EMADOC-1700519818-1976306

# European Medicines Agency decision

EMA/PE/0000228536

of 19 March 2025

on the acceptance of a modification of an agreed paediatric investigation plan for enlicitide (decanoate) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

**Disclaimer**

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

**Only the English text is authentic.**

# European Medicines Agency decision

EMA/PE/0000228536

of 19 March 2025

on the acceptance of a modification of an agreed paediatric investigation plan for enlicitide (decanoate) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0133/2024 issued on 12 April 2024,

Having regard to the application submitted by Merck Sharp & Dohme B.V. on 7 October 2024 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 31 January 2025, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

***Article 1***

Changes to the agreed paediatric investigation plan for enlicitide (decanoate), are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

***Article 2***

This decision is addressed to Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem, Netherlands.

EMADOC-1700519818-1758903

Amsterdam, 31 January 2025

# Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMA/PE/0000228536

## Scope of the application

**Active substance(s):**

Enlicitide (decanoate)

**Invented name and authorisation status:**

See Annex II

**Condition(s):**

Treatment of hypercholesterolaemia

**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 B.V.

## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Merck Sharp & Dohme B.V. submitted to the European Medicines Agency on 7 October 2024 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0133/2024 issued on 12 April 2024.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 25 November 2024.

## Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

## Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

   The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

# Annex I

# The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

# Waiver

## *1.1. Condition:*

Treatment of hypercholesterolaemia

The waiver applies to:

- the paediatric population from birth to less than 6 years of age;
- film-coated tablet, age-appropriate formulation, oral use;
- 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:*

Treatment of hypercholesterolaemia

### 2.1.1. Indication(s) targeted by the PIP

Treatment of heterozygous familial hypercholesterolaemia (HeFH)

### 2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 6 years to less than 18 years of age

### 2.1.3. Pharmaceutical form(s)

Film-coated tablet

Age-appropriate formulation

### 2.1.4. Measures

| **Area** | **Description** |
|---|---|
| Quality-related studies | **Study 1**<br><br>Development of an age-appropriate formulation for use in children from 6 years to less than 18 years of age. |
| Non-clinical studies | Not applicable |
| Clinical studies | **Study 2**<br><br>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 ≥130 mg/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 the age-appropriate formulation developed in PIP study 1 in children younger than 12 years of age. |
| Modelling and simulation analyses | **Study 3**<br>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 | Not applicable |
| Extrapolation plan | Not applicable |

# 3. Follow-up, completion and deferral of PIP

| | |
|---|---|
| Concerns on potential long term safety/efficacy issues in relation to paediatric use: | No |
| Date of completion of the paediatric investigation plan: | By August 2035 |
| Deferral for one or more measures contained in the paediatric investigation plan: | Yes |

# Annex II

# Information about the authorised medicinal product

***Information provided by the applicant:***

**The product is not authorised anywhere in the European Community.**