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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

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

MHRA-101595-PIP01-24

Scope of the Application

Active Substance(s)

efinopegdutide

Condition(s)

Treatment of metabolic dysfunction-associated steatohepatitis

Pharmaceutical Form(s)

Solution for injection in pre-filled syringe

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Merck Sharp & Dohme (UK) Ltd.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Merck Sharp & Dohme (UK) Ltd. submitted to the licensing authority on 27/09/2024 15:10 BST an application for a Paediatric Investigation Plan

The procedure started on 05/11/2024 08:39 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-101595-PIP01-24

Of 19/02/2025 14:50 GMT

On the adopted decision for efinopegdutide (MHRA-101595-PIP01-24) 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 efinopegdutide, Solution for injection in pre-filled syringe , SUBCUTANEOUS USE .

This decision is addressed to Merck Sharp & Dohme (UK) Ltd. , 120 Moorgate, London, UNITED KINGDOM, EC2M 6UR

ANNEX I

1. Waiver

1.1 Condition:

Treatment of metabolic dysfunction-associated steatohepatitis The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 8 years of age Pharmaceutical form(s): Solution for injection in pre-filled syringe Route(s) of administration: SUBCUTANEOUS USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of metabolic dysfunction-associated steatohepatitis

2.2 Indication(s) targeted by the PIP:

Treatment of metabolic dysfunction-associated steatohepatitis (MASH) in patients from 8 years of age.

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

The paediatric population from 8 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Solution for injection in pre-filled syringe

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 Double-blind, randomised, placebo-controlled trial to evaluate safety and efficacy of efinopegdutide in children from 8 years to less than 18 years of age (and adults) with metabolic dysfunction-associated steatohepatitis (MASH).
Extrapolation, Modeling & Simulation Studies	1	Study 2 PopPK(/PD) study to predict initial paediatric doses to be used in PIP study 1.
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:	31/12/2041
Deferral of one or more studies contained in the paediatric investigation plan:	Yes