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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

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

MHRA-101519-PIP01-24

Scope of the Application

Active Substance(s)

Mezagitamab

Condition(s)

Treatment of immune thrombocytopenia

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS 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 15/07/2024 19:28 BST an application for a Paediatric Investigation Plan

The procedure started on 25/09/2025 19:44 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-101519-PIP01-24

Of 03/11/2025 16:05 GMT

On the adopted decision for Mezagitamab (MHRA-101519-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 Mezagitamab, Solution for injection , SUBCUTANEOUS 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 immune thrombocytopenia The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 years of age Pharmaceutical form(s): Solution for injection Route(s) of administration: SUBCUTANEOUS USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of immune thrombocytopenia

2.2 Indication(s) targeted by the PIP:

Treatment of persistent or chronic primary immune thrombocytopenia (ITP) in patients who had insufficient response to other therapy.

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):

Solution for injection

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, single-arm study to evaluate pharmacokinetics and safety of mezagitamab in paediatric patients from 6 years to less than 18 years of age with immune thrombocytopenia.
Extrapolation, Modeling & Simulation Studies	2	Study 2 Use of population pharmacokinetics (PopPK) to confirm or modify the paediatric posology compared to the regimen used in adult clinical trials. Extrapolation Plan Studies 1 and 2 are part of an extrapolation plan covering the paediatric population from 6 years to less than 18 years of age.
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:	31/01/2034
Deferral of one or more studies contained in the paediatric investigation plan:	Yes