European Medicines Agency
Press office

London, 29 May 2007
Doc. Ref. EMEA/235491/2007

PRESS RELEASE
Protherics withdraws its marketing authorisation application for Voraxaze

The European Medicines Agency (EMEA) has been formally notified by Protherics PLC of its decision to withdraw the application for a centralised marketing authorisation for the medicinal product Voraxaze (glucarpidase) powder for solution for injection 1000 Units.

Voraxaze was expected to be used in the adjunctive treatment of patients who are experiencing or at risk of methotrexate toxicity. This is a rare, life-threatening condition that can occur in patients who receive methotrexate, a medicine used to treat certain cancers and autoimmune diseases. Signs of methotrexate toxicity include kidney failure, reduction in blood count and mucosal ulcers.

The application for marketing authorisation for Voraxaze was submitted to the EMEA on 29 July 2005. 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 Voraxaze was based on the CHMP's request for additional information, to which the company was unable to respond within the required timeframe.

More information about Voraxaze 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 after the next meeting of the CHMP on 19-22 June 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, can be found on the EMEA website: http://www.emea.europa.eu

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