EMA/873551/2022

European Medicines Agency decision

P/0476/2022

of 1 December 2022

on the acceptance of a modification of an agreed paediatric investigation plan for durlobactam / sulbactam (SUL-DUR), (EMEA-002807-PIP01-20-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 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/0499/2020 issued on 22 December 2020,

Having regard to the application submitted by Entasis Therapeutics Inc. on 27 June 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 14 October 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.

(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 durlobactam / sulbactam (SUL-DUR), powder for solution for injection, intravenous use, 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 Entasis Therapeutics Inc., Gatehouse Park Biohub, 35 Gatehouse Drive, 02451 – Waltham, USA.

EMA/PDCO/653014/2022
Amsterdam, 14 October 2022

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

EMEA-002807-PIP01-20-M01

Scope of the application

Active substance(s):

Durlobactam / sulbactam (SUL-DUR)

Invented name and authorisation status:

See Annex II

Condition(s):

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

Pharmaceutical form(s):

Powder for solution for injection

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Entasis Therapeutics Inc.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Entasis Therapeutics Inc. submitted to the European Medicines Agency on 27 June 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/0499/2020 issued on 22 December 2020.

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

The procedure started on 16 August 2022.

Scope of the modification

Some 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)

Waiver

Not applicable

1. Paediatric investigation plan

1.1. Condition:

Treatment of infections due to organisms of the Acinetobacter baumannii-calcoaceticus complex (ABC)

1.1.1. Indication(s) targeted by the PIP

Treatment of infections due to Acinetobacter baumannii-calcoaceticus complex in patients with limited treatment options

1.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 18 years of age

1.1.3. Pharmaceutical form(s)

Powder for solution for injection

1.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Development of an age-appropriate dosage, compatible for use in neonates
Non-clinical studies	**Study 2** Definitive juvenile toxicity study in rats
Clinical studies	**Study 3** Open-label, multiple dose study to characterise the PK, safety and tolerability of SUL-DUR in paediatric inpatients from birth to less than 18 years receiving systemic antibiotic therapy for suspected or confirmed infection with *Acinetobacter baumannii-calcoaceticus* complex (ABC)
Extrapolation, modelling and simulation studies	**Study 4** Modelling and simulation study to evaluate the use of SUL-DUR in the treatment of infections due to *Acinetobacter baumannii-calcoaceticus* complex (ABC) in in children from birth to less than 18 years of age with limited treatment options

	Study 5 Extrapolation study to evaluate the use of SUL-DUR in the treatment of infections due to *Acinetobacter baumannii-calcoaceticus* complex (ABC) in children from birth to less than 18 years of age with limited treatment options
Other studies	Not applicable
Other measures	Not applicable

2. 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 June 2027
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.