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-101189-PIP01-23

Scope of the Application

Active Substance(s)

N-((1R,2R)-2-methoxycyclobutyl)-7-(methylamino)-5-((2-oxo-2H-[1,2'-bipyridin]-3-yl)amino)pyrazolo[1,5-a]pyrimidine-3-carboxamide

Condition(s)

Treatment of Psoriasis

Pharmaceutical Form(s)

Film-coated tablet Age appropriate formulation

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Takeda UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Takeda UK Limited submitted to the licensing authority on 02/10/2023 16:57 BST an application for a Paediatric Investigation Plan

The procedure started on 07/03/2025 14:28 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.

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Final Decision Letter

MHRA-101189-PIP01-23

Of 15/05/2025 13:09 BST

On the adopted decision for N-((1R,2R)-2-methoxycyclobutyl)-7-(methylamino)-5-((2-oxo-2H-[1,2'-bipyridin]-3-yl)amino)pyrazolo[1,5-a]pyrimidine-3-carboxamide (MHRA-101189-PIP01-23) 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 N-((1R,2R)-2-methoxycyclobutyl)-7-(methylamino)-5-((2-oxo-2H-[1,2'-bipyridin]-3-yl)amino)pyrazolo[1,5-a]pyrimidine-3-carboxamide, Film-coated tablet Age appropriate formulation , ORAL USE .

This decision is addressed to Takeda UK Limited, 1 Kingdom Street, London, UNITED KINGDOM, W2 6BD

ANNEX I

1. Waiver

1.1 Condition:

Treatment of Psoriasis The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth less than 6 years of age Pharmaceutical form(s): Film-coated tablet Route(s) of administration: ORAL USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments. Reason for Refusing Waiver: Not Applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of Psoriasis

2.2 Indication(s) targeted by the PIP:

Treatment of moderate to severe chronic plaque psoriasis

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

The paediatric population from 6 years of age to less than 18 years of age

2.4 Pharmaceutical Form(s):

Film-coated tablet Age-appropriate oral formulation

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an oral age-appropriate formulation for use in children aged from 6 years to less than 18 years.
Non-Clinical Studies	0	Not applicable
Clinical Studies	1	Study 2 Two-part double-blind, randomised, placebo-controlled study to evaluate the pharmacokinetics, safety and efficacy of zasocitinib in children from 6 years to less than 18 years of age with moderate to severe plaque psoriasis (Part A), with an open label non-comparative cohort (Part B) to evaluate pharmacokinetics of zasocitinib and acceptability/ palatability of the age-appropriate formulation developed in PIP study 1 in children from 6 years to less than 12 years of age
Extrapolation, Modeling & Simulation Studies	1	Study 3 Modelling and simulation analyses to determine the zasocitinib paediatric dose(s) to be used in children from 6 years to less than 12 years of age with moderate to severe plaque psoriasis.
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:	No
Date of completion of the paediatric investigation plan:	31/05/2030
Deferral of one or more studies contained in the paediatric investigation plan:	Yes