European Medicines Agency
Press office

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PRESS RELEASE
Novagali Pharma S.A. withdraws its marketing authorisation application for Vekacia (ciclosporin)

The European Medicines Agency (EMEA) has been formally notified by Novagali Pharma S.A. of its decision to withdraw its application for a centralised marketing authorisation for the medicine Vekacia (ciclosporin) 0.05% eye drops. Vekacia was expected to be used for the treatment of vernal keratoconjunctivitis. Vekacia was designated as an orphan medicine on 6 April 2006.

The application for the marketing authorisation for Vekacia was submitted to the EMEA on 27 July 2007. 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 CHMP's view that the data provided did not allow the Committee to conclude on a positive benefit-risk balance for Vekacia at that time.

More information about Vekacia 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 EMEA website in due course.

-- 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 on the work of the EMEA, can be found on the EMEA website: 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