MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

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

MHRA-100552-PIP01-22-M01

Scope of the Application

Active Substance(s)

RILPIVIRINE HYDROCHLORIDE

Condition(s)

Treatment of human immunodeficiency virus (HIV-1) infection

Pharmaceutical Form(s)

Film-coated tablet; Age-appropriate solid oral formulation

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Janssen-Cilag Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Janssen-Cilag Limited submitted to the licensing authority on 31/05/2022 22:27 BST an application for a Modification

The procedure started on 20/12/2022 21:22 GMT

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-100552-PIP01-22-M01

Of 06/01/2023 13:10 GMT

On the adopted decision for RILPIVIRINE HYDROCHLORIDE (MHRA-100552-PIP01-22-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 HYDROCHLORIDE, Film-coated tablet; Age-appropriate solid oral formulation , ORAL USE .

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

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): Film-coated tablet Age-appropriate solid 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 as clinical studies(s) are not feasible

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of human immunodeficiency virus (HIV-1) infection

2.2 Indication(s) targeted by the PIP:

Rilpivirine is indicated in combination with other antiretroviral (ARV) medicinal products, for the treatment of human immunodeficiency virus (HIV-1) infection in ARV-naïve paediatric patients from 2 to less than 18 years with a baseline viral load below 100,000 HIV-1 RNA copies / ml.

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 solid oral formulation.

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of age-appropriate formulation for oral use.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	4	Study 2 (TMC278IFD1008) Open-label, randomised, crossover trial to compare the oral bioavailability of the age-appropriate oral paediatric formulation of rilpivirine hydrochloride relative to that of the 25 mg tablet and to assess the food effect. Study 3 (TMC278-TiDP38-C213 – Cohort 1) Open-label, non-comparative trial to evaluate pharmacokinetics, safety, tolerability and antiviral activity of rilpivirine (as hydrochloride) in HIV-1 infected treatment naïve adolescents from 12 years to less than 18 years of age. Study 4 (TMC278-TiDP38-C213 – Cohort 2) Open-label, non-comparative trial to evaluate pharmacokinetics, safety, tolerability and antiviral activity of rilpivirine (as hydrochloride) in HIV-1 infected treatment naïve children from 6 years to less than 12 years of age. Study 5 Was deleted in procedure EMEA-000317-PIP01-08-M11. Study 6 (TMC278HTX2002)

		(added in procedure EMEA-000317-PIP01-08-M11) Open-label, non-comparative trial to evaluate the pharmacokinetics, safety, tolerability and antiviral activity of switching to rilpivirine (in combination with other antiretrovirals) in HIV-1-infected children from 2 years to less than 12 years of age who are virologically suppressed.
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:	31/12/2022
Deferral of one or more studies contained in the paediatric investigation plan:	Yes