EMADOC-1700519818-2039209

European Medicines Agency decision

EMA/PE/0000237220

of 14 April 2025

on the acceptance of a modification of an agreed paediatric investigation plan for rezafungin acetate (Rezzayo) 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/0014/2019 issued on 3 January 2019, the decision P/0395/2021 issued on 8 September 2021, the decision P/0342/2022 issued on 10 August 2022, and the decision P/0343/2024 issued on 13 September 2024,

Having regard to the application submitted by Mundipharma GmbH on 22 November 2024 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 28 February 2025, 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 rezafungin acetate (Rezzayo), 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 GmbH, De-Saint-Exupery-Strasse 10, Flughafen, 60549 - Frankfurt Am Main, Germany.

EMADOC-1700519818-1803938
Amsterdam, 28 February 2025

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

EMA/PE/0000237220

Scope of the application

Active substance(s):

Rezafungin acetate

Invented name and authorisation status:

See Annex II

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 GmbH

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Mundipharma GmbH submitted to the European Medicines Agency on 22 November 2024 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, the decision P/0395/2021 issued on 8 September 2021, the decision P/0342/2022 issued on 10 August 2022, and the decision P/0343/2024 issued on 13 September 2024.

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

The procedure started on 2 January 2025.

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 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 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	**Study 2** (Deleted during procedure EMEA-002319-PIP01-17-M03) **Study 3** (Deleted during procedure EMEA-002319-PIP01-17-M03) **Study 7** (Added during procedure EMEA-002319-PIP01-17-M03) Open-label, uncontrolled trial to evaluate safety, tolerability, PK and activity of rezafungin acetate for prevention of invasive candidiasis in immunocompromised children from birth to less than 18 years of age (MR907-2503) **Study 8** (Added during procedure EMEA-002319-PIP01-17-M03) Open-label, uncontrolled trial to evaluate safety, tolerability, PK and activity of rezafungin acetate in children from birth to less than 18 years of age with suspected or confirmed invasive candidiasis
Extrapolation, modelling and simulation studies	**Study 9** (Added during procedure EMEA-002319-PIP01-17-M03) Population PK modelling of rezafungin acetate to confirm the paediatric posology 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:	Yes
Date of completion of the paediatric investigation plan:	By April 2030
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 invasive candidiasis

Authorised indication(s):

- Rezzayo is indicated for the treatment of invasive candidiasis in adults
  - Invented name(s): Rezzayo
  - Authorised pharmaceutical form(s): Powder for concentrate for solution for infusion
  - Authorised route(s) of administration: Intravenous use
  - Authorised via centralised procedure