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Press Office

Press release

GlaxoSmithKline withdraws its application for an extension of the indication for Tyverb (lapatinib)

The European Medicines Agency has been formally notified by GlaxoSmithKline Research & Development of its decision to withdraw its application for an extension of the therapeutic indication for the centrally authorised medicine Tyverb (lapatinib), 250 mg film-coated tablets.

On 14 April 2011, GlaxoSmithKline submitted an application to extend the marketing authorisation for Tyverb in combination with paclitaxel for the treatment of patients with metastatic breast cancer whose tumours overexpress HER2 (ErbB2). The patients in the registration study were not previously treated with trastuzumab in either the adjuvant or metastatic setting. At the time of withdrawal, the application was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

Tyverb was given conditional approval and was first authorised in the European Union on 10 June 2008. It is currently authorised for treatment of 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;
- in combination with an aromatase inhibitor for postmenopausal women with hormone receptor positive metastatic disease, not currently intended for chemotherapy.

In its official letter, the company stated that its decision to withdraw the application was based on the CHMP's assessment that the lack of an active-controlled trial hampers the proper assessment of the benefit-risk balance in European patients in the applied indication.

Tyverb continues to be authorised in the currently approved indications.

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More information about Tyverb and the state of the scientific assessment at the time of withdrawal will be made available in a question-and-answer document. This document, together with the withdrawal letter from the company, will be published on the Agency's website after the 13-16 February CHMP meeting.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
3. Conditional approval means that there is more evidence to come about the medicine, in particular its effects on the spread of breast cancer. Every year, the European Medicines Agency will review any new information that becomes available and this summary will be updated as necessary.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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