

EMA/236249/2023

European Medicines Agency decision P/0238/2023

of 14 June 2023

on the acceptance of a modification of an agreed paediatric investigation plan for regdanvimab (Regkirona), (EMEA-002961-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 726/2004¹,

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 Agency²,

Having regard to the European Medicines Agency's decision P/0234/2021 issued on 8 June 2021 and the decision P/0166/2022 issued on 13 May 2022,

Having regard to the application submitted by Celltrion Healthcare Hungary Kft. on 19 January 2023 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 26 April 2023, 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 regdanvimab (Regkirona), concentrate for solution for infusion, 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 Celltrion Healthcare Hungary Kft., Váci út 1-3. WestEnd Office Building B torony, 1062 – Budapest, Hungary.

EMA/PDCO/49589/2023
Amsterdam, 26 April 2023

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-002961-PIP01-21-M02

Scope of the application

Active substance(s):

Regdanvimab

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of coronavirus disease 2019 (COVID-19)

Pharmaceutical form(s):

Concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Celltrion Healthcare Hungary Kft.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Celltrion Healthcare Hungary Kft. submitted to the European Medicines Agency on 19 January 2023 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0234/2021 issued on 8 June 2021 and the decision P/0166/2022 issued on 13 May 2022.

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

The procedure started on 27 February 2023.

Scope of the modification

Some 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 paediatric patients with COVID-19 who are at risk of progressing to severe disease

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)

Concentrate for solution for infusion

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	Study 1 Single-arm, open-label study to evaluate the safety, tolerability, pharmacokinetics, and efficacy of regdanvimab in combination with standard of care (SoC) in paediatric patients from birth to less than 18 years of age with mild or moderate COVID-19 who are at increased risk of adverse outcomes and severe COVID-19
Extrapolation, modelling and simulation studies	Study 2 Modelling and simulation study to characterise the pharmacokinetics (PK) of regdanvimab, to perform dose selection for Study 1 as well as exposure predictions in support of extrapolation of efficacy from adults to paediatric patients
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 October 2028
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Treatment of adults with coronavirus disease 2019 (COVID-19) who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19

Authorised indication(s):

- Treatment of adults with coronavirus disease 2019 (COVID-19) who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19
 - Invented name(s): Regkirona
 - Authorised pharmaceutical form(s): Concentrate for solution for infusion
 - Authorised route(s) of administration: Intravenous use
 - Authorised via centralised procedure