



European Medicines Agency

Doc. Ref. EMEA/259189/2008
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EUROPEAN MEDICINES AGENCY DECISION

of 23 May 2008

on the application for agreement of a Paediatric Investigation Plan for adenovirus-mediated Herpes simplex virus-thymidine kinase gene (EMEA-000140-PIP01-07) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use as amended and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004¹,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency²,

Having regard to the application submitted by Ark Therapeutics Ltd. on 11 January 2008 under Article 16.1 of Regulation (EC) No 1901/2006 as amended also including a request for a waiver under Article 13 of said Regulation and a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, formulated on 11 April 2008, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation and Article 21 of said Regulation,

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

WHEREAS:

- (1) The Paediatric Committee of the European Medicines Agency, has given a positive opinion,
- (2) It is therefore appropriate to adopt a Decision following the Paediatric Committee's opinion on the Paediatric Investigation Plan.
- (3) It is therefore appropriate to adopt a Decision granting a waiver.
- (4) It is therefore appropriate to adopt a Decision granting a deferral.

¹ OJ L 378, 27.12.2006, p.1

² OJ L 136, 30.4.2004, p. 1

HAS ADOPTED THIS DECISION:

Article 1

A Paediatric Investigation Plan for adenovirus-mediated Herpes simplex virus-thymidine kinase gene, concentrate for solution for injection, intracerebral use, the details of which are set out in the Opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A waiver for adenovirus-mediated Herpes simplex virus-thymidine kinase gene, concentrate for solution for injection, intracerebral use, the details of which are set out in the Opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A deferral for adenovirus-mediated Herpes simplex virus-thymidine kinase gene, concentrate for solution for injection, intracerebral use, the details of which are set out in the Opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

This decision is addressed to Ark Therapeutics Ltd, 79 New Cavendish Street, W1W 6XB London, United Kingdom.

Done at London, 23 May 2008

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)



European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

EMA/259189/2008
EMA-000140-PIP01-07

**POSITIVE OPINION OF THE PAEDIATRIC COMMITTEE ON
A REQUEST FOR AGREEMENT OF
A PAEDIATRIC INVESTIGATION PLAN FOR**

Scope of the application

Active substance:

Adenovirus-mediated Herpes simplex virus-thymidine kinase gene

Condition(s):

High-grade glioma

Pharmaceutical form(s):

Concentrate for solution for injection

Route(s) of administration:

Intracerebral use

Name/corporate name of the PIP applicant:

Ark Therapeutics Ltd.

Basis for opinion

Pursuant to Article 16.1 of Regulation (EC) No 1901/2006 as amended, Ark Therapeutics Ltd. submitted for agreement to the EMA on 11 January 2008 a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 14 February 2008.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree the paediatric investigation plan in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended,
- to grant a deferral in accordance with Article 21 of Regulation (EC) No 1901/2006 as amended
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended and concluded in accordance with Article 11(1)(b) of Regulation (EC) No 1901/2006 as amended, on the grounds that the disease or condition for which the specific medicinal product is intended occurs only in adult populations.

The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the Agency, together with its annex(es) and appendix(ces).

London, 11 April 2008

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

THE MEASURES AND TIMELINES OF THE AGREED PAEDIATRIC INVESTIGATION PLAN AND THE SUBSET(S) OF THE PAEDIATRIC POPULATION AND CONDITION(S) COVERED BY THE WAIVER

A. CONDITION(S) / DISEASE(S)

High-grade glioma

B. WAIVER

- **Condition**

High-grade glioma

- **Subset(s) of the paediatric population, pharmaceutical form(s) and route(s) of administration covered**

The waiver applies to:

Children aged 0 to less than 1 month for the concentrate for solution for injection for intracerebral use

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

High-grade glioma

- **Paediatric investigation plan indication**

Treatment of operable supratentorial high-grade glioma

- **Subset(s) covered**

Children aged 1 month to less than 18 years

- **Formulation(s)**

Concentrate for solution for injection

- **Studies / Measures**

#	Area	Subarea	Description
1	Clinical	Safety	Open-label, uncontrolled safety study of adenovirus-mediated Herpes simplex virus-thymidine kinase gene and nucleoside analogue treatment of children with high-grade glioma

Need for paediatric measures in a EU-Risk Management Plan: Yes

Date of completion of the paediatric investigation plan: 4 years after initiation of study

A deferral has been granted: Yes