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

MHRA-100840-PIP01-23

Scope of the Application

Active Substance(s)

Odronextamab

Condition(s)

Treatment of mature B cell malignancies

Pharmaceutical Form(s)

Solution for infusion

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

Regeneron UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Regeneron UK Limited submitted to the licensing authority on 28/02/2023 10:43 GMT an application for a Paediatric Investigation Plan

The procedure started on 05/07/2023 16:48 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 agree a paediatric investigation plan and grant a 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

Of 01/09/2023 08:48 BST

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

This decision is addressed to Regeneron UK Limited, The Charter Building, Vine Street, 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):

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