MHRA
10 South Colonnade
Canary Wharf
London
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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

MHRA-100053-PIP01-21

Scope of the Application

Active Substance(s)

REGN10987

Condition(s)

Treatment of coronavirus disease 2019 (COVID-19), Prevention of coronavirus disease 2019 (COVID-19)

Pharmaceutical Form(s)

Solution for infusion; Solution for injection

Route(s) of Administration

Intravenous use; Subcutaneous use

Name / Corporate name of the PIP applicant

Roche Products Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Roche Products Ltd submitted to the licensing authority on 12/03/2021 17:03 GMT an application for a

The procedure started on 29/03/2021 10:37 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:

The agreement of a paediatric investigation plan and on the granting of 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-100053-PIP01-21

Of 04/08/2021 11:26 BST

On the adopted decision for REGN10987 (MHRA-100053-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 for REGN10987 , Solution for infusion; Solution for injection , Intravenous use, Subcutaneous use, Intramuscular use .

This decision is addressed to Roche Products Ltd, 6 Falcon Way, Shire Park, Welwyn Garden City, London, United Kingdom, AL7 1TW

ANNEX I

1. Waiver

1.1 Condition:

Not applicable.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of Coronavirus Disease 2019 (COVID-19); Treatment of Coronavirus Disease 2019 (COVID-19)

2.2 Indication(s) targeted by the PIP:

Prevention of Coronavirus Disease 2019 (COVID-19) in paediatric patients; Treatment of Coronavirus Disease 2019 (COVID-19) in paediatric patients

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):

Solution for infusion; Solution 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	4	Study 1_An adaptive phase 1,2 and 3, randomized, double-blinded, master protocol study in paediatric (and adult) ambulatory patients with COVID-19 and at least 1 risk factor for severe disease; Study 2_ An open-label, single-dose study to evaluate the safety, tolerability and PK of casirivimab and imdevimab in hospitalised paediatric patients with COVID-19; Study 3_A randomized, double-blinded, placebo-controlled, single-dose study in adolescent (and adult) household contacts of a person infected with SARS-CoV-2; Study 4_ A Phase 1, Open-label study assessing the safety, tolerability, pharmacokinetics, and immunogenicity of subcutaneous anti-spike sars-cov-2 monoclonal antibodies (casirivimab and imdevimab) in paediatric subjects less than 12 years of age.
Extrapolation, Modeling & Simulation Studies	2	Study 5_ Population PK model to analyse PK data collected from Studies 1,2,3, and 4 (and adults) to inform dosing recommendations of casirivimab and imdevimab in paediatric population from birth to less than 18 years of age; Study 6_Extrapolation study to support the

		use of casirivimab and imdevimab for each weight-tiered group of paediatric outpatients with COVID-19, hospitalized paediatric patients with COVID-19, and paediatric patients for prevention of SARS-CoV-2 infection.
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:	30/09/2023
Deferral of one or more studies contained in the paediatric investigation plan:	Yes