EMA/631719/2019

European Medicines Agency decision

P/0414/2019

of 6 December 2019

on the acceptance of a modification of an agreed paediatric investigation plan for itacitinib (EMEA-002178-PIP01-17-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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on the acceptance of a modification of an agreed paediatric investigation plan for itacitinib (EMEA-002178-PIP01-17-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/0208/2018 issued on 17 July 2018,

Having regard to the application submitted by Incyte Biosciences Distribution B.V on 9 July 2019 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 18 October 2019, 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 itacitinib, prolonged-release tablet, age-appropriate liquid dosage form, age-appropriate solid dosage form, oral 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 Incyte Biosciences Distribution B.V, Paasheuvelweg 25, 1105 BP Amsterdam, The Netherlands.

EMA/PDCO/412607/2019
Amsterdam, 18 October 2019

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

EMEA-002178-PIP01-17-M01

Scope of the application

Active substance(s):

Itacitinib

Condition(s):

Treatment of acute graft versus host disease

Pharmaceutical form(s):

Prolonged-release tablet

Age-appropriate liquid dosage form

Age-appropriate solid dosage form

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Incyte Biosciences Distribution B.V

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Incyte Biosciences Distribution B.V submitted to the European Medicines Agency on 9 July 2019 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0208/2018 issued on 17 July 2018.

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

The procedure started on 20 August 2019.

Scope of the modification

Some measures and 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 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

Treatment of acute graft versus host disease

The waiver applies to:

- the paediatric population from birth to less than 28 days of age;
- prolonged-release tablet, age-appropriate liquid dosage form, age-appropriate solid dosage form, oral 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).

2. Paediatric investigation plan

2.1. Condition

Treatment of acute graft versus host disease

2.1.1. Indication(s) targeted by the PIP

Treatment of steroid naïve paediatric population with acute graft versus host disease after allogeneic hematopoietic stem cell transplantation

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

From 28 days to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Prolonged release tablet

Age-appropriate liquid dosage form

Age-appropriate solid dosage form

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	2	**Study 1** Development an age-appropriate solid dosage form for children who can't swallow tablets. **Study 2** Development an age-appropriate liquid dosage form and presentation.

Non-clinical studies	1	**Study 3** Definitive repeat-dose toxicity study of itacitinib in juvenile rats with 8-week recovery.
Clinical studies	2	**Study 4** Open label, two phase study with a safety run-in and expansion part in five different cohorts in paediatric subjects from 28 days to less than 18 years of age with acute graft versus host disease (aGvHD). **Study 5** Randomised, double-blind, placebo-controlled study of itacitinib or placebo in combination with corticosteroids for the treatment of steroid-naive acute graft-versus-host disease (aGVHD) paediatric subjects from 28 days to less than 18 years of age.
Extrapolation, modelling and simulation studies	1	**Study 6** Population pharmacokinetic modelling in paediatric patients with GvHD.
Other studies	0	
Other measures	0	

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 December 2029
Deferral for one or more measures contained in the paediatric investigation plan:	Yes