EMA/876002/2022

# European Medicines Agency decision

P/0540/2022

of 30 December 2022

on the acceptance of a modification of an agreed paediatric investigation plan for tecovirimat (monohydrate) (Tecovirimat SIGA), (EMEA-001205-PIP02-19-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/0274/2020 issued on 17 July 2020, and decision P/0496/2021 issued on 3 December 2021,

Having regard to the application submitted by SIGA Technologies, Inc. on 12 July 2022 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 11 November 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 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, 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 tecovirimat (monohydrate) (Tecovirimat SIGA), 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, USA.

EMA/PDCO/695494/2022
Amsterdam, 11 November 2022

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

EMEA-001205-PIP02-19-M02

## Scope of the application

**Active substance(s):**

Tecovirimat (monohydrate)

**Invented name and authorisation status:**

See Annex II

**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 12 July 2022 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, and decision P/0496/2021 issued on 3 December 2021.

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

The procedure started on 12 September 2022.

## 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 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 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

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

| | |
|---|---|
| | **Study 6 (AP-09-026G)**<br><br>Juvenile animal pharmacology study to determine the minimum effective dose of tecovirimat in treating symptomatic (lesional) disease in NHPs infected with MPXV<br><br>**Study 7 (2083-003-001 SN9)**<br><br>Placental transfer and milk transfer study of tecovirimat |
| Clinical studies | **Study 8 (SIGA-246-027)**<br><br>*This study was removed with procedure EMEA-001205-PIP02-19-M02*<br><br>**Study 9 (SIGA-246-029)**<br><br>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 | **Study 10 (Population PK Model for Paediatric Dose Determination)**<br><br>Modelling and simulation study to determine dosing of tecovirimat in in paediatric patients from birth to less than 18 years 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: | No |
| Date of completion of the paediatric investigation plan: | By August 2024 |
| Deferral for one or more measures contained in the paediatric investigation plan: | Yes |

# Annex II

# Information about the authorised medicinal product

## *Information provided by the applicant:*

## Condition(s) and authorised indication(s)

1. Treatment of smallpox, monkeypox, cowpox, and vaccinia virus

Authorised indication(s):

Tecovirimat SIGA is indicated for the treatment of the following viral infections in adults and children with body weight at least 13 kg: Smallpox, Monkeypox, Cowpox. Tecovirimat SIGA is also indicated to treat complications due to replication of vaccinia virus following vaccination against smallpox in adults and children with body weight at least 13 kg

- Invented name(s): Tecovirimat SIGA
- Authorised pharmaceutical form(s): Hard capsules
- Authorised route(s) of administration: oral route
- Authorised via centralised procedure