European Medicines Agency

London, 19 November 2009
Doc. Ref. EMEA/726915/2009
EMEA/H/C/1194

Questions and answers on the withdrawal of the marketing authorisation application for Zactima
vandetanib

On 27 October 2009, AstraZeneca officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Zactima, for use in combination with chemotherapy, for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) who have previously received anticancer treatment.

What is Zactima?
Zactima is a medicine that contains the active substance vandetanib. It was to be available as tablets.

What was Zactima expected to be used for?
Zactima was expected to be used in combination with chemotherapy (medicines to treat cancer) to treat patients with NSCLC who have previously received anticancer treatment. It was to be used in patients whose cancer is advanced or metastatic (has spread to other parts of the body).

How was Zactima expected to work?
The active substance in Zactima, vandetanib, is a tyrosine kinase inhibitor. This means that it blocks specific enzymes known as tyrosine kinases. Vandetanib was thought to block the activity of a tyrosine kinase called VEGF receptor, an enzyme that makes blood vessels grow. By attaching to VEGF receptor, Zactima was expected to stop the cancer cells from developing their own blood supply, helping to slow down the growth of the cancer. Vandetanib was also expected to work by blocking another enzyme called EGFR, which is involved in the growth and spread of cancer cells.

What documentation did the company present to support its application to the CHMP?
The effects of Zactima were first tested in experimental models before being studied in humans.
The company presented results of two main studies in 1,927 patients with NSCLC that was advanced or had spread to other parts of the body. The patients had previously received anticancer treatment. Patients were given docetaxel or pemetrexed (other anticancer medicines used in NSCLC) together with either Zactima or placebo (a dummy treatment). The main measure of effectiveness was how long the patients lived without their disease getting worse.

How far into the evaluation was the application when it was withdrawn?
The application was at day 96 when the company withdrew. The CHMP was evaluating the initial documentation provided by the company.
The CHMP normally takes up to 210 days to evaluate a new application. Based on the review of the initial documentation, the CHMP prepares a list of questions at day 120, which is sent to the company. Once the company has supplied responses to the questions, the CHMP reviews them and may, before giving an opinion, ask any remaining questions at day 180. Following the CHMP's opinion, it usually takes around two months for the European Commission to issue a decision on this opinion.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 71 29
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

What was the recommendation of the CHMP at that time?
The CHMP was evaluating the initial documentation provided by the company and had not yet made any recommendations.

What were the reasons given by the company for withdrawing the application?
The letter from the company notifying the CHMP of the withdrawal of the application is available here.

What are the consequences of the withdrawal for patients in clinical trials or compassionate use programmes using Zactima?
The company informed the CHMP that ongoing clinical trials in NSCLC and other conditions will continue. Zactima will continue to be made available to patients in these trials.