

**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-101813-PIP01-25

### **Scope of the Application**

#### **Active Substance(s)**

Islatravir; LENACAPAVIR SODIUM

#### **Condition(s)**

Treatment of human immunodeficiency virus-1 (HIV-1) infection

#### **Pharmaceutical Form(s)**

Film-coated tablet; Age-appropriate oral 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 19/03/2025 12:41 GMT an application for a Paediatric Investigation Plan

The procedure started on 10/04/2025 15:15 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-101813-PIP01-25

Of 16/10/2025 16:03 BST

On the adopted decision for Islatravir; LENACAPAVIR SODIUM (MHRA-101813-PIP01-25) 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 Islatravir; LENACAPAVIR SODIUM, Film-coated tablet; Age-appropriate oral 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 human immunodeficiency virus-1 (HIV-1) infection The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age  
Pharmaceutical form(s): Film-coated tablet Age-appropriate oral 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 human immunodeficiency virus-1 (HIV-1) infection

## 2.2 Indication(s) targeted by the PIP:

As a complete regimen for the treatment of HIV-1 infection in paediatric patients weighing  $\geq 10$  kg to replace the current antiretroviral (ARV) regimen in those who are virologically suppressed (HIV-1 RNA 50 copies/mL) on a stable ARV regimen with no resistance to islatravir (ISL) or lenacapavir sodium (LEN).

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

The paediatric population from 2 years to less than 18 years of age

## 2.4 Pharmaceutical Form(s):

Film-coated tablet Age-appropriate oral formulation

## 2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate oral solid dosage form.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 2 (GS-US-563-6252) Open-label, single-arm clinical study to evaluate pharmacokinetics, safety, tolerability, and antiviral activity of Lenacapavir/Islatravir (ISL/LEN) oral fixed dose combination administered once weekly in virologically suppressed paediatric participants with HIV-1 infection from 2 years to less than 18 years of age, weighing at least 10 kg, on stable antiretroviral therapy.
Extrapolation, Modeling & Simulation Studies	2	Study 3 Modelling and simulation study to determine the paediatric dose and support the use of islatravir/lenacapavir sodium fixed dose combination in children from 2 years to less than 18 years of age. Extrapolation Plan Study 2 (GS-US-563-6252) and Study 3 are part of the extrapolation of efficacy and safety data from adults to children from 2 years to less than 18 years of age in condition as agreed by the Regulatory Agency.
Other Studies	0	Not applicable.
Other Measures	0	Not applicable.

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

<b>Concerns on potential long term safety and efficacy issues in relation to paediatric use:</b>	No
<b>Date of completion of the paediatric investigation plan:</b>	30/06/2032
<b>Deferral of one or more studies contained in the paediatric investigation plan:</b>	Yes