AstraZeneca

Dr Eric Abadie
European Medicines Agency
7 Westferry Circus
Canary Wharf
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E14 4HB
United Kingdom

27th October 2009

Subject: Withdrawal of the Marketing Authorisation Application for Zactima™ (Vandetinib) 100mg tablets. EMEA/H/C/001194/0000

Dear Dr Abadie,

I would like to inform you that AstraZeneca has taken the decision to withdraw the application for Marketing Authorisation of Zactima™ (vandetanib) 100mg tablets, which was submitted for the indication for "use 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."

AstraZeneca has taken this decision on the basis of preliminary comments from the Rapporteur and Co-Rapporteur, which indicate that CHMP is unlikely to conclude a favourable benefit-risk balance, at this point in time, for the use of Zactima™ 100mg in combination with chemotherapy as a treatment for NSCLC.

The Company intends to continue the development of this product and will continue to make Zactima™ available to patients in ongoing clinical trials in NSCLC. Ongoing clinical studies in other indications will also continue.

AstraZeneca reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

I agree for this letter to be published on the EMEA website.

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