European Medicines Agency
Press office

London, 2 March 2006
Doc. Ref. EMEA/76945/2006

Press release
Alcon Laboratories withdraws its application for RETAANE

The European Medicines Agency has been formally notified by Alcon Laboratories (UK) Ltd of its decision to withdraw its application for marketing authorisation for the medicinal product RETAANE (Anecortave acetate) 30mg/ml suspension for depot injection.

Alcon Laboratories (UK) Ltd submitted an application for marketing authorisation to the EMEA on 29 November 2004. At the time of the withdrawal, it was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

The indication applied for was the treatment of exudative age-related macular degeneration (AMD). Macular degeneration is a progressive disorder affecting the macula, which results in a loss of central vision. The exudative form of the disorder relates to the growth of abnormal blood vessels under the retina causing leakage of blood and other fluid from behind the retina into the eye.

In their formal withdrawal letter the company stated their research and development and marketing strategies as reasons for the withdrawal.

More information about RETAANE and the current 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 EMEA website, after the next meeting of the Committee for Medicinal Products for Human Use (CHMP) on 20-23 March 2006.

--ENDS--

NOTES

1. The legal basis for the publication of this withdrawal is Article 11 and Article 80 of Regulation (EC) No 726/2004.
2. Withdrawal of an application does not prejudice the possibility of a company to make a new application at a later stage.
3. This press release, together with other information about the work of the EMEA, may be found on the EMEA website: http://www.emea.eu.int

Media enquiries only to:
Martin Harvey Allchurch
Tel: (44-20) 74 18 84 27, E-mail: press@emea.eu.int