

EMA/666659/2017

European Medicines Agency decision

P/0330/2017

of 31 October 2017

on the agreement of a paediatric investigation plan and on the granting of a waiver for *Lactobacillus reuteri* (IBP-9414) (EMA-001895-PIP01-15) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Infant Bacterial Therapeutics AB on 13 February 2017 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 September 2017, in accordance with Article 18 of Regulation (EC) No 1901/2006 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 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 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 lactobacillus reuteri (IBP-9414), powder for oral suspension, gastrointestinal 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 waiver for lactobacillus reuteri (IBP-9414), powder for oral suspension, gastrointestinal 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 Infant Bacterial Therapeutics AB, Bryggargatan 10, 11121 – Stockholm, Sweden.

EMA/PDCO/393736/2017
London, 15 September 2017

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

EMA-001895-PIP01-15

Scope of the application

Active substance(s):

Lactobacillus reuteri (IBP-9414)

Condition(s):

Prevention of necrotising enterocolitis

Pharmaceutical form(s):

Powder for oral suspension

Route(s) of administration:

Gastroenteral use

Name / corporate name of the PIP applicant:

Infant Bacterial Therapeutics AB

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Infant Bacterial Therapeutics AB submitted for agreement to the European Medicines Agency on 13 February 2017 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 21 March 2017.

Supplementary information was provided by the applicant on 19 June 2017. 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 18 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)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population, and Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

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 subset(s) of the paediatric population and condition(s) 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

Prevention of necrotising enterocolitis

The waiver applies to:

- the paediatric population from 28 days to less than 18 years;
- powder for oral suspension, gastroenteral use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

And

- term newborn infants (from birth to less than 28 days) and preterm infants beyond 32 weeks gestation;
- powder for oral suspension, gastroenteral use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric investigation plan

2.1. Condition

Prevention of necrotising enterocolitis

2.1.1. Indication(s) targeted by the PIP

Prevention of necrotising enterocolitis

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

Preterm infants up to 32 weeks gestation

2.1.3. Pharmaceutical form(s)

Powder for oral suspension

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.

Clinical studies	2	Study 1 Randomized, double-blind, parallel-group, dose escalation, placebo-controlled, multi-centre study to investigate the safety and tolerability of IBP-9414 as compared to placebo in preterm infants ≤ 32 weeks gestation (IBP-9414-010). Study 2 Randomized, double-blind, placebo-controlled, multi-centre study to investigate the safety and efficacy of IBP-9414 as compared to placebo in preterm infants ≤ 32 weeks gestation.
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:	No
Date of completion of the paediatric investigation plan:	By December 2019
Deferral for one or more measures contained in the paediatric investigation plan:	No