EMA/103746/2023

European Medicines Agency decision

P/0118/2023

of 13 April 2023

on the agreement of a paediatric investigation plan and on the granting of a deferral for vilobelimab (EMEA-003080-PIP03-22) 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 application submitted by InflaRx GmbH on 1 June 2022 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 24 February 2023, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

A paediatric investigation plan for vilobelimab, concentrate for solution for infusion, 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 vilobelimab, concentrate for solution for infusion, 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 InflaRx GmbH, Winzlaer Str. 2, 07745 - Jena, Germany.

EMA/PDCO/916862/2022
Amsterdam, 24 February 2023

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

EMEA-003080-PIP03-22

Scope of the application

Active substance(s):

Vilobelimab

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:

InflaRx GmbH

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, InflaRx GmbH submitted for agreement to the European Medicines Agency on 1 June 2022 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 16 August 2022.

Supplementary information was provided by the applicant on 21 November 2022. 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 Paediatric Committee member of Norway 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 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 COVID-19

2.1.1. Indication(s) targeted by the PIP

Treatment of 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)

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 (IFX-1-P3.5)** Single-arm, open-label study to determine the safety, tolerability, pharmacokinetics and pharmacodynamics of vilobelimab for the treatment of COVID-19 in paediatric patients from birth to less than 18 years of age who are on invasive mechanical ventilation (IMV) or extracorporeal membrane oxygenation (ECMO).
Modelling and simulation studies	Population PK modelling and PK/PD exposure-response study to select the doses of vilobelimab across weight bands or a weight-based dosing regimen in children from birth to less than 18 years of age with COVID-19 who are on invasive mechanical ventilation (IMV) or extracorporeal membrane oxygenation (ECMO).
Other studies	Not applicable
Extrapolation plan	Studies IFX-1-P2.3 HS; IFX-1-P2.4 HS; IFX-1-P2.9 (PANAMO study) in adults, IFX-1-P3.5 (Study 1 of this PIP), and study IFX-1-POPPK-Paed (Study 2 of this PIP) are part of the extrapolation plan of efficacy and safety data from adult to paediatric patients from birth to less than 18 years of age with COVID-19 who are on invasive mechanical ventilation (IMV) or extracorporeal membrane oxygenation (ECMO).

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 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:

The product is not authorised anywhere in the European Community.