European Medicines Agency
Press office

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PRESS RELEASE
AstraZeneca withdraws its marketing authorisation application for Zactima (vandetanib)

The European Medicines Agency has been formally notified by AstraZeneca of its decision to withdraw its application for a centralised marketing authorisation for the medicine Zactima (vandetanib), 100 mg film-coated tablets.

Zactima was expected to be used in combination with chemotherapy, for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) who have received prior anticancer therapy.

The application for the marketing authorisation for Zactima was submitted to the Agency on 30 June 2009. At the time of the withdrawal, it was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

In its official letter, the company stated that the withdrawal of the application was based on the preliminary comments from the Rapporteur and Co-Rapporteur, which indicate that at this point in time the Committee would be unlikely to conclude on a favourable benefit-risk balance for the product in the treatment of NSCLC in combination with chemotherapy.

More information about Zactima 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 next CHMP meeting of 16-19 November 2009.

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Notes:

1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
2. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.emea.europa.eu

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* The international non-proprietary name of the product has been corrected from vandetinib to vandetanib.