European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 24 April 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
TYVERB

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

On 24 April 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a conditional marketing authorisation for the medicinal product Tyverb, 250 mg, film-coated tablet, intended for treatment of patients with advanced or metastatic breast cancer whose tumours overexpress ErbB2 (HER2) and who have received prior therapy including anthracyclines, taxanes and trastuzumab. The applicant for this medicinal product is Glaxo Group Limited.

The active substance of Tyverb is lapatinib, a protein-tyrosine kinase inhibitor (L01XE07) that inhibits tumour cell growth by dually inhibiting the growth factor receptors ErbB1 (EGFR) and ErbB2 (HER2).

The benefits with Tyverb are in terms of increased time to progression evaluated in a randomized phase III trial comparing lapatinib in combination with capecitabine vs. capecitabine in patients with ErbB2(Her2)-over-expressing, locally advanced or metastatic breast cancer. The most common side effects are gastrointestinal disorders *(*diarrhoea, nausea, vomiting, dyspepsia, stomatitis, constipation and abdominal pain), skin disorders (rash, dry skin, and palmar-plantar erythrodysesthesia), anorexia, fatigue, pain in extremities and back, mucosal inflammation and insomnia.

A pharmacovigilance plan for Tyverb, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: Tyverb, in combination with capecitabine, is indicated for the treatment of patients with advanced or metastatic breast cancer whose tumours overexpress ErbB2 (HER2). Patients should have progressive disease following prior therapy which must include anthracyclines and taxanes and therapy with trastuzumab in the metastatic setting.

It is proposed that Tyverb is prescribed by physicians experienced in the administration of anti-cancer agents.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Tyverb and therefore recommends the granting of the marketing authorisation. The marketing authorisation is conditional***.

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* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants 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.

*** A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is likely to provide comprehensive clinical data at a later stage.

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