EMA/784348/2018

European Medicines Agency decision

P/0349/2018

of 16 November 2018

on the agreement of a paediatric investigation plan for brincidofovir (EMEA-001904-PIP03-18) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Contact EMA www.ema.europa.eu/contact

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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

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 and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

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 Agency[2],

Having regard to the application submitted by Chimerix UK Limited on 18 January 2018 under Article 16(1) of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 19 October 2018, in accordance with Article 17 of Regulation (EC) No 1901/2006,

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

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the agreement of a paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

[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 brincidofovir, oral suspension, film-coated tablet, oral 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

This decision is addressed to Chimerix UK Limited, 5th Floor, 6 St Andrew Street, EC4A 3AE - London, United Kingdom.

EMA/PDCO/514456/2018
London, 19 October 2018

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan

EMEA-001904-PIP03-18

Scope of the application

Active substance(s):

Brincidofovir

Condition(s):

Treatment of smallpox

Pharmaceutical form(s):

Oral suspension

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Chimerix UK Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Chimerix UK Limited submitted for agreement to the European Medicines Agency on 18 January 2018 an application for a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 27 February 2018.

Supplementary information was provided by the applicant on 10 July 2018.

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 17(1) of said Regulation.

   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 are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

Not applicable

1.1. Condition:

Treatment of smallpox

2. Paediatric investigation plan

2.1. Condition:

Treatment of smallpox

2.1.1. Indication(s) targeted by the PIP

Treatment of smallpox

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

- Oral suspension
- Film-coated tablet

2.1.4. Studies

Area	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	0	Not applicable
Extrapolation, modelling and simulation studies	2	**Study 1** Modelling and simulation study to evaluate the use of brincidofovir (BCV) for the treatment of smallpox in children from birth to less than 18 years of age who receive treatment with brincidofovir as part of their clinical care. **Study 2** Extrapolation study to estimate BCV plasma exposures based on PBPK modelling for the treatment of smallpox in children from birth to less than 3 months of age.

Other studies	0	Not applicable
Other measures	0	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By September 2019
Deferral for one or more measures contained in the paediatric investigation plan:	No