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

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-100324-PIP01-21) and to the deferral

MHRA-100324-PIP01-21-M01

Scope of the Application

Active Substance(s)

LONCASTUXIMAB TESIRINE

Condition(s)

Treatment of mature B-cell neoplasms

Pharmaceutical Form(s)

Powder for concentrate for solution for infusion

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

Swedish Orphan Biovitrum AB

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Swedish Orphan Biovitrum AB submitted to the licensing authority on 16/05/2024 16:34 BST an application for a Modification

The procedure started on 05/06/2024 07:34 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-100324-PIP01-21-M01

Of 02/09/2024 14:21 BST

On the adopted decision for LONCASTUXIMAB TESIRINE (MHRA-100324-PIP01-21-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 LONCASTUXIMAB TESIRINE, Powder for concentrate for solution for infusion , INTRAVENOUS USE .

This decision is addressed to Swedish Orphan Biovitrum AB, SE-112 76 Stockholm, Stockholm, SWEDEN, SE-112 76

ANNEX I

1. Waiver

1.1 Condition:

Treatment of mature B-cell neoplasms The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 months of age Pharmaceutical form(s): Powder for 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):

Treatment of mature B-cell neoplasms

2.2 Indication(s) targeted by the PIP:

Treatment of paediatric patients with relapsed/refractory B-cell non-Hodgkin lymphoma (R/R B-NHL)

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):

Powder for 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 Adaptive prospective multicentre platform clinical trial to evaluate the safety and efficacy of novel agents including loncastuximab tesirine in combination with chemotherapy (Arm II on the platform study) for the treatment of children, and adolescents with relapsed or refractory B-cell non-Hodgkin lymphoma (R/R B-cell NHL).
Extrapolation, Modeling & Simulation Studies	1	Study 2 Modelling and simulation study to predict the doses of loncastuximab tesirine in the proposed paediatric indication in children from 6 months to less than 18 years of age with relapsed or refractory non-Hodgkin lymphoma.
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:	31/12/2029

Deferral of one or more studies contained in the paediatric investigation plan:	Yes