European Medicines Agency
Press office

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PRESS RELEASE
Merck Sharp & Dohme Ltd withdraws its marketing authorisation application for Vorinostat MSD (vorinostat)

The European Medicines Agency (EMEA) has been formally notified by Merck Sharp & Dohme Ltd of its decision to withdraw its application for a centralised marketing authorisation for the medicine Vorinostat MSD (vorinostat), 100 mg hard capsules.

Vorinostat MSD was expected to be used for the treatment of patients with advanced stage cutaneous T-cell lymphoma (CTCL) who have progressive, persistent or recurrent disease, and who have failed at least two prior systemic therapies. Vorinostat MSD was designated as an orphan medicine on 21 June 2004.

The application for the marketing authorisation for Vorinostat MSD was submitted to the EMEA on 29 October 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 Vorinostat MSD at that time.

More information about Vorinostat MSD 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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