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EPAR summary for the public

Tarceva

erlotinib

This document is a summary of the European public assessment report (EPAR) for Tarceva. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Tarceva.

What is Tarceva and what is it used for?

Tarceva is a cancer medicine used in non-small-cell lung cancer (NSCLC) that is advanced (the cancer has started to spread) or metastatic (it has already spread to other parts of the body). It is used in the following patients:

- patients whose cancer cells have certain changes ('activating mutations') in the gene for a protein called epidermal growth factor receptor (EGFR) and have not received previous chemotherapy (medicines to treat cancer);
- patients with EGFR activating mutations whose disease is stable after initial chemotherapy. Stable means that the cancer had neither improved nor worsened with chemotherapy;
- patients with EGFR activating mutations who have had at least one previous chemotherapy treatment that has failed;
- patients without EGFR activating mutations who have had at least one previous chemotherapy treatment that has failed and when other treatments are considered unsuitable.

Tarceva is also used in patients with metastatic pancreatic cancer, in combination with gemcitabine (another cancer medicine).

The medicine contains the active substance erlotinib.

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How is Tarceva used?

Tarceva can only be obtained with a prescription and treatment should be supervised by a doctor who has experience in the use of cancer medicines. In patients who have not yet received chemotherapy, EGFR mutation testing should be performed before starting Tarceva therapy.

The medicine is available as tablets (25, 100 and 150 mg). For lung cancer, the recommended daily dose is 150 mg. For pancreatic cancer, it is 100 mg. Tarceva is taken at least one hour before or two hours after food. If needed (for example because of side effects), the dose may be reduced in 50 mg steps. As Tarceva seems to be more effective in patients with pancreatic cancer who develop a rash, treatment should be re-assessed after four to eight weeks if no rash has developed. Patients taking Tarceva should stop smoking, as smoking can decrease the amount of the medicine in the blood.

How does Tarceva work?

The active substance in Tarceva, erlotinib, is a cancer medicine that belongs to the group 'EGFR inhibitors'. Erlotinib blocks EGFRs, which can be found on the surface of some tumour cells. As a result of this block, the tumour cells can no longer receive the messages needed for growth, progression and spreading (metastasis). As a result, Tarceva helps to stop the cancer from growing, multiplying and spreading through the body.

How has Tarceva been studied?

NSCLC

In NSCLC, Tarceva has been mainly studied in four studies:

- the first study compared Tarceva with chemotherapy in 173 patients with advanced NSCLC with activating EGFR mutations who had not received previous chemotherapy. Patients taking Tarceva lived without their disease getting worse for an average of 10.4 months compared with 5.1 months for those receiving chemotherapy medicines.
- the second study compared Tarceva with placebo (a dummy treatment) in 889 patients with advanced or metastatic NSCLC whose disease had not got worse following an initial course of treatment with 4 cycles of platinum-containing chemotherapy. Overall, Tarceva caused a marginal increase in how long the patients lived without their disease getting worse and in how long they survived. The greatest benefit was observed in a subgroup of 49 patients with EGFR activating mutations: those taking Tarceva (22 patients) lived for an average of 44.6 weeks without their disease getting worse, compared with 13 weeks for those taking placebo (27 patients).
- a third study compared Tarceva with placebo in 643 patients with advanced NSCLC whose cancer cells did not have EGFR activating mutations and whose disease was stable after initial treatment with 4 cycles of platinum-containing chemotherapy. The study compared how long patients survived when Tarceva was used early in the study with how long they survived when Tarceva was used later in the study. The study found no advantage to early use of the medicine, as patients treated with Tarceva early in the study did not live longer than those treated with Tarceva later in the study (after the disease had progressed).
- the fourth study compared Tarceva with placebo in 731 patients who had not responded to at least one previous chemotherapy treatment. Patients taking Tarceva survived for an average of 6.7 months, compared with 4.7 months for the patients taking placebo. Among the patients who took

Tarceva, the average survival was 8.6 months in those whose tumours were 'EGFR IHC-positive' (had EGFRs on the cell surface), and 5.0 months in those whose tumours were EGFR IHC-negative.

Pancreatic cancer

In pancreatic cancer, Tarceva in combination with gemcitabine has been studied in 569 patients with pancreatic cancer that was advanced, unresectable (that cannot be removed by surgery) or metastatic. Patients with metastatic cancer taking Tarceva as initial therapy lived without their disease getting worse for an average of 5.9 months, compared with 5.1 months in those taking placebo. However, there was no advantage for patients whose cancer had not spread beyond the pancreas.

What is the risk associated with Tarceva?

In studies, the most common side effects with Tarceva when used as monotherapy for lung cancer were rash (seen in 75% of patients), diarrhoea (seen in 54% of patients), loss of appetite and tiredness (each seen in 52% of patients). In the study of Tarceva used in combination with gemcitabine for pancreatic cancer, the most common side effects were tiredness (seen in 73% of patients), rash (seen in 69% of patients) and diarrhoea (seen in 48% of patients). For the full list of side effects and restrictions with Tarceva, see the package leaflet.

Why has Tarceva been approved?

The European Medicines Agency decided that Tarceva's benefits are greater than its risks and recommended that it be given marketing authorisation.

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

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

Other information about Tarceva

The European Commission granted a marketing authorisation valid throughout the European Union for Tarceva on 19 September 2005.

The full EPAR for Tarceva 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 Tarceva, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2018.