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-100052-PIP01-21

Scope of the Application

Active Substance(s)

REGN10933

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 Limited

Basis for the Decision

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

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-100052-PIP01-21

Of 04/08/2021 09:28 BST

On the adopted decision for REGN10933 (MHRA-100052-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 REGN10933, Solution for infusion; Solution for injection , Intravenous use, Subcutaneous use, Intramuscular use .

This decision is addressed to Roche Products Limited, 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 injection/infusion

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