EMA/205675/2022

European Medicines Agency decision

P/0180/2022

of 13 May 2022

on the acceptance of a modification of an agreed paediatric investigation plan for brincidofovir (EMEA-001904-PIP03-18-M02) 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.

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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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0349/2018 issued on 16 November 2018 and the decision P/0320/2020 issued on 12 August 2020,

Having regard to the application submitted by Chimerix IRL Limited on 17 December 2021 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 25 March 2022, in accordance with Article 22 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 acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for brincidofovir, oral suspension, film-coated tablet, oral use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Chimerix IRL Limited, 10 Earlsfort Terrace, Post Code 2 – Dublin, Ireland.

EMA/PDCO/5273/2022
Amsterdam, 25 March 2022

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-001904-PIP03-18-M02

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 IRL Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Chimerix IRL Limited submitted to the European Medicines Agency on 17 December 2021 an application for modification of the agreed paediatric investigation plan as set out in the European Medicines Agency's decision P/0349/2018 issued on 16 November 2018 and the decision P/0320/2020 issued on 12 August 2020.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 31 January 2022.

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

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

2. The measures and timelines of the 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 annex 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	Description
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	Not applicable
Extrapolation, modelling and simulation studies	**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 simulate BCV plasma exposures based on PopPK modelling for the treatment of smallpox in children from birth to less than 3 months of age.
Other studies	Not applicable
Other measures	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 December 2021
Deferral for one or more measures contained in the paediatric investigation plan:	No