European Medicines Agency
Press office

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PRESS RELEASE
Ark Therapeutics withdraws its marketing authorisation application for Cerepro

The European Medicines Agency (EMEA) has been formally notified by Ark Therapeutics Ltd of its decision to withdraw the application for a centralised marketing authorisation for the medicinal product Cerepro (adenovirus-mediated *Herpes simplex* virus-thymidine kinase gene*)*.

Cerepro was expected to be used in combination with ganciclovir sodium to treat high-grade glioma in patients who are eligible for surgery. Glioma is a type of brain tumour that begins in 'glial' cells (the cells that surround and support nerve cells).

The application for marketing authorisation for Cerepro was submitted to the EMEA on 4 October 2005. The Committee for Medicinal Products for Human Use (CHMP) had given a negative opinion recommending the refusal of a marketing authorisation in April 2006. The company had requested a re-examination of the negative opinion, which had not yet finished when the company withdrew.

In its official letter, the company stated that the results of a multicentre study of the efficacy and safety of Cerepro, which the company believes would satisfy the CHMP's concerns, are not expected to become available until 2008.

More information about Cerepro 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 about the work of the EMEA, can be found on the EMEA website: http://www.emea.europa.eu

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