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-100687-PIP01-22-M01

Scope of the Application

Active Substance(s)

OBINUTUZUMAB

Condition(s)

Treatment of systemic lupus erythematosus

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 09/09/2022 14:46 BST an application for a Modification

The procedure started on 21/02/2023 09:10 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 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.

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

gov.uk/mhra

Final Decision Letter

MHRA-100687-PIP01-22-M01

Of 11/05/2023 08:09 BST

On the adopted decision for OBINUTUZUMAB (MHRA-100687-PIP01-22-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 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:

Treatment of systemic lupus erythematosus The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 5 years 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 over existing treatments.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of systemic lupus erythematosus

2.2 Indication(s) targeted by the PIP:

Treatment of lupus nephritis (LN) in child onset systemic lupus erythematosus (cSLE)

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):

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	2	Study 1 (WA42985 -Adolescent Cohort). Randomised double-blind, placebo-controlled study of efficacy, safety and pharmacokinetics of obinutuzumab as add-on to mycophenolate mofetil (MMF) and oral corticosteroids in paediatric patients from 12 years to less than 18 years of age with lupus nephritis. Study 2 Single arm study to evaluate the safety, tolerability, and pharmacokinetics of obinutuzumab as add-on to mycophenolate mofetil and oral corticosteroids in paediatric patients from 5 years to less than 12 years of age with lupus nephritis.
Extrapolation, Modeling & Simulation Studies	2	Study 3 Population pharmacokinetic (PopPK) model in lupus nephritis patients to support dose selection for the planned paediatric clinical studies based on an exposure-matching strategy, to analyse exposure response and to predict exposure in patients with LN from 5 years to less than 12 years of age. Study 4 Exploratory population PK-PD analyses in lupus nephritis adult and adolescent patients treated with obinutuzumab to

		support extrapolation of efficacy in paediatric patients with LN based on relationship between obinutuzumab exposure and PD markers.
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:	30/06/2029
Deferral of one or more studies contained in the paediatric investigation plan:	Yes