



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 March 2010
EMA/151854/2010
Press Office

Press release

Ark Therapeutics Ltd withdraws its marketing authorisation application for Cerepro (sitimagene ceradenovec)

The European Medicines Agency has been formally notified by Ark Therapeutics Ltd of its decision to withdraw its application for a centralised marketing authorisation for the advanced therapy medicinal product Cerepro (sitimagene ceradenovec).

Cerepro received an orphan designation on 6 February 2002 and was intended for the treatment of patients with high-grade operable glioma.

Following the adoption of a negative opinion for Cerepro by the Committee for Medicinal Products for Human Use (CHMP) in December 2009, the company had requested a re-examination of the opinion. This procedure started on 18 February 2010.

In its official letter, the company stated that it has been unable to demonstrate to the Committee that its main study provides clear evidence of a clinically meaningful benefit in relation to risk. Based on this, the company decided to withdraw its marketing authorisation application.

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 Agency's website after the next CHMP meeting on 15-18 March 2010.

Notes

1. The question and answer document for the negative opinion for Cerepro adopted in December 2009 can be found here:
http://www.ema.europa.eu/pdfs/human/opinion/Cerepro_Q&A_828428en.pdf
2. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.



3. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu

Contact our press officers

Martin Harvey Allchurch or Monika Benstetter

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu