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

**gov.uk/mhra**

# Decision Cover Letter

## Decision of the licensing authority to:

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

MHRA-100053-PIP01-21-M01

# Scope of the Application

## Active Substance(s)

IMDEVIMAB

## Condition(s)

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

## Pharmaceutical Form(s)

Solution for injection/infusion

## 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 29/10/2021 17:18 BST an application for a Modification

The procedure started on 24/11/2021 16:53 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-100053-PIP01-21-M01

Of 18/02/2022 08:15 GMT

On the adopted decision for IMDEVIMAB (MHRA-100053-PIP01-21-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 IMDEVIMAB, Solution for injection/infusion , Intravenous use, Subcutaneous use .

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

## ANNEX I

### 1. Waiver

### 1.1 Condition:

| |
|---|
| Not applicable |

### 2. Paediatric Investigation Plan:

### 2.1 Condition(s):

| |
|---|
| Treatment of coronavirus disease 2019 (COVID-19); Prevention of coronavirus disease 2019 (COVID-19) |

### 2.2 Indication(s) targeted by the PIP:

| |
|---|
| Treatment of coronavirus disease 2019 (COVID-19); Prevention of coronavirus disease 2019 (COVID-19) |

## 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 | (For Treatment of coronavirus disease 2019) Study 1 (R10933-10987-COV-2067) Randomised, double-blinded, single-dose master protocol to evaluate the pharmacokinetics (PK) safety and tolerability of single dose casirivimab and imdevimab for the treatment of COVID-19 in paediatric patients from birth to less than 18 years who are at risk of severe disease. Study 2 (R10933-10987-COV-2114) Open-label, single-dose study to evaluate the safety, tolerability and PK of casirivimab and imdevimab for the treatment of hospitalised paediatric patients with COVID-19. (For Prevention of coronavirus disease 2019) Study 3 (R10933-10987-COV-2069) A randomised, double-blinded, placebo-controlled, single-dose study in adolescent (and adult) household contacts of a person infected with SARS-CoV-2 and are either SARS-CoV-2 RT-qPCR negative at baseline (Cohort A) or SARS-CoV-2 RT-qPCR positive at baseline (Cohort B). Study 4 (R10933-10987-COV-2121) Open-label, single arm study to assess the safety, tolerability, pharmacokinetics, and immunogenicity of subcutaneous casirivimab and imdevimab in paediatric subjects from birth to less than 12 years of age. |

| | | |
|---|---|---|
| **Extrapolation, Modeling & Simulation Studies** | 3 | Study 5 (Modelling and Simulation Study) Population PK model for dose prediction and confirmation for the intravenous and subcutaneous routes of administration of casirivimab and imdevimab in paediatric population from29 weeks of gestational age to less than 18 years of age. (Same study 5 for both Treatment and Prevention of coronavirus disease 2019). Study 6 (Extrapolation-Treatment) PK bridging and extrapolation of efficacy and safety to support the use of single IV dose casirivimab and imdevimab for the treatment of COVID-19 from adult patients to paediatric patients from 29 weeks gestational age at birth to less than 18 years of age. Study 7 (Extrapolation-Prevention) PK bridging and extrapolation of efficacy and safety to support the use of a single dose of casirivimab and imdevimab for the prevention of COVID-19 from adults to children from birth to less than18 years of age. |
| **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 |