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-101172-PIP01-23

Scope of the Application

Active Substance(s)

Disitamab vedotin

Condition(s)

Treatment of solid tumours including central nervous system malignancies

Pharmaceutical Form(s)

Powder for concentrate for solution for infusion

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

SEAGEN UK Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, SEAGEN UK Ltd submitted to the licensing authority on 05/12/2023 17:16 GMT an application for a Paediatric Investigation Plan

The procedure started on 12/02/2024 07:33 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

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-101172-PIP01-23

Of 27/03/2024 16:08 GMT

On the adopted decision for Disitamab vedotin (MHRA-101172-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 Disitamab vedotin, Powder for concentrate for solution for infusion , INTRAVENOUS USE .

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

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of solid tumours including central nervous system malignancies

2.2 Indication(s) targeted by the PIP:

Treatment of paediatric patients with solid tumours expression HER2

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

All subsets of the paediatric population from birth 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	1	Study 1 Development of an age appropriate dosage form.
Non-Clinical Studies	2	Study 2 In vitro pharmacology evaluation of cytotoxicity in relation to HER2 expression. Study 3 In vivo non-clinical pharmacology evaluation.
Clinical Studies	2	Study 4 Open-label, single arm, two part trial to evaluate a recommended Phase 2 dose (RP2D), pharmacokinetics, pharmacodynamics and safety (part one) and activity (part two) of disitamab vedotin (DV) in children from birth to less than 18 years of age with relapsed/ refractory solid tumours expressing HER2 (part one and two), including central nervous system (CNS) tumours (part B). (Selection of condition further informed based on results from PIP studies 2 and 3.) Study 5 Randomised controlled trial to evaluate safety and efficacy of disitamab vedotin (DV) against appropriate standard of care in a selected paediatric population to be further defined based on results from study 4.
Extrapolation, Modeling & Simulation Studies	1	Study 6 Modelling and simulation analyses to evaluate the use of the product in the proposed paediatric indication in children from birth to less than 18 years of age.
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:	31/12/2039
Deferral of one or more studies contained in the paediatric investigation plan:	Yes