European Medicines Agency
Press office

London, 16 March 2009
Doc. Ref. EMEA/158824/2009

PRESS RELEASE
Schering-Plough Europe withdraws its marketing authorisation application for Cylatron (peginterferon alfa-2b)

The European Medicines Agency (EMEA) has been formally notified by SP Europe of its decision to withdraw its application for a centralised marketing authorisation for the medicine Cylatron (peginterferon alfa-2b), 200 micrograms /0.5 ml, 300 micrograms /0.5 ml and 600 micrograms/0.5 ml.

Cylatron was expected to be used for the adjuvant treatment of patients with stage III melanoma as evidenced by microscopic, non-palpable nodal involvement.

The application for the marketing authorisation for Cylatron was submitted to the EMEA on 7 September 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 were not sufficient to allow the Committee to conclude on a positive benefit-risk balance for Cylatron at that time.

More information about Cylatron 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

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