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 and grant a waiver

MHRA-101489-PIP01-24

Scope of the Application

Active Substance(s)

Enlicitide (decanoate)

Condition(s)

Treatment of hypercholesterolemia

Pharmaceutical Form(s)

Film-coated tablet; Age appropriate formulation

Route(s) of Administration

ORAL 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 16/05/2024 16:31 BST an application for a Paediatric Investigation Plan

The procedure started on 10/09/2024 15:22 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 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-101489-PIP01-24

Of 29/10/2024 08:55 GMT

On the adopted decision for Enlicitide (decanoate) (MHRA-101489-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 Enlicitide (decanoate), Film-coated tablet; Age appropriate formulation , ORAL 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 hypercholesterolaemia The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 years of age Pharmaceutical form(s): Film-coated tablet Age appropriate formulation Route(s) of administration: ORAL 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 hypercholesterolaemia

2.2 Indication(s) targeted by the PIP:

Treatment of heterozygous familial hypercholesterolaemia (HeFH)

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

The paediatric population from 6 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Film-coated tablet Age appropriate formulation

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate formulation for use in children from 6 years to less than 18 years of age.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 2 Two-part double-blind, randomised, placebo-controlled trial to evaluate pharmacokinetics, safety, efficacy of enlicitide (decanoate) in children from 6 years to less than 18 years of age with heterozygous familial hypercholesterolaemia (HeFH) and LDL-C $\geq$ 130mg/dL despite use of stable background lipid-lowering therapy (Part B), with an open label non-comparative cohort (Part A) to evaluate pharmacokinetics and safety of enlicitide (decanoate) and acceptability/palatability of an age-appropriate formulation developed in PIP study 1 in children younger than 12 years of age.
Extrapolation, Modeling & Simulation Studies	1	Study 3 Modelling and simulation analyses to determine the enlicitide (decanoate) paediatric dose(s) for use in children from 6 years to less than 18 years of age with HeFH.
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:	31/08/2035
Deferral of one or more studies contained in the paediatric investigation plan:	Yes