EMA/660371/2020

European Medicines Agency decision

P/0499/2020

of 22 December 2020

on the agreement of a paediatric investigation plan and on the granting of a deferral for durlobactam / sulbactam (SUL-DUR) (EMEA-002807-PIP01-20) 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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the application submitted by Entasis Therapeutics Inc. on 20 March 2020 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 13 November 2020, 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.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for durlobactam / sulbactam (SUL-DUR), powder for solution for injection, intravenous use, 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 durlobactam / sulbactam (SUL-DUR), powder for solution for injection, intravenous use, 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 Entasis Therapeutics Inc., Gatehouse Park Biohub, 35 Gatehouse Drive, 02451 - Waltham, United States.

EMA/PDCO/452709/2020
Amsterdam, 13 November 2020

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

EMEA-002807-PIP01-20

Scope of the application

Active substance(s):

Durlobactam / sulbactam (SUL-DUR)

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 16(1) of Regulation (EC) No 1901/2006 as amended, Entasis Therapeutics Inc. submitted for agreement to the European Medicines Agency on 20 March 2020 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 30 April 2020.

Supplementary information was provided by the applicant on 5 August 2020. 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 Norwegian Paediatric Committee member 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 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 infections due to organisms of the *Acinetobacter baumannii-calcoaceticus* complex (ABC)

2.1.1. Indication(s) targeted by the PIP

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

Powder for solution for injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of an age-appropriate dosage, compatible for use in neonates
Non-clinical studies	1	**Study 2** Definitive juvenile toxicity study in rats
Clinical studies	1	**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	1	**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	0	Not applicable.
Other measures	0	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 June 2027
Deferral for one or more measures contained in the paediatric investigation plan:	Yes