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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

accept of change(s) to the agreed paediatric investigation plan (MHRA-100840-PIP01-23) and to the deferral.

MHRA-100840-PIP01-23-M01

Scope of the Application

Active Substance(s)

Odronextamab

Condition(s)

Treatment of mature B cell malignancies

Pharmaceutical Form(s)

Concentrate for solution for infusion

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

Regeneron UK Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Regeneron UK Ltd submitted to the licensing authority on 10/10/2023 10:05 BST an application for a Modification

The procedure started on 13/11/2023 16:06 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.

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Final Decision Letter

MHRA-100840-PIP01-23-M01

Of 27/11/2023 14:57 GMT

On the adopted decision for Odronextamab (MHRA-100840-PIP01-23-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 Odronextamab, Concentrate for solution for infusion , INTRAVENOUS USE .

This decision is addressed to Regeneron UK Ltd, The Charter Building, Uxbridge, UNITED KINGDOM, UB8 1JG

ANNEX I

1. Waiver

1.1 Condition:

Not applicable.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of mature B cell malignancies.

2.2 Indication(s) targeted by the PIP:

Treatment of relapsed/ refractory aggressive mature B- cell Non-Hodgkin Lymphoma (NHL) including Burkitt lymphoma (BL), diffuse large B-cell lymphoma (DLBCL), primary mediastinal B-cell lymphoma (PMBL) in paediatric patients from birth to less than 18 years of age.

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

The paediatric population from birth 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 (IRAS 1004701) Open-label two part, two cohort trial to evaluate a recommended phase 2 dose (RP2D) pharmacokinetics (PK), pharmacodynamics (PD), safety (Part 1) and activity and immunogenicity (Part 2) of odronextamab in children from birth to less than 18 years old (and adults) with relapsed/refractory (r/r) aggressive mature B-NHL in first relapsed (cohort 1a) and r/r aggressive mature B-NHL in second or higher relapse (cohort 1b).
Extrapolation, Modeling & Simulation Studies	1	Study 2 Modelling and simulation study to support the use of odronextamab in patients from birth to less than 18 years of age (and adults) with relapsed/ refractory aggressive mature 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:	31/10/2028
Deferral of one or more studies contained in the paediatric investigation plan:	Yes