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-100678-PIP01-22-M01

Scope of the Application

Active Substance(s)

vamikibart

Condition(s)

Treatment of uveitic macular oedema

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

INTRAVITREAL 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 29/04/2024 16:06 BST an application for a Modification

The procedure started on 01/07/2024 14:51 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-100678-PIP01-22-M01

Of 11/07/2024 15:00 BST

On the adopted decision for vamikibart (MHRA-100678-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 vamikibart, Solution for injection , INTRAVITREAL USE .

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

ANNEX I

1. Waiver

1.1 Condition:

Treatment of uveitic macular oedema The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age. Pharmaceutical form(s): Solution for injection Route(s) of administration: INTRAVITREAL USE Reason for granting waiver: On the grounds the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of uveitic macular oedema.

2.2 Indication(s) targeted by the PIP:

Treatment of uveitic macular oedema.

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

The paediatric population from 2 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	2	Study 1 Double blind, randomised trial to evaluate pharmacokinetics, pharmacodynamics, safety and efficacy of RO7200220 compared to sham control in children from 2 years to less than 18 years of age (and adults) with uveitic macular oedema (UME). Study 2 Double blind, randomised trial to evaluate pharmacokinetics, pharmacodynamics, safety and efficacy of RO7200220 compared to sham control in children from 2 years to less than 18 years of age (and adults) with uveitic macular oedema (UME).
Extrapolation, Modeling & Simulation Studies	1	Study 3 Population pharmacokinetic (PopPK) analysis of RO7200220.
Other Studies	0	Not applicable.
Other Measures	1	Extrapolation Plan Studies 1, 2 and 3 are part of an extrapolation plan covering the paediatric population from 2 years to less than 18 years of age as agreed by the Regulatory Agency.

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:	31/01/2029
Deferral of one or more studies contained in the paediatric investigation plan:	Yes