EMA/638306/2022

European Medicines Agency decision

P/0343/2022

of 10 August 2022

on the acceptance of a modification of an agreed paediatric investigation plan for imdevimab (Ronapreve), (EMEA-002965-PIP01-21-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0348/2021 issued on 16 August 2021 and the decision P/0045/2022 issued on 3 February 2022,

Having regard to the application submitted by Roche Registration GmbH on 18 March 2022 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 24 June 2022, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for imdevimab (Ronapreve), solution for injection/infusion, subcutaneous use, intravenous use, including changes to the deferral, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Roche Registration GmbH, Emil-Barell-Strasse 1, 79639 - Grenzach-Wyhlen, Germany.

EMA/PDCO/177970/2022
Amsterdam, 24 June 2022

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-002965-PIP01-21-M02

Scope of the application

Active substance(s):

Imdevimab

Invented name:

Ronapreve

Condition(s):

Prevention of coronavirus disease 2019 (COVID-19)

Treatment of coronavirus disease 2019 (COVID-19)

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection/infusion

Route(s) of administration:

Subcutaneous use

Intravenous use

Name/corporate name of the PIP applicant:

Roche Registration GmbH

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Roche Registration GmbH submitted to the European Medicines Agency on 18 March 2022 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0348/2021 issued on 16 August 2021 and the decision P/0045/2022 issued on 3 February 2022.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

The procedure started on 25 April 2022.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan and to the deferral in the scope set out in the Annex I of this opinion.

   The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

Not applicable

2. Paediatric investigation plan

2.1. Condition:

Treatment of coronavirus disease 2019 (COVID-19)

2.1.1. Indication(s) targeted by the PIP

Treatment of coronavirus disease 2019 (COVID-19)

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Solution for injection/infusion

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**Study 1 (R19033-10987-COV-2067)** Randomized, double-blinded, pharmacokinetics (PK), safety and tolerability study of single-dose casirivimab and imdevimab for the treatment of COVID-19 in paediatric patients (and adults) who are at risk of severe disease. **Study 2 (R10933-10987-COV-2114)** Study deleted in EMEA-002965-PIP01-21-M02.
Extrapolation, modelling and simulation studies	**Study 3 (Modelling and simulation Study)** PopPK model for dosing prediction and confirmation for the intravenous (IV) and subcutaneous (SC) routes of administration in paediatric patients from birth less than 18 years of age. *This study is the same as study 3 in condition 2 (Prevention of coronavirus disease 2019 (COVID-19)* **Study 4 (Extrapolation - Treatment)** PK bridging and extrapolation of safety and efficacy to support the use of a single-dose of casirivimab and imdevimab for the treatment of COVID-19 from adults to paediatric patients from birth to less than 18 years of age

Other studies	Not applicable
Other measures	Not applicable

2.2. Condition:

Prevention of coronavirus disease 2019 (COVID-19)

2.2.1. Indication(s) targeted by the PIP

Prevention of coronavirus disease 2019 (COVID-19)

2.2.2. Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 18 years of age.

2.2.3. Pharmaceutical form(s)

Solution for injection/infusion

2.2.4. Measures

Area	**Description**
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**Study 5 (R19033-10987-COV-2069)** Randomized, double-blinded, placebo-controlled study of casirivimab and imdevimab to evaluate efficacy, safety and tolerability in asymptomatic adolescents (and adults) who are household contacts of a person infected with SARS-CoV-2 and are SARSCoV-2 RT-qPCR negative at baseline (Cohort A) or SARS-CoV-2 RT-qPCR positive at baseline (Cohort B) **Study 6 (R19033-10987-COV-2121)** Open-label, single-dose study to assess the pharmacokinetics, tolerability and safety of subcutaneous casirivimab and imdevimab in paediatric subjects from birth to less than 12 years of age.
Extrapolation, modelling and simulation studies	**Study 3 *(*Modelling and simulation Study)** PopPK model for dosing prediction and confirmation for the intravenous (IV) and subcutaneous (SC) routes of administration in paediatric subjects from birth less than 18 years of age. *This study is the same as study 3 in condition 1 (Treatment of coronavirus disease 2019 (COVID-19))* **Study 7 (Extrapolation -Prevention)** PK bridging and extrapolation of safety and efficacy to support the

	use of a single-dose of casirivimab and imdevimab for the prevention of COVID-19 from adults to paediatric subjects from birth less than 18 years of age
Other studies	Not applicable
Other measures	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan	By March 2023
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

Prevention of coronavirus disease 2019 (COVID-19)

Treatment of coronavirus disease 2019 (COVID-19)

Authorised indication(s):

- Ronapreve is indicated for:
- Treatment of COVID-19 in adults and adolescents aged 12 years and older weighing at least 40 kg who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19.
- Prevention of COVID-19 in adults and adolescents aged 12 years and older weighing at least 40 kg.

Authorised pharmaceutical form(s):

Solution for injection/infusion

Authorised route(s) of administration:

Intravenous infusion

Subcutaneous injection