EMADOC-1700519818-2113581

European Medicines Agency decision

EMA/PE/0000232777

of 16 May 2025

on the agreement of a paediatric investigation plan and on the granting of a deferral for zosurabalpin 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

EMA/PE/0000232777

of 16 May 2025

on the agreement of a paediatric investigation plan and on the granting of a deferral for zosurabalpin 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 726/2004[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 application submitted by Roche Registration GmbH on 29 May 2024 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 28 March 2025, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a 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

A paediatric investigation plan for zosurabalpin, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for zosurabalpin, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Roche Registration GmbH, Emil-Barell-Strasse 1, Grenzach - 79639, Germany.

EMADOC-1700519818-1851583
Amsterdam, 28 March 2025

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral

EMA/PE/0000232777

Scope of the application

Active substance(s):

Zosurabalpin

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of infections due to *Acinetobacter baumannii-calcoaceticus* complex

Pharmaceutical form(s):

Solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Roche Registration GmbH

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Roche Registration GmbH submitted for agreement to the European Medicines Agency on 29 May 2024 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 8 July 2024.

Supplementary information was provided by the applicant on 17 December 2024. The applicant proposed modifications to the paediatric investigation plan.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation.

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

2. The measures and timelines of the agreed 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 infections due to Acinetobacter baumannii-calcoaceticus complex.

2.1.1. Indication(s) targeted by the PIP

Treatment of infections due to Acinetobacter baumannii-calcoaceticus (ABC organisms) in pediatric patients with limited treatment options.

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)

Solution for infusion

2.1.4. Measures

Area	**Description**
Quality-related studies	***Study 1*** Development of an age-appropriate formulation and method of administration of the solution for infusion of zosurabalpin for use in paediatric patients.
Non-clinical studies	Not applicable
Clinical studies	***Study 2*** Open-label, multiple dose trial to evaluate pharmacokinetics, safety, and tolerability of zosurabalpin (as add-on to standard of care) in male and female paediatric participants from birth (including preterm neonates) to less than 18 years of age receiving intravenous (IV) antibiotic therapy for pneumonia or bacteraemia suspected or confirmed to be caused by *Acinetobacter baumannii-calcoaceticus* complex (ABC) organisms.
Modelling and simulation analyses	***Study 3*** Use of physiologically based pharmacokinetic modelling for prediction of paediatric doses for zosurabalpin.

	Study 4 Use of population pharmacokinetic modelling for dose selection of zosurabalpin, definition of sample size and pharmacokinetic sampling timelines required in study 2 and to support extrapolation of efficacy.
Other studies	Not applicable
Extrapolation plan	Adult phase 1 and 3 studies (BP41732, BP43532, BP43628, BP43629, BP43792, BP43949, BP44069, BP44773 and YV44878) and PIP studies 2, 3 and 4 are part of an extrapolation plan covering the paediatric population from birth to less than 18 years of age, as agreed by the PDCO.

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 January 2034
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:

The product is not authorised anywhere in the European Community.