European Medicines Agency
Press office

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PRESS RELEASE
DOR BIOPHARMA UK Ltd withdraws marketing authorisation application for orBec (beclomethasone dipropionate)

The European Medicines Agency (EMEA) has been formally notified by DOR BIOPHARMA UK Ltd of its decision to withdraw the application for a centralised marketing authorisation for the medicine orBec (beclomethasone dipropionate) 1 mg tablets and 1 mg gastro-resistant tablets.

orBec was expected to be used for the treatment of gastrointestinal graft-versus-host disease. It was designated as an orphan medicine on 13 March 2002.

The application for marketing authorisation for orBec was submitted to the EMEA on 2 November 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 orBec was based on the CHMP's request for additional clinical data, to which the company was unable to respond within the permitted timeframe.

More information about orBec 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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