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

MHRA-100381-PIP01-21

Scope of the Application

Active Substance(s)

Regdanvimab

Condition(s)

Treatment of Coronavirus disease 2019 (COVID-19)

Pharmaceutical Form(s)

Concentrate for solution for infusion

Route(s) of Administration

Intravenous use

Name / Corporate name of the PIP applicant

Celltrion Healthcare United Kingdom Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Celltrion Healthcare United Kingdom Limited submitted to the licensing authority on 08/12/2021 08:14 GMT an application for a Paediatric Investigation Plan

The procedure started on 22/12/2021 12:19 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 agree a paediatric investigation plan and grant a 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-100381-PIP01-21

Of 19/01/2022 07:18 GMT

On the adopted decision for Regdanvimab (MHRA-100381-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 Regdanvimab, Concentrate for solution for infusion , Intravenous use .

This decision is addressed to Celltrion Healthcare United Kingdom Limited , The Switch, 1-7 The Grove Berkshire, Slough, United Kingdom, Berkshire, Slough, United Kingdom, SL1 1QP

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 paediatric patients with COVID-19 who are at risk of progressing to severe disease

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

All subsets of the paediatric population from birth to less than 18 years of age

2.4 Pharmaceutical Form(s):

Concentrate for solution for infusion

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable
Non-Clinical Studies	0	Not applicable
Clinical Studies	1	Study 1 Single-arm, open-label study to evaluate the safety, tolerability, pharmacokinetics, and efficacy of regdanvimab in combination with standard of care (SoC) in paediatric patients from birth to less than 18 years of age with mild or moderate COVID-19 who are at increased risk of adverse outcomes and severe COVID-19.
Extrapolation, Modeling & Simulation Studies	1	Study 2 Modelling and simulation study to characterise the pharmacokinetics (PK) of regdanvimab, to perform dose selection as well as exposure predictions in support of extrapolation of efficacy from adults to paediatric patients.
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:	31/03/2024
Deferral of one or more studies contained in the paediatric investigation plan:	Yes