer is locally advanced (has started to spread to nearby areas) and cannot be removed by surgery, and whose disease has not worsened during or after treatment with platinum-based chemotherapy plus radiation therapy;
- in patients whose cancer cells have mutations known as 'activating mutations' and whose cancer is advanced or has spread; Tagrisso is then given as the first treatment;
- in patients whose cancer cells have T790M mutations and whose cancer is locally advanced or metastatic (has spread to other parts of the body).

Tagrisso can also be used in combination with pemetrexed and platinum-based chemotherapy (other cancer medicines) as the first treatment in adults with advanced NSCLC with Ex19del or L858R mutations.

Tagrisso contains the active substance osimertinib.

How is Tagrisso used?

Tagrisso can only be obtained with a prescription and treatment should be started and supervised by a doctor who is experienced in the use of cancer medicines. Before starting treatment, the doctor should use a genetic test to confirm that the patient has an EGFR mutation.

Tagrisso is available as tablets to be taken once a day for as long as the disease improves or remains stable, or does not come back after surgery, and as long as the side effects are tolerable. If certain

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

side effects occur, the doctor may decide to reduce the dose, or interrupt or permanently stop treatment.

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

How does Tagrisso work?

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

What benefits of Tagrisso have been shown in studies?

Studies in patients with NSCLC have found Tagrisso on its own to be effective at shrinking tumours and at slowing down the worsening of the cancer. One study has also found it to be effective at helping to prevent the cancer from coming back in patients who had surgery to completely remove the cancer.

In two studies involving 411 previously treated patients who had the T790M mutation, the overall response rate (the proportion of patients whose tumours shrank) with Tagrisso was 66% and the response lasted an average of 12.5 months. In these studies, Tagrisso was not compared with any other treatment.

A third study in 419 previously treated patients with the T790M mutation 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.

In a fourth 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).

In a fifth study in 216 previously treated patients with locally advanced NSCLC with Ex19del or L858R mutations, patients taking Tagrisso lived for 39.1 months without their disease getting worse, compared with 5.6 months in patients given a placebo (dummy treatment).

Finally, in a study involving 682 patients with Ex19del or L858R mutations who had surgery to completely remove the cancer, 89% (302 out of 339) of patients taking Tagrisso were still alive and disease-free after at least 1 year of treatment compared with 54% (184 out of 343) of patients taking a placebo.

Another study investigated the use of Tagrisso as first treatment in 557 patients with advanced NSCLC with Ex19del or L858R mutations. The study showed that patients treated with Tagrisso in combination with pemetrexed and platinum-based chemotherapy lived on average for 25.5 months without the disease getting worse, compared with 16.7 months for patients treated with Tagrisso on its own.

What are the risks associated with Tagrisso?

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

The most common side effects with Tagrisso when used on its own (which may affect more than 1 in 5 people) include diarrhoea, rash, paronychia (nail bed infection), dry skin, and stomatitis (inflammation of the lining of the mouth).

Tagrisso must not be used together with St. John's wort (a herbal preparation used to treat depression).

Why is Tagrisso authorised in the EU?

Tagrisso, both alone and in combination with other cancer medicines, has been shown in studies to be effective at shrinking tumours and slowing down the worsening of the cancer in patients with NSCLC whose tumours have EGFR mutations . The medicine is also effective at preventing NSCLC from coming back in patients whose tumours have EGFR mutations and who have had surgery to completely remove the cancer. Regarding safety, the side effects with Tagrisso when used on its own are similar to those seen with 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.

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. Suspected 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 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/medicines/human/EPAR/tagrisso.

This overview was last updated in 12-2024.