8 March 2009

[redacted]

Dr Eric Abadie
Chairman, Committee for Medicinal Products for Human Use
European Medicines Agency
7 Westferry Circus
Canary Wharf
London E14 4HB

Subject: Withdrawal of the Marketing Authorisation Application for Cerepro (sitimagene ceradenovec) (EMEA/H/C/1103)

Dear Dr Abadie

I would like to inform you that Ark Therapeutics Ltd has taken the decision to withdraw its Marketing Authorisation Application for Cerepro, an orphan drug intended for the treatment of patients with high-grade operable glioma.

The company has been unable to demonstrate to the satisfaction of the CHMP and its committees that Study 904 provides clear evidence of a clinically meaningful benefit in relation to risk and on the basis of this has decided to withdraw its application.

There are currently no patients in the EU receiving Cerepro as part of an on-going clinical trial or a formal compassionate use programme. The company reserves the right to respond to bona fide unsolicited requests from healthcare professionals in the EU to supply Cerepro for use by neurosurgeons for patients with high-grade operable glioma in order to fulfil special medical needs pursuant to Article 5(1) of Directive 2001/83/EU or the equivalent provisions in the domestic laws of the member States.

Ark Therapeutics reserves the right to make further submissions at a future date in this or other therapeutic indication(s).

I agree to the publication of this letter on the EMA website.

Yours sincerely

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