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-100604-PIP01-22-M01

Scope of the Application

Active Substance(s)

REMDESIVIR

Condition(s)

Treatment of Coronavirus disease 2019 (COVID-19)

Pharmaceutical Form(s)

Powder for concentrate for solution for infusion

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

Gilead Sciences Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Gilead Sciences Ltd submitted to the licensing authority on 28/07/2022 11:40 BST an application for a Modification

The procedure started on 31/08/2022 10:43 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-100604-PIP01-22-M01

Of 16/11/2022 08:15 GMT

On the adopted decision for REMDESIVIR (MHRA-100604-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 REMDESIVIR, Powder for concentrate for solution for infusion , INTRAVENOUS USE .

This decision is addressed to Gilead Sciences Ltd, 280 High Holborn , London, UNITED KINGDOM, WC1V 7EE

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of Coronavirus disease 2019 (COVID-19)

2.2 Indication(s) targeted by the PIP:

Treatment of Coronavirus disease 2019 (COVID-19)

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

The paediatric population from 32 weeks gestational age to less than 18 years of age

2.4 Pharmaceutical Form(s):

Powder for concentrate for solution for infusion

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Assessment of the compatibility and stability of the powder for concentrate for solution to support dilution into glucose 50 mg/ml solution and dilution into syringe.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 2 (GS-US-540-5823) Open-label, single-arm study to evaluate the pharmacokinetics, safety, tolerability, and efficacy of remdesivir (RDV) in hospitalised children, from 32 weeks gestational age to less than 18 years of age, with COVID-19.
Extrapolation, Modeling & Simulation Studies	2	Study 3 (Modelling and Simulation Study) Population PK modelling and simulation study to determine a paediatric dose/posology in paediatric subjects from 32 weeks gestational age to less than 18 years of age that should achieve the systemic exposures equivalent to that observed in adults. Study 4 (Extrapolation of efficacy and safety study) Extrapolation study of efficacy and safety of remdesivir from adult subjects to paediatric patients from 32 weeks gestational age (GA) to less than 18 years of age with confirmed COVID-19.
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:	31/12/2023
Deferral of one or more studies contained in the paediatric investigation plan:	Yes