



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/582972/2021

European Medicines Agency decision P/0457/2021

of 29 October 2021

on the agreement of a paediatric investigation plan and on the granting of a deferral for live-attenuated La Reunion strain of chikungunya virus (VLA1553) (EMEA-002873-PIP01-20) 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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency²,

Having regard to the application submitted by Valneva Austria GmbH on 10 August 2020 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 10 September 2021, 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.

² OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for live-attenuated La Reunion strain of chikungunya virus (VLA1553), powder and solvent for 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 live-attenuated La Reunion strain of chikungunya virus (VLA1553), powder and solvent for 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.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/342746/2021
Amsterdam, 10 September 2021

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

EMA-002873-PIP01-20

Scope of the application

Active substance(s):

Live-attenuated La Reunion strain of chikungunya virus (VLA1553)

Condition(s):

Prevention of chikungunya disease

Pharmaceutical form(s):

Powder and solvent for 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 10 August 2020 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 15 September 2020.

Supplementary information was provided by the applicant on 2 June 2021. The applicant proposed modifications to the paediatric investigation plan and withdrew its request for a waiver.



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 Norwegian Paediatric Committee member 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 chikungunya disease

2.1.1. Indication(s) targeted by the PIP

Active immunisation for the prevention of disease caused by chikungunya virus

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)

Powder and solvent for suspension for injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.
Clinical studies	5	Study 1 (VLA1553-321) Randomized, double-blinded, multicentre study to evaluate the immunogenicity and safety of the adult dose of VLA1553 28 days following vaccination in adolescents from 12 years to less than 18 years of age after a single immunization. Study 2 (VLA1553-221) Randomized, observer-blinded, prospective, multicentre study to evaluate the safety, tolerability and immunogenicity of the adult dose and half dose of VLA1553 compared to control, to identify the optimal dose of VLA1553 in healthy subjects from 1 year to less than 12 years of age. Study 3 (VLA1553-322) Randomized, double-blinded, multicentre study to evaluate the immunogenicity and safety of the final paediatric dose VLA1553 28

Area	Number of measures	Description
		<p>days following vaccination in healthy subjects from 1 year to less than 12 years of age.</p> <p>Study 4 (VLA1553-222)</p> <p>Randomized, observer-blinded, prospective, multicentre study to evaluate either one or two dose levels of VLA1553 in male and female infants from birth to less than 1 year of age, in comparison to a control.</p> <p>Study 5 (VLA1553-323)</p> <p>Randomized, double-blinded, prospective, multicentre, dose-confirmation study to evaluate the final infant dose of VLA1553 in comparison to control, in subjects from birth to less than 1 year of age.</p>
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	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 April 2030
Deferral for one or more measures contained in the paediatric investigation plan:	Yes