

EMA/22773/2024

European Medicines Agency decision P/0034/2024

of 31 January 2024

on the granting of a product specific waiver for ruxolitinib (phosphate) (Jakavi, Opzelura), (EMA-002618-PIP04-23) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency²,

Having regard to the application submitted by Incyte Biosciences Distribution B.V. on 6 September 2023 under Article 13 of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 December 2023 in accordance with Article 13 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

- (1) The Paediatric Committee has given an opinion on the granting of a product specific waiver.
- (2) 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 waiver for ruxolitinib (phosphate) (Jakavi, Opzelura), 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 2

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

EMA/PDCO/448306/2023
Amsterdam, 15 December 2023

Opinion of the Paediatric Committee on the granting of a product-specific waiver

EMA-002618-PIP04-23

Scope of the application

Active substance(s):

Ruxolitinib (phosphate)

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of prurigo nodularis

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 13 of Regulation (EC) No 1901/2006 as amended, Incyte Biosciences Distribution B.V. submitted to the European Medicines Agency on 6 September 2023 an application for a product-specific waiver on the grounds set out in Article 11 of said Regulation for the above mentioned medicinal product.

The procedure started on 16 October 2023.

Opinion

1. The Paediatric Committee, having assessed the waiver application in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to grant a product-specific waiver for all subsets of the paediatric population and the above mentioned condition(s) 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 grounds for the granting of the waiver are set out in 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

Grounds for the granting of the waiver

1. Waiver

1.1. Condition:

Treatment of prurigo nodularis

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- cream, cutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Conditions and authorised indications

1. Treatment of myelofibrosis

Authorised indication:

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

2. Treatment of polycythaemia vera

Authorised indication:

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

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

3. Treatment of graft versus host disease

Authorised indication:

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

4. Treatment of vitiligo

Authorised indication:

Opzelura is indicated for the treatment of non-segmental vitiligo with facial involvement in adults and adolescents from 12 years of age.

- Invented name: Opzelura
- Authorised pharmaceutical form: Cream
- Authorised route of administration: Cutaneous use
- Authorised via centralised procedure
- Marketing Authorisation Holder: Incyte Biosciences Distribution B.V