17 December 2015
EMA/CHMP/816956/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Tarceva

erlotinib

On 17 December 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Tarceva. The marketing authorisation holder for this medicinal product is Roche Registration Limited.

The CHMP adopted a change to one of the existing indications of Tarceva as follows[2]:

> "Tarceva is also indicated ~~as monotherapy~~ for **switch** maintenance treatment in patients with locally advanced or metastatic NSCLC with **EGFR activating mutations and** stable disease after ~~4 cycles of standard platinum-based~~ first-line chemotherapy."

For information, the full indications for Tarceva will be as follows:

> *"Non-Small Cell Lung Cancer (NSCLC):*
>
> Tarceva is indicated for the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with EGFR activating mutations.
>
> Tarceva is also indicated for switch maintenance treatment in patients with locally advanced or metastatic NSCLC with EGFR activating mutations and stable disease after first-line chemotherapy.
>
> Tarceva is also indicated for the treatment of patients with locally advanced or metastatic NSCLC 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 Epidermal Growth Factor Receptor (EGFR)-IHC negative tumours.
>
> *Pancreatic cancer:*
>
> Tarceva in combination with gemcitabine is indicated for the treatment of patients with metastatic pancreatic cancer.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] New text in bold, removed text as strikethrough

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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 recommendations 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 a decision on this change to the marketing authorisation has been granted by the European Commission.