EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 June 2013
EMA/CHMP/364588/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Tyverb

lapatinib

On 27 June 2013, 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 Tyverb. The marketing authorisation holder for this medicinal product is Glaxo Group Ltd.

Tyverb is indicated for the treatment of adult patients with breast cancer whose tumours overexpress HER2 (ErbB2) in combination with capecitabine or an aromatase inhibitor. The CHMP has now recommended it for the treatment in combination with trastuzumab.

The full indication for Tyverb will now be as follows[2]:

"Tyverb is indicated for the treatment of adult patients with breast cancer, whose tumours overexpress HER2 (ErbB2);

- in combination with capecitabine for patients with advanced or metastatic disease with progression following prior therapy, which must have included anthracyclines and taxanes and therapy with trastuzumab in the metastatic setting (see section 5.1).
- **in combination with trastuzumab for patients with hormone receptor-negative metastatic disease that has progressed on prior trastuzumab therapy(ies) in combination with chemotherapy (see Section 5.1).**
- in combination with an aromatase inhibitor for postmenopausal women with hormone receptor positive metastatic disease, not currently intended for chemotherapy. The patients in the registration study were not previously treated with trastuzumab or an aromatase inhibitor (see section 5.1). No data are available on the efficacy of this combination relative to trastuzumab in combination with an aromatase inhibitor in this patient population."

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

[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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(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.