MHRA
10 South Colonnade
Canary Wharf
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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-100109-PIP01-21

Scope of the Application

Active Substance(s)

islatravir

Condition(s)

Prevention of human immunodeficiency virus (HIV-1) infection

Pharmaceutical Form(s)

Tablet

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 19/06/2021 15:55 BST an application for a Paediatric Investigation Plan

The procedure started on 22/04/2022 07:30 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-100109-PIP01-21

Of 27/05/2022 09:23 BST

On the adopted decision for islatravir (MHRA-100109-PIP01-21) 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, Tablet , 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:

Prevention of human immunodeficiency virus (HIV-1) infection The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 12 years of age Pharmaceutical form(s): Tablet Route(s) of administration: Oral use Reason for granting waiver: on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of human immunodeficiency virus (HIV-1) infection

2.2 Indication(s) targeted by the PIP:

Pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in at-risk adolescents aged 12 years and older.

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

The paediatric population from 12 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Tablet

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable
Non-Clinical Studies	0	Not applicable
Clinical Studies	2	Study 1 (P022) Randomised, double-blind, event driven study to evaluate the efficacy, in terms of superiority versus active control, the safety and tolerability of islatravir for the prevention of human immunodeficiency virus (HIV-1) infection from sexual acquisition in cis-gender female participants from 16 years to less than 18 years of age (and adults). Study 2 (P024) Randomised, double-blind study to evaluate the efficacy, safety and tolerability of islatravir for the prevention of HIV-1 infection from sexual acquisition in cisgender males and transgender female subjects from 16 years to less than 18 years of age (and adults) who have sex with men.
Extrapolation, Modeling & Simulation Studies	2	Study 3 Modelling and simulation study to predict islatravir exposure in paediatric subjects from 12 year to less than 16 years of age and weighing at least 35 kg. Study 4 Study to support extrapolation of efficacy of islatravir for the prevention of HIV-1 infection in adolescents from 12 years to less than 16 years of age.
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:	31/08/2025
Deferral of one or more studies contained in the paediatric investigation plan:	Yes