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 and to the deferral

MHRA-101006-PIP01-23-M01

Scope of the Application

Active Substance(s)

IMLIFIDASE

Condition(s)

Prevention of graft rejection following solid organ transplantation

Pharmaceutical Form(s)

Powder for concentrate for solution for infusion

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

Hansa Biopharma AB

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Hansa Biopharma AB submitted to the licensing authority on 02/06/2023 09:20 BST an application for a Modification

The procedure started on 16/08/2023 13:36 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-101006-PIP01-23-M01

Of 23/08/2023 10:13 BST

On the adopted decision for IMLIFIDASE (MHRA-101006-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 IMLIFIDASE, Powder for concentrate for solution for infusion , INTRAVENOUS USE .

This decision is addressed to Hansa Biopharma AB, Scheelevägen 22, Lund, SWEDEN, 223 63

ANNEX I

1. Waiver

1.1 Condition:

Prevention of graft rejection following solid organ transplantation The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 1 year 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 disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of graft rejection following solid organ transplantation.

2.2 Indication(s) targeted by the PIP:

Pre-transplant treatment to make patients with donor specific IgG eligible for kidney transplantation

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

The paediatric population from 1 year 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, non-randomised, exploratory trial to evaluate efficacy of IdeS in creating a negative crossmatch test in children from 1 year to less than 18 years of age who are planned to undergo kidney transplantation.
Extrapolation, Modeling & Simulation Studies	1	Study 2 Extrapolation study to evaluate the use of IdeS in children from 1 year to less than 18 years of age who are planned to undergo kidney transplantation.
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:	No
Date of completion of the paediatric investigation plan:	31/03/2025
Deferral of one or more studies contained in the paediatric investigation plan:	Yes