18 March 2010
EMA/CHMP/86080/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (post authorisation)

Tarceva

erlotinib

On 18 March 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Tarceva. The marketing authorisation holder for this medicinal product is Roche Registration Limited. They may request a re-examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted *a* new indication as follows:

Tarceva is indicated as monotherapy for maintenance treatment in patients with locally advanced or metastatic non-small cell lung cancer with stable disease after 4 cycles of standard platinum-based first-line chemotherapy.

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

For information, the full indication for Tarceva will be as follows[2]:

"Non-small cell lung cancer (NSCLC):

Tarceva is indicated as monotherapy for maintenance treatment in patients with locally advanced or metastatic non-small cell lung cancer with stable disease after 4 cycles of standard platinum-based first-line chemotherapy.

Tarceva is **also** indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of at least one prior chemotherapy regimen.

When prescribing Tarceva, factors associated with prolonged survival should be taken into account.

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.
[2] The text in bold represents the new or the amended indication.

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No survival benefit or other clinically relevant effects of the treatment have been demonstrated in patients with EGFR – negative tumours (see section 5.1).

Pancreatic cancer:

Tarceva in combination with gemcitabine is indicated for the treatment of patients with metastatic pancreatic cancer.

When prescribing Tarceva, factors associated with prolonged survival should be taken into account (see section 4.2 and 5.1).

No survival advantage could be shown for patients with locally advanced disease."