EMA/418668/2021

European Medicines Agency decision

P/0348/2021

of 16 August 2021

on the agreement of a paediatric investigation plan and on the granting of a deferral for imdevimab (REGN10987), (EMEA-002965-PIP01-21) 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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the application submitted by Regeneron Ireland DAC on 11 February 2021 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 23 July 2021, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

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

Has adopted this decision:

Article 1

A paediatric investigation plan for imdevimab (REGN10987), solution for injection, concentrate for solution for infusion, subcutaneous use, intravenous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for imdevimab (REGN10987), solution for injection, concentrate for solution for infusion, subcutaneous use, intravenous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Regeneron Ireland DAC, One Warrington Place, Dublin 2, D02 HH27 - Dublin, Ireland.

EMA/PDCO/420402/2021 Corr
Amsterdam, 23 July 2021

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral

EMEA-002965-PIP01-21

Scope of the application

Active substance(s):

Imdevimab (REGN10987)

Conditions:

Treatment of coronavirus disease 2019 (COVID-19)

Prevention of coronavirus disease 2019 (COVID-19)

Pharmaceutical form(s):

Solution for injection

Concentrate for solution for infusion

Route(s) of administration:

Subcutaneous use

Intravenous use

Name/corporate name of the PIP applicant:

Regeneron Ireland DAC

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Regeneron Ireland DAC submitted for agreement to the European Medicines Agency on 11 February 2021 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 23 February 2021.

Supplementary information was provided by the applicant on 30 April 2021. The applicant proposed modifications to the paediatric investigation plan.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation.

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

2. The measures and timelines of the agreed 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 annex 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

Concentrate for solution for infusion

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	2	**Study 1 (R19033-10987-COV-2067)** Randomised, double-blinded, pharmacokinetics (PK), safety and tolerability study of single-dose casirivimab and imdevimab for the treatment of COVID-19 in paediatric patients from birth to less than 18 years of age (and adults) who are at risk of severe disease. **Study 2 (R10933-10987-COV-2114)** Open-label, single-dose study to evaluate safety, tolerability and PK of casirivimab and imdevimab for the treatment of paediatric patients from 29 weeks gestational age (at birth) to less than 18 years of age with COVID-19 who require hospitalisation.
Extrapolation, modelling and	2	**Study 3 (Modelling and simulation Study)** PopPK model for dosing prediction and confirmation for the intravenous (IV) and subcutaneous (SC) routes of administration in

simulation studies		paediatric patients from 29 weeks of gestational age (at birth) (GA) to less than 18 years of age. *This study is the same as study 3 in condition "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 administered intravenously (IV) for the treatment of COVID-19 from adults to children from 29 weeks gestational age (at birth) to less than 18 years of age.
Other studies	0	Not applicable
Other measures	0	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

Concentrate for solution for infusion

2.2.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	2	**Study 5 (R19033-10987-COV-2069)** Randomised, double-blinded, placebo-controlled study of casirivimab and imdevimab to evaluate efficacy, safety and tolerability in asymptomatic adolescents from 12 to less than 18 years of age (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 pharmacokinetics, safety, and tolerability of a single-dose of subcutaneous casirivimab and imdevimab in paediatric subjects from birth to less than 12 years of age.
Extrapolation, modelling and simulation studies	2	**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 29 weeks of gestational age (at birth) (GA) to less than 18 years of age. *This study is the same as study 3 in condition "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 administered subcutaneously (SC) for the prevention of COVID-19 from adults to children from at birth to less than 18 years of age
Other studies	0	Not applicable
Other measures	0	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 September 2023
Deferral for one or more measures contained in the paediatric investigation plan:	Yes