MHRA
10 South Colonnade
Canary Wharf
London
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-100324-PIP01-21

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

ADC Therapeutics SA

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, ADC Therapeutics SA submitted to the licensing authority on 17/12/2021 12:36 GMT an application for a Paediatric Investigation Plan

The procedure started on 21/03/2022 16:02 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 agree a paediatric investigation plan and grant a deferral and grant a waiver

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

Of 30/03/2022 17:16 BST

On the adopted decision for Loncastuximab tesirine (MHRA-100324-PIP01-21) 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 Loncastuximab tesirine, Powder for concentrate for solution for infusion , Intravenous use .

This decision is addressed to ADC Therapeutics SA, Route de la Corniche 3B, Epalinges, Switzerland, CH-1066

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 Open-label, single-arm, dose escalation (standard 3+3 dose escalation design)/dose expansion trial to evaluate pharmacokinetics, safety and activity of loncastuximab tesirine in combination with chemotherapy in children from 6 months to less than 18 years of age with relapsed or refractory B-cell non-Hodgkin lymphoma.
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:	31/07/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes