EMA/19222/2023

European Medicines Agency decision

P/0018/2023

of 31 January 2023

on the acceptance of a modification of an agreed paediatric investigation plan for SARS-CoV-2 virus, beta-propiolactone inactivated adjuvanted with CpG 1018 (VLA2001) (COVID-19 Vaccine (inactivated, adjuvanted) Valneva), (EMEA-003077-PIP01-21-M01) 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/0184/2022 issued on 13 May 2022

Having regard to the application submitted by Valneva Austria GmbH on 7 September 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 16 December 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.

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

[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 SARS-CoV-2 virus, beta-propiolactone inactivated adjuvanted with CpG 1018 (VLA2001) (COVID-19 Vaccine (inactivated, adjuvanted) Valneva), suspension for injection, suspension for injection, 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 Valneva Austria GmbH, 3 Campus Vienna Biocenter, 1030 – Vienna, Austria.

EMA/PDCO/769581/2022 Corr[1]
Amsterdam, 16 December 2022

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

EMEA-003077-PIP01-21-M01

Scope of the application

Active substance(s):

SARS-CoV-2 virus, beta-propiolactone inactivated adjuvanted with CpG 1018 (VLA2001)

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of Coronavirus disease 2019 (COVID-19)

Pharmaceutical form(s):

Suspension for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Valneva Austria GmbH

[1] 30 January 2023

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Valneva Austria GmbH submitted to the European Medicines Agency on 7 September 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/0184/2022 issued on 13 May 2022.

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

The procedure started on 17 October 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 in the scope set out in the Annex I of this opinion.

   The Paediatric Committee members of Liechtenstein and Norway agree 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 measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

Not applicable

2. Paediatric investigation plan

2.1. Condition:

Prevention of Coronavirus disease 2019 (COVID-19)

2.1.1. Indication(s) targeted by the PIP

Prevention 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)

Suspension for injection

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**Study 1 (VLA2001-301)** Randomised, observer blinded, controlled study to evaluate the safety, tolerability and immunogenicity of a booster dose of SARS-CoV-2 virus, beta-propiolactone inactivated adjuvanted with CpG 1018 (VLA2001) in adolescents from 12 years to less than 18 years of age (and adults). **Study 2 (VLA2001-321)** Randomised, double-blinded, active-controlled study to evaluate the safety, reactogenicity, and immunogenicity of SARS-CoV-2 virus, beta-propiolactone inactivated adjuvanted with CpG 1018 (VLA2001) in children from 2 years to less than 12 years of age. **Study 3** Randomised, double-blinded, active-controlled study to evaluate the safety, reactogenicity, and immunogenicity of SARS-CoV-2 virus, beta-propiolactone inactivated adjuvanted with CpG 1018 (VLA2001) in children from birth to less than 2 years of age.

	Study 4 Randomised, open label study to evaluate safety, reactogenicity, and immunogenicity of two dosing regimens of SARS-CoV-2 virus, beta-propiolactone inactivated adjuvanted with CpG 1018 (VLA2001) in immunocompromised children from birth to less than 18 years of age.
Extrapolation, modelling and simulation studies	Not applicable
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 June 2025
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. Prevention of Coronavirus disease 2019 (COVID-19)

Authorised indication(s):

- Active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 to 50 years of age
  - Invented name(s): COVID-19 Vaccine (inactivated, adjuvanted) Valneva
  - Authorised pharmaceutical form(s): Suspension for injection (injection)
  - Authorised route(s) of administration: Intramuscular use
  - Authorised via centralised procedure