European Medicines Agency
Press office

London, 15 March 2007
Doc. Ref. EMEA/116976/2007

PRESS RELEASE
Eli Lilly withdraws its marketing authorisation application for ARXXANT

The European Medicines Agency (EMEA) has been formally notified by Eli Lilly Nederland B.V. of its decision to withdraw the application for a centralised marketing authorisation for the medicinal product ARXXANT (ruboxistaurin).

ARXXANT was expected to be used for the treatment of moderate to severe non-proliferative diabetic retinopathy (damage to the blood vessels in the retina) in adult patients. Diabetic retinopathy is a complication of diabetes and can cause severe vision loss or even blindness.

The application for marketing authorisation for ARXXANT was submitted to the EMEA on 30 May 2006. 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 ARXXANT was due to the fact that it is not able to respond to the CHMP's request for additional information within the allowed timeframe.

More information about ARXXANT 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 CHMP on 19-22 March 2007.

--ENDS--

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 about the work of the EMEA, may be found on the EMEA website: http://www.emea.europa.eu

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