EMA/789884/2018

European Medicines Agency decision

P/0390/2018

of 7 December 2018

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for SER-109 (Eubacterial Spores, Purified Suspension, Encapsulated) (EMEA-001970-PIP02-17) 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 Seres Therapeutics UK Ltd. on 26 February 2018 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 19 October 2018, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation and Article 13 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 and on the granting of a waiver.

(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.

(4) It is therefore appropriate to adopt a decision granting a waiver.

[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 SER-109 (Eubacterial Spores, Purified Suspension, Encapsulated), capsule, hard, oral suspension, oral 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 SER-109 (Eubacterial Spores, Purified Suspension, Encapsulated), capsule, hard, oral suspension, oral 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

A waiver for SER-109 (Eubacterial Spores, Purified Suspension, Encapsulated), capsule, hard, oral suspension, oral 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 4

This decision is addressed to Seres Therapeutics UK Ltd., One Fetter Lane c/o Legalinx Limited, EC4A 1BR – London, United Kingdom.

EMA/PDCO/535102/2018
London, 19 October 2018

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

EMEA-001970-PIP02-17

Scope of the application

Active substance(s):

SER-109 (Eubacterial Spores, Purified Suspension, Encapsulated)

Condition(s):

Treatment of Clostridium difficile infection

Pharmaceutical form(s):

Capsule, hard

Oral suspension

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Seres Therapeutics UK Ltd.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Seres Therapeutics UK Ltd. submitted for agreement to the European Medicines Agency on 26 February 2018 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 3 April 2018.

Supplementary information was provided by the applicant on 9 July 2018. 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;
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population.

   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 and the subsets of the paediatric population and condition covered by the waiver 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

1.1. Condition:

Treatment of Clostridium difficile infection

The waiver applies to:

- the paediatric population from birth to less than 4 years of age;
- capsule, hard, oral suspension, oral use;
- on the grounds that the specific medicinal product is likely to be ineffective or unsafe.

2. Paediatric investigation plan

2.1. Condition:

Treatment of Clostridium difficile infection(CDI)

2.1.1. Indication(s) targeted by the PIP

Reduction of recurrences of Clostridium difficile infection (CDI) in patients who have received antibacterial drug treatment for recurrent CDI.

2.1.2. Reduction of recurrence of Clostridium difficile infection (CDI) in patients who have received antibacterial drug treatment for recurrent CDI. Subset(s) of the paediatric population concerned by the paediatric development

From 4 years to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Capsule, hard

Oral suspension

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	Study 1 Development of a liquid formulation for oral use, including administration through enteral tube.
Non-clinical studies	0	Not applicable.

Clinical studies	2	Study 2 Open label, multicentre, dose escalating study to evaluate the safety and tolerability of SER-109 in children from 4 years to less than 18 years with recurrent CDI who have received antibacterial drug treatment for CDI. Study 3 Double-blind, randomised, placebo-controlled, parallel-group study to evaluate the efficacy, safety, and tolerability of SER-109 versus placebo to reduce recurrence of CDI in paediatric subjects aged from 4 years to less than 18 years with recurrent CDI who have received antibacterial drug treatment for CDI.
Extrapolation, modelling and simulation studies	0	Not applicable.
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:	Yes
Date of completion of the paediatric investigation plan:	By January 2028
Deferral for one or more measures contained in the paediatric investigation plan:	Yes