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-102485-PIP01-26

Scope of the Application

Active Substance(s)

Povorcitinib

Condition(s)

Treatment of hidradenitis suppurativa

Pharmaceutical Form(s)

Film-coated tablet

Route(s) of Administration

ORAL 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 23/04/2026 13:46 BST an application for a Paediatric Investigation Plan

The procedure started on 22/05/2026 13:33 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-102485-PIP01-26

Of 28/07/2026 17:33 BST

On the adopted decision for Povorcitinib (MHRA-102485-PIP01-26) 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 Povorcitinib, Film-coated tablet , ORAL 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 hidradenitis suppurativa The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 12 years of age Pharmaceutical form(s): Film-coated tablet Route(s) of administration: Oral use Reason for granting waiver: on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of hidradenitis suppurativa

2.2 Indication(s) targeted by the PIP:

Treatment of patients with moderate to severe hidradenitis suppurativa who have a history of inadequate response, intolerance, or contraindication to an adequate course of at least one anti-tumour necrosis factor (TNF) drug

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

The paediatric population from 12 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Film-coated tablet

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 1 Open label study to evaluate the safety, pharmacokinetics and activity of povorcitinib in adolescent patients from 12 years to less than 18 years of age with moderate to severe hidradenitis suppurativa.
Extrapolation, Modeling & Simulation Studies	2	Study 2 Population pharmacokinetic (PK) model to evaluate the exposure-response and support the extrapolation of povorcitinib use in children from 12 years to less than 18 years of age with moderate to severe hidradenitis suppurativa. Extrapolation Plan Studies 1 and 2 are part of the extrapolation plan for efficacy data from adults to adolescents from 12 years to less than 18 years of age with moderate to severe hidradenitis suppurativa.
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:	28/02/2029
Deferral of one or more studies contained in the paediatric investigation plan:	Yes