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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-100448-PIP01-22) and to the deferral

MHRA-100448-PIP01-22-M01

Scope of the Application

Active Substance(s)

RUXOLITINIB PHOSPHATE

Condition(s)

Vitiligo

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 29/04/2024 14:39 BST an application for a Modification

The procedure started on 04/06/2024 15:25 BST

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 accept change(s) to the agreed paediatric investigation plan and to the deferral

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.

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Final Decision Letter

MHRA-100448-PIP01-22-M01

Of 09/09/2024 16:14 BST

On the adopted decision for RUXOLITINIB PHOSPHATE (MHRA-100448-PIP01-22-M01) 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 modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification 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 7 TW

ANNEX I

1. Waiver

1.1 Condition:

Treatment of vitiligo The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 years of age Pharmaceutical form(s): Cream Route(s) of administration: TOPICAL USE Reason for granting waiver: 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(s):

Treatment of vitiligo

2.2 Indication(s) targeted by the PIP:

Topical treatment of vitiligo

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

The paediatric population from 6 years 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	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	4	Study 1 (INCB 18424-306) Double-blind, randomised, placebo-controlled trial to evaluate efficacy and safety of ruxolitinib cream in adolescents from 12 years of age (and adults) with non-segmental vitiligo. Study 2 (INCB 18424-307) Double-blind, randomised, placebo-controlled trial to evaluate efficacy and safety of ruxolitinib cream in adolescents from 12 years of age (and adults) with non-segmental vitiligo. Study 3 (INCB 18424-308) Double-blind, randomised, placebo-controlled extension trial to evaluate long-term efficacy and safety of ruxolitinib cream in adolescents from 12 years of age (and adults) with non-segmental vitiligo. Study 4 (INCB 18424-309) Double-blind, randomised, placebo-controlled trial to evaluate efficacy and safety of ruxolitinib cream in children from 6 years to less than 12 years of age with non-segmental vitiligo.
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:	31/12/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes