EMA/579337/2022

European Medicines Agency decision

P/0221/2022

of 24 June 2022

on the acceptance of a modification of an agreed paediatric investigation plan for remdesivir (Veklury), (EMEA-002826-PIP01-20-M03) 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/0201/2020 issued on 19 May 2020, the decision P/0060/2021 issued on 5 February 2021 and the decision P/0338/2021 issued on 9 August 2021,

Having regard to the application submitted by Gilead Sciences International Ltd. on 18 February 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 20 May 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 remdesivir (Veklury), powder for 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 Gilead Sciences International Ltd., Flowers Building, Granta Park, Great Abington, CB21 6GT - Cambridge, United Kingdom.

EMA/PDCO/128286/2022
Amsterdam, 20 May 2022

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

EMEA-002826-PIP01-20-M03

Scope of the application

Active substance(s):

Remdesivir

Invented name:

Veklury

Condition(s):

Treatment of coronavirus disease 2019 (COVID-19)

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder for concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Gilead Sciences International Ltd.

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Gilead Sciences International Ltd. submitted to the European Medicines Agency on 18 February 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/0201/2020 issued on 19 May 2020, the decision P/0060/2021 issued on 5 February 2021 and the decision P/0338/2021 issued on 9 August 2021.

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

The procedure started on 21 March 2022.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified. A pharmaceutical form was removed.

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 32 weeks gestational age (GA) to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Powder for concentrate for solution for infusion

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Assessment of the compatibility and stability of the powder for concentrate for solution for infusion to support dilution into glucose 50 mg/ml solution and dilution into syringe
Non-clinical studies	Not applicable
Clinical studies	**Study 2 (GS-US-540-5823)** Open-label, single-arm study to evaluate the pharmacokinetics, safety, tolerability, and efficacy of remdesivir (RDV) in hospitalized children, from 32 weeks gestational age to less than 18 years of age, with confirmed COVID-19
Extrapolation, modelling and simulation studies	**Study 3 (Modelling and Simulation Study)** Population PK modelling and simulation study to determine a paediatric dose/posology in paediatric subjects from 32 weeks gestational age to less than 18 years of age that should achieve the systemic exposures equivalent to that observed in adults **Study 4 (Extrapolation of efficacy and safety study)** Extrapolation study of efficacy and safety of remdesivir from adult subjects to paediatric patients from 32 weeks gestational age (GA) to less than 18 years of age with confirmed COVID-19

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 December 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):

1. Treatment of coronavirus disease 2019 (COVID-19)

Authorised indication:

- Treatment of coronavirus disease 2019 (COVID-19) in adults and adolescents (aged 12 years and older with body weight at least 40 kg) with pneumonia requiring supplemental oxygen (low- or high-flow oxygen or other non-invasive ventilation at start of treatment).

Authorised pharmaceutical form(s):

Concentrate for solution for infusion

Authorised route(s) of administration:

Intravenous use