MHRA
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Canary Wharf
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept of change(s) to the agreed paediatric investigation plan and to the deferral

MHRA-100865-PIP01-23-M01

Scope of the Application

Active Substance(s)

RILPIVIRINE

Condition(s)

Treatment of human immunodeficiency virus (HIV-1) infection

Pharmaceutical Form(s)

Prolonged-release suspension for injection

Route(s) of Administration

INTRAMUSCULAR USE

Name / Corporate name of the PIP applicant

Janssen-Cilag Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Janssen-Cilag Ltd submitted to the licensing authority on 08/02/2023 10:47 GMT an application for a Modification

The procedure started on 12/06/2023 16:13 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 accept change(s) to the agreed paediatric investigation plan and to the deferral

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-100865-PIP01-23-M01

Of 23/06/2023 09:33 BST

On the adopted decision for RILPIVIRINE (MHRA-100865-PIP01-23-M01) 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 modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan);

This decision applies to a Modification for RILPIVIRINE, Prolonged-release suspension for injection , INTRAMUSCULAR USE .

This decision is addressed to Janssen-Cilag Ltd, 50-100 Holmers Farm Way, High Wycombe, UNITED KINGDOM, HP12 4EG

ANNEX I

1. Waiver

1.1 Condition:

Treatment of human immunodeficiency virus (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): Prolonged-release suspension for injection. Route(s) of administration: INTRAMUSCULAR 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 (HIV-1) infection.

2.2 Indication(s) targeted by the PIP:

Treatment of human immunodeficiency virus (HIV-1) infection, in combination with long-acting cabotegravir.

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):

Prolonged-release suspension for injection.

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 (Same as study 3 of the cabotegravir adopted UK-PIP EMEA-001418-PIP01-13-M01 and subsequent modifications thereof.) Multi-centre, open-label, non-comparative trial to evaluate the pharmacokinetics, safety, tolerability and acceptability of oral and long-acting (LA) formulations of rilpivirine and cabotegravir in virologically suppressed adolescents from 12 years to less than 18 years of age with HIV-1 infection. Study 2 Multi-centre open-label, non-comparative study to evaluate pharmacokinetics (PK), safety and tolerability of cabotegravir and rilpivirine [oral and long acting (LA) formulations] in children from 2 years to less than 12 years of age with HIV-1 infection. This is the same as Study 6 in the adopted UK-PIP EMEA-001418-PIP01-13-M02 for cabotegravir in condition: Treatment of human immunodeficiency virus (HIV-1) infection. To note, there are 2 pending UK modification

		requests for this adopted UK-PIP (MHRA-100901-PIP01-23-M01 and MHRA-100901-PIP01-23-M02).
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
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:	Yes
Date of completion of the paediatric investigation plan:	30/09/2025
Deferral of one or more studies contained in the paediatric investigation plan:	Yes