European Medicines Agency
Evaluation of Medicines for Human Use

London, 14 December 2006
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
POST-AUTHORISATION SUMMARY OF POSITIVE OPINION*
for
TARCEVA

International Nonproprietary Name (INN): ***erlotinib***

On 14 December 2006 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion** to recommend the variation to the terms of the marketing authorisation for the medicinal product Tarceva. The Marketing Authorisation Holder for this medicinal product is Roche Registration Ltd.

The new indication adopted by CHMP is:

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

Detailed conditions for the use of this product will be described in the updated Summary of Product Characteristics (SPC) 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 of Tarceva will be as follows***:

"Non-small cell lung cancer (NSCLC):
Tarceva is 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.

No survival benefit or other clinically relevant effects of the treatment have been demonstrated in patients with EGFR- negative tumours.

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

* 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.

** Marketing Authorisation Holders may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

*** The text in bold represents the new or the amended indication.

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