European Medicines Agency
Press office

London, 19 June 2008
Doc. Ref. EMEA/CHMP/323118/2008

PRESS RELEASE
Euro Nippon Kayaku GmbH withdraws its marketing authorisation application for Spanidin (gusperimus)

The European Medicines Agency (EMEA) has been formally notified by Euro Nippon Kayaku GmbH of its decision to withdraw its application for a centralised marketing authorisation application for the medicine Spanidin (gusperimus) 50 mg/ml powder for solution for injection.

Spanidin was expected to be used for induction of remission in adult patients suffering from clinically refractory Wegener's granulomatosis, where standard treatment with cyclophosphamide and glucocorticoids failed to induce or maintain remission. Wegener's granulomatosis is a rare auto-immune disease that causes inflammation of the blood vessels.

The application for marketing authorisation for Spanidin was submitted to the EMEA on 5 December 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 Spanidin was based on the request of the CHMP for an additional controlled study, which the company was not able to provide within the timeframe allowed by the centralised procedure.

More information about Spanidin 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 shortly.

-- 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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