EMA/207903/2022

European Medicines Agency decision

P/0184/2022

of 13 May 2022

on the agreement of a paediatric investigation plan and on the granting of a deferral for SARS-CoV-2 virus, beta-propiolactone inactivated adjuvanted with CpG 1018 (VLA2001) (EMEA-003077-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 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 Valneva Austria GmbH on 23 July 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 25 March 2022, 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 SARS-CoV-2 virus, beta-propiolactone inactivated adjuvanted with CpG 1018 (VLA2001), suspension for injection, intramuscular 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 for SARS-CoV-2 virus, beta-propiolactone inactivated adjuvanted with CpG 1018 (VLA2001), suspension for injection, intramuscular 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 Valneva Austria GmbH, Campus Vienna Biocenter 3, 1030 – Vienna, Austria.

EMA/PDCO/11695/2022
Amsterdam, 25 March 2022

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

EMEA-003077-PIP01-21

Scope of the application

Active substance(s):

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

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

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Valneva Austria GmbH submitted for agreement to the European Medicines Agency on 23 July 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 14 September 2021.

Supplementary information was provided by the applicant on 20 December 2021.

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 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:

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 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