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

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Decision Cover Letter

Decision of the licensing authority to:

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

MHRA-100448-PIP01-22

Scope of the Application

Active Substance(s)

RUXOLITINIB PHOSPHATE

Condition(s)

Treatment of 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 04/03/2022 15:52 GMT an application for a Paediatric Investigation Plan

The procedure started on 11/05/2022 15:45 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 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.

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Final Decision Letter

MHRA-100448-PIP01-22

Of 19/05/2022 11:44 BST

On the adopted decision for RUXOLITINIB PHOSPHATE (MHRA-100448-PIP01-22) 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 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:	30/06/2024
Deferral of one or more studies contained in the paediatric investigation plan:	Yes