



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/673781/2022 Corr

European Medicines Agency decision P/0342/2022

of 10 August 2022

on the acceptance of a modification of an agreed paediatric investigation plan for rezafungin acetate (EMA-002319-PIP01-17-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.



European Medicines Agency decision

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on the acceptance of a modification of an agreed paediatric investigation plan for rezafungin acetate (EMA-002319-PIP01-17-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 726/2004¹,

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 Agency²,

Having regard to the European Medicines Agency's decision P/0014/2019 issued on 3 January 2019, and decision P/0395/2021 issued on 8 September 2021,

Having regard to the application submitted by Mundipharma Corporation (Ireland) Limited on 21 March 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 24 June 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 rezafungin acetate, powder for concentrate for solution for infusion, age-appropriate dosage form for parenteral use, intravenous 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 Mundipharma Corporation (Ireland) Limited, Millbank House, 18 Arkle Road, Sandyford Industrial Estate, D18 C6R3 – Dublin, Ireland.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/194328/2022 Corr2
Amsterdam, 24 June 2022

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-002319-PIP01-17-M02

Scope of the application

Active substance(s):

Rezafungin acetate

Condition(s):

Treatment of invasive candidiasis

Pharmaceutical form(s):

Powder for concentrate for solution for infusion

Age-appropriate dosage form for parenteral use

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Mundipharma Corporation (Ireland) Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Mundipharma Corporation (Ireland) Limited submitted to the European Medicines Agency on 21 March 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/0014/2019 issued on 3 January 2019, and decision P/0395/2021 issued on 8 September 2021.

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

The procedure started on 25 April 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 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 invasive candidiasis

2.1.1. Indication(s) targeted by the PIP

Treatment of invasive candidiasis

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)

Powder for concentrate for solution for infusion

Age-appropriate dosage form for parenteral use

2.1.4. Measures

Area	Description
Quality-related studies	Study 1 Development of an age-appropriate dosage form for parenteral use suitable for the paediatric population from birth with polysorbate 80 level safe for young infants
Non-clinical studies	Study 4 (Added during procedure EMEA-002319-PIP01-17-M02) Single-dose juvenile toxicokinetic study in rats Study 5 (Added during procedure EMEA-002319-PIP01-17-M02) Dose range-finding juvenile toxicity study in rats Study 6 (Added during procedure EMEA-002319-PIP01-17-M02) Definitive juvenile toxicity study in rats

Clinical studies	<p>Study 2</p> <p>Open-label, uncontrolled trial to evaluate PK, safety and tolerability of a single IV dose of rezafungin acetate profile in children from birth to less than 18 years of age receiving systemic antifungals prophylactically or to treat a suspected or confirmed fungal infection</p> <p>Study 3</p> <p>Open-label, randomised, active-controlled trial to evaluate safety, tolerability and efficacy of rezafungin acetate in children from birth to less than 18 years of age with suspected or confirmed invasive candidiasis</p>
Extrapolation, modelling and simulation studies	Not applicable
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 September 2029
Deferral for one or more measures contained in the paediatric investigation plan:	Yes