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

**gov.uk/mhra**

# Decision Cover Letter

## Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral.

MHRA-101908-PIP01-25-M01

# Scope of the Application

## Active Substance(s)

MOSUNETUZUMAB

## Condition(s)

Treatment of mature B-cell neoplasms

## Pharmaceutical Form(s)

Solution for infusion; Solution for injection

## Route(s) of Administration

INTRAVENOUS USE; SUBCUTANEOUS USE

## Name / Corporate name of the PIP applicant

Roche Products Limited

## Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Roche Products Limited submitted to the licensing authority on 24/04/2025 13:10 BST an application for a Modification

The procedure started on 06/06/2025 11:12 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 accept change(s) to the agreed paediatric investigation plan and to the deferral.

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-101908-PIP01-25-M01

Of 21/07/2025 15:09 BST

On the adopted decision for MOSUNETUZUMAB (MHRA-101908-PIP01-25-M01) 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 modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan).

This decision applies to a Modification for MOSUNETUZUMAB, Solution for infusion; Solution for injection , INTRAVENOUS USE; SUBCUTANEOUS USE .

This decision is addressed to Roche Products Limited, 6 Falcon Way, Welwyn Garden City, UNITED KINGDOM, AL7 1TW

## ANNEX I

### 1. Waiver

### 1.1 Condition:

| |
|---|
| Treatment of mature B-cell neoplasms The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 months of age. Pharmaceutical form(s): Solution for infusion, Solution for injection Route(s) of administration: INTRAVENOUS USE, SUBCUTANEOUS USE Reason for granting waiver: On the grounds the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible. |

### 2. Paediatric Investigation Plan:

### 2.1 Condition(s):

| |
|---|
| Treatment of mature B-cell neoplasms |

## 2.2 Indication(s) targeted by the PIP:

Treatment of children with relapsed or refractory high-grade mature B-cell non-Hodgkin lymphoma (B-NHL), including Burkitt lymphoma (BL), Burkitt leukaemia (mature B-cell acute lymphoblastic leukaemia FAB L3; B-AL), and diffuse large B-cell lymphoma (DLBCL).

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

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

## 2.4 Pharmaceutical Form(s):

Solution for infusion 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, two-part trial to evaluate safety, tolerability, pharmacokinetics (PK), and antitumor activity of mosunetuzumab in combination with chemotherapy in children from 6 months to less than 18 years of age with relapsed/refractory (R/R) mature B-cell non-Hodgkin lymphoma (B-NHL). Part 2 (cohort expansion) is gated on Part 1 results (safety, PK, and preliminary antitumor activity). |
| **Extrapolation, Modeling & Simulation Studies** | 1 | Study 2 Modelling and simulation study to determine the dose of the product in the proposed paediatric indication in children from 6 months to less than 18 years of age with relapsed/refractory (R/R) mature B-cell non-Hodgkin lymphoma (B-NHL). |
| **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:** | 30/06/2027 |
| **Deferral of one or more studies contained in the paediatric investigation plan:** | Yes |