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-100792-PIP01-22

Scope of the Application

Active Substance(s)

OBINUTUZUMAB

Condition(s)

Prevention of cytokine release syndrome induced by anti CD20/CD3 antibodies

Pharmaceutical Form(s)

Concentrate for solution for infusion

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

Roche Products Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Roche Products Ltd submitted to the licensing authority on 25/11/2022 13:49 GMT an application for a Paediatric Investigation Plan

The procedure started on 18/01/2023 16:04 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-100792-PIP01-22

Of 27/03/2023 07:05 BST

On the adopted decision for OBINUTUZUMAB (MHRA-100792-PIP01-22) 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 OBINUTUZUMAB, Concentrate for solution for infusion , INTRAVENOUS USE .

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

ANNEX I

1. Waiver

1.1 Condition:

Prevention of cytokine release syndrome induced by anti CD20/CD3 antibodies The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 months of age Pharmaceutical form(s): Concentrate for solution for infusion Route(s) of administration: INTRAVENOUS 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):

Prevention of cytokine release syndrome induced by anti CD20/CD3 antibodies

2.2 Indication(s) targeted by the PIP:

As pre-treatment to reduce the risk of cytokine release syndrome (CRS) induced by glofitamab in children between 6 months and less than 18 years of age

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):

Concentrate for solution for infusion

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 (Paediatric Study CO43810) Open-label, single-arm, two-part, trial to evaluate safety, tolerability, pharmacokinetics (PK), and antitumor activity of glofitamab in combination with chemotherapy in paediatric patients 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). All study participants must receive mandatory obinutuzumab pre-treatment 7 days prior to the first dose of glofitamab for the purpose of CRS risk mitigation.
Extrapolation, Modeling & Simulation Studies	1	Study 2 Modelling and simulation study to determine the single pre-treatment intravenous dose of obinutuzumab in children for 6 months to less than 18 years of age with relapsed/refractory (R/ R) mature B-cell non-Hodgkin lymphoma (B-NHL) who will be treated with glofitamab.
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:	31/03/2029
Deferral of one or more studies contained in the paediatric investigation plan:	Yes