MHRA
10 South Colonnade
Canary Wharf
London
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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-101461-PIP01-24

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; Zasocitinib

Condition(s)

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and juvenile idiopathic arthritis)

Pharmaceutical Form(s)

Film coated tablet

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 05/06/2024 03:08 BST an application for a Paediatric Investigation Plan

The procedure started on 20/08/2025 11:48 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-101461-PIP01-24

Of 04/09/2025 11:33 BST

On the adopted decision for Zasocitinib (MHRA-101461-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 Zasocitinib, Film coated tablet , 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 chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and juvenile idiopathic arthritis) The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 5 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 as clinical studies(s) are not feasible

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and juvenile idiopathic arthritis)

2.2 Indication(s) targeted by the PIP:

Treatment of juvenile psoriatic arthritis (JPsA)

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

The paediatric population from 5 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	1	Study 1 (Same study as Study 1 included in MHRA-101189-PIP01-23 and subsequent modifications thereof) Development of an age-appropriate oral formulation for use in children from 5 years to less than 18 years of age.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 2 Randomised, controlled trial to evaluate safety, efficacy, tolerability and pharmacokinetics of zasocitinib in children from 5 years to less than 18 years of age with juvenile psoriatic arthritis (JPsA).
Extrapolation, Modeling & Simulation Studies	2	Study 3 Modelling and simulation analyses to evaluate the use of zasocitinib in the treatment of children from 5 years to less than 18 years of age with JPsA Extrapolation Plan Studies 2, 3 and 4 are part of the extrapolation plan of efficacy data from adults to the paediatric population from 5 years to less than 18 years of age with JPsA.
Other Studies	1	Study 4 Literature summaries and analyses to support the use of zasocitinib in the treatment of children from 5 years to less than 18 years of age with JPsA.
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:	30/09/2032
Deferral of one or more studies contained in the paediatric investigation plan:	Yes