EMA/616460/2021

European Medicines Agency decision

P/0496/2021

of 3 December 2021

on the acceptance of a modification of an agreed paediatric investigation plan for tecovirimat (monohydrate) (EMEA-001205-PIP02-19-M01) 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 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 European Medicines Agency's decision P/0274/2020 issued on 17 July 2020,

Having regard to the application submitted by SIGA Technologies, Inc., on 9 July 2021 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 October 2021, 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 and to the deferral.

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

Changes to the agreed paediatric investigation plan for tecovirimat (monohydrate), capsule, hard, powder for oral suspension, oral use, gastric use, including changes to the deferral, 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 SIGA Technologies, Inc., 4575 SW Research Way, Suite 110, 97333 - Corvallis, United States.

EMA/PDCO/403249/2021
Amsterdam, 15 October 2021

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

EMEA-001205-PIP02-19-M01

Scope of the application

Active substance(s):

Tecovirimat (monohydrate)

Condition(s):

Treatment of orthopoxvirus disease (smallpox, monkeypox, cowpox, and vaccinia)

Pharmaceutical form(s):

Capsule, hard

Powder for oral suspension

Route(s) of administration:

Oral use

Gastric use

Name/corporate name of the PIP applicant:

SIGA Technologies, Inc.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, SIGA Technologies, Inc. submitted to the European Medicines Agency on 9 July 2021 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0274/2020 issued on 17 July 2020.

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

The procedure started on 17 August 2021.

Scope of the modification

Some measures and timelines 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 and to the deferral in the scope set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee member 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

2. Paediatric investigation plan

2.1. Condition:

Treatment of orthopoxvirus disease (smallpox, monkeypox, cowpox, and vaccinia)

2.1.1. Indication(s) targeted by the PIP

Treatment of orthopoxvirus disease (smallpox, monkeypox, cowpox, and vaccinia)

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)

Capsule, hard

Powder for oral suspension

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of powder for oral suspension
Non-clinical studies	6	**Study 2 (246-TX-007)** Dose range-finding juvenile toxicity study to evaluate potential subchronic toxicity, and pharmacokinetics/toxicokinetics of tecovirimat **Study 3 (2083-003-001-SN6)** Dose range-finding juvenile toxicity study to evaluate the toxicity of tecovirimat, and to determine the reversibility of any toxic effects. **Study 4 (MPI 1151-065)** Repeat dosing pharmacokinetics of tecovirimat **Study 5 (FY10-087)** Juvenile animal pharmacology study to evaluate pharmacokinetics and efficacy of tecovirimat after monkeypox virus (MPXV) challenge

		Study 6 (AP-09-026G) Juvenile animal pharmacology study to determine the minimum effective dose of tecovirimat in treating symptomatic (lesional) disease in NHPs infected with MPXV **Study 7 (2083-003-001 SN9)** Placental transfer and milk transfer study of tecovirimat
Clinical studies	2	**Study 8 (SIGA-246-027)** Open-label, single dose, crossover, PK study evaluating prototype powder for reconstitution liquid suspension formulations of tecovirimat in healthy adult subjects compared to Tecovirimat SIGA 200 mg capsules. **Study 9 (SIGA-246-029)** Open-label, single oral dose, crossover pharmacokinetic study of tecovirimat capsules versus tecovirimat powder for reconstitution to liquid suspension dosed in fed state in healthy adult subjects
Extrapolation, modelling and simulation studies	1	**Study 10 (Population PK Model for Paediatric Dose Determination)** Modelling and simulation study to determine dosing of tecovirimat in in paediatric patients from birth to less than 18 years 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:	No
Date of completion of the paediatric investigation plan:	By April 2025
Deferral for one or more measures contained in the paediatric investigation plan:	Yes