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Ark Therapeutics Ltd
79 New Cavendish Street
London W1W 6XB

Phone: +44 (0) 20 7388 7722
Fax: +44 (0) 20 7388 7805
www.arktherapeutics.com

Dr Eric Abadie
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Subject: Withdrawal of Cerepro (adenovirus-mediated Herpes Simplex Virus-thymidnie kinase gene) EMEA/H/C/000694/000

Dear Dr Abadie

For the withdrawal of initial marketing authorisation application

I would like to inform you that, at this point of time, Ark Therapeutics Ltd has taken the decision to withdraw the application for Marketing Authorisation of Cerepro, which was intended to be used in conjunction with ganciclovir sodium for the treat met of patients with high-grade operable glioma.

This withdrawal is based on the following reason:

- *the CHMP considers that the data provided do not allow the Committee to conclude on a positive benefit risk balance*

It is clear to Ark Therapeutics that the Committee's concern should be satisfied by a larger clinical study. Ark is conducting Study 904, a controlled, randomised, parallel group, multicentre study of the efficacy and safety of Cerepro, and recruitment of the 250 patients is complete. The study is expected to report in 2008 and Ark believes that this will address the outstanding issues and lead to a satisfactory conclusion of the regulatory process for Cerepro.

Since Cerepro is given as a single administration and the fact that all the 250 patients have been treated in Study 904, there is no consequence of this withdrawal on the clinical trial. Compassionate use studies are not on-going.

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

I agree for this letter to be published on the EMEA website.

Yours sincerely,

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