EMA/871497/2022

European Medicines Agency decision

P/0486/2022

of 2 December 2022

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for ruxolitinib (phosphate) (Jakavi), (EMEA-002618-PIP03-21) 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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the application submitted by Incyte Biosciences Distribution B.V. on 15 February 2021 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 14 October 2022, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

A paediatric investigation plan for ruxolitinib (phosphate) (Jakavi), cream, cutaneous 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 ruxolitinib (phosphate) (Jakavi), cream, cutaneous 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 ruxolitinib (phosphate) (Jakavi), cream, cutaneous 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 covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/0349/2017 issued on 01/12/2017; P/0061/2018 issued on 16/03/2018, including subsequent modifications thereof.

Article 5

This decision is addressed to Incyte Biosciences Distribution B.V., Paasheuvelweg 25, 1105 BP – Amsterdam, The Netherlands.

EMA/PDCO/656777/2022 Corr
Amsterdam, 14 October 2022

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

EMEA-002618-PIP03-21

Scope of the application

Active substance(s):

Ruxolitinib (phosphate)

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of atopic dermatitis

Pharmaceutical form(s):

Cream

Route(s) of administration:

Cutaneous use

Name/corporate name of the PIP applicant:

Incyte Biosciences Distribution B.V.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Incyte Biosciences Distribution B.V. submitted for agreement to the European Medicines Agency on 15 February 2021 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 23 March 2021.

Supplementary information was provided by the applicant on 4 July 2022. 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)(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 Paediatric Committee member of Norway 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 annexes 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 atopic dermatitis

The waiver applies to:

- the paediatric population from birth to less than 3 months of age;
- cream, cutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric investigation plan

2.1. Condition:

Treatment of atopic dermatitis

2.1.1. Indication(s) targeted by the PIP

Topical treatment of moderate atopic dermatitis in patients 3 months of age and older who are inadequately controlled with, have a contraindication to, or are intolerant to other topical therapies including corticosteroids and calcineurin inhibitors

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

From 3 months to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Cream

2.1.4. Measures

Area	Description
Quality-related studies	Study 1: Development of an age-appropriate topical formulation
Non-clinical studies	Not applicable
Clinical studies	Study 2: Double-blind, randomised, placebo-controlled trial to evaluate efficacy and safety of ruxolitinib cream in paediatric patients from 12 years to less than 18 years of age (and adults) with atopic dermatitis (INCB 18424-303)

	Study 3: Double-blind, randomised, placebo-controlled trial to evaluate efficacy and safety of ruxolitinib cream in paediatric patients from 12 years to less than 18 years of age (and adults) with atopic dermatitis (INCB 18424-304) Study 4: Double-blind, randomised, placebo-controlled trial to evaluate efficacy and safety of ruxolitinib cream in paediatric patients from 6 years to less than 18 years of age with atopic dermatitis (INCB 18424-316) Study 5: Double-blind, randomised, placebo-controlled trial to evaluate efficacy and safety of ruxolitinib cream in paediatric patients from 2 years to less than 6 years of age with atopic dermatitis (INCB 18424-327) Study 6: Double-blind, randomised, placebo-controlled trial to evaluate efficacy and safety of ruxolitinib cream in paediatric patients from 3 months to less than 2 years of age with atopic dermatitis (INCB 18424-328) Study 7: Open-label, non-comparative trial to evaluate safety and pharmacokinetics of ruxolitinib cream in paediatric patients from 2 years to less than 18 years of age with atopic dermatitis (INCB 18424-102) Study 8: Open-label, maximum use trial to evaluate pharmacokinetics, safety and efficacy of ruxolitinib cream in paediatric patients from 12 years to less than 18 years of age (and adults) with atopic dermatitis (INCB 18424-103)
Modelling and simulation studies	Not applicable
Other studies	Not applicable
Extrapolation plan	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 June 2034
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Treatment of myelofibrosis

Authorised indication(s):

Jakavi is indicated for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis.

- Invented name(s): Jakavi
- Authorised pharmaceutical form(s): Tablet
- Authorised route(s) of administration: Oral use
- Authorised via centralised procedure
- Marketing Authorisation Holder: Novartis Europharm Limited

2. Treatment of polycythaemia vera

Authorised indication(s):

Jakavi is indicated for the treatment of adult patients with polycythaemia vera who are resistant to or intolerant of hydroxyurea.

- Invented name(s): Jakavi
- Authorised pharmaceutical form(s): Tablet
- Authorised route(s) of administration: Oral use
- Authorised via centralised procedure
- Marketing Authorisation Holder: Novartis Europharm Limited

3. Treatment of graft versus host disease

Authorised indication(s):

Jakavi is indicated for the treatment of patients aged 12 years and older with acute graft versus host disease or chronic graft versus host disease who have inadequate response to corticosteroids or other systemic therapies.

- Invented name(s): Jakavi
- Authorised pharmaceutical form(s): Tablet
- Authorised route(s) of administration: Oral use
- Authorised via centralised procedure
- Marketing Authorisation Holder: Novartis Europharm Limited