MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-101661-PIP01-24

Scope of the Application

Active Substance(s)

RUXOLITINIB PHOSPHATE

Condition(s)

Treatment of atopic dermatitis

Pharmaceutical Form(s)

Cream

Route(s) of Administration

TOPICAL USE

Name / Corporate name of the PIP applicant

INCYTE BIOSCIENCES UK LIMITED

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, INCYTE BIOSCIENCES UK LIMITED submitted to the licensing authority on 06/12/2024 15:05 GMT an application for a Paediatric Investigation Plan

The procedure started on 13/01/2025 14:34 GMT

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to agree a paediatric investigation plan and grant a deferral and grant a waiver

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Final Decision Letter

MHRA-101661-PIP01-24

Of 22/04/2025 14:11 BST

On the adopted decision for RUXOLITINIB PHOSPHATE (MHRA-101661-PIP01-24) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for RUXOLITINIB PHOSPHATE, Cream , TOPICAL USE .

This decision is addressed to INCYTE BIOSCIENCES UK LIMITED, First Floor 1, Q1 The Square, Randalls Way, Leatherhead, UNITED KINGDOM, KT22 7TW

ANNEX I

1. Waiver

1.1 Condition:

Treatment of atopic dermatitis The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 3 months of age Pharmaceutical form(s): Cream Route(s) of administration: TOPICAL USE Reason for granting waiver: 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(s):

Treatment of atopic dermatitis

2.2 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 contraindications to, or are intolerant to other topical therapies including corticosteroids and calcineurin inhibitors.

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from 3 months to less than 18 years of age

2.4 Pharmaceutical Form(s):

Cream

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate topical formulation.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	7	Study 2 (INCB 18424-303) 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. Study 3 (INCB 18424-304) 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. Study 4 (INCB 18424-316) 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. Study 5 (INCB 18424-327) 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. Study 6 (INCB 18424-328) 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. Study 7 (INCB 18424-102) 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. Study 8 (INCB 18424-103) 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.
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
Other Studies	0	Not applicable.
Other Measures	0	Not applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	30/06/2034
Deferral of one or more studies contained in the paediatric investigation plan:	Yes