EMA/393807/2021

European Medicines Agency decision

P/0314/2021

of 11 August 2021

on the acceptance of a modification of an agreed paediatric investigation plan for lactobacillus reuteri (IBP-9414), (EMEA-001895-PIP01-15-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 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 European Medicines Agency's decision P/0330/2017 issued on 31 October 2017,

Having regard to the application submitted by Infant Bacterial Therapeutics AB on 15 March 2021 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 25 June 2021, 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.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for lactobacillus reuteri (IBP-9414), powder for oral suspension, gastroenteral 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 Infant Bacterial Therapeutics AB, Bryggargatan 10, 11121 - Stockholm, Sweden.

EMA/PDCO/189803/2021
Amsterdam, 25 June 2021

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

EMEA-001895-PIP01-15-M01

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 22 of Regulation (EC) No 1901/2006 as amended, Infant Bacterial Therapeutics AB submitted to the European Medicines Agency on 15 March 2021 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/0330/2017 issued on 31 October 2017.

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

The procedure started on 27 April 2021.

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

2. The measures and timelines of the 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 of age;
- 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 of age) 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 November 2022
Deferral for one or more measures contained in the paediatric investigation plan:	No