EMA/533540/2023

European Medicines Agency decision

P/0501/2023

of 24 November 2023

on the acceptance of a modification of an agreed paediatric investigation plan for live-attenuated La Reunion strain of chikungunya virus (VLA1553) (EMEA-002873-PIP01-20-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.

European Medicines Agency decision

P/0501/2023

of 24 November 2023

on the acceptance of a modification of an agreed paediatric investigation plan for live-attenuated La Reunion strain of chikungunya virus (VLA1553) (EMEA-002873-PIP01-20-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/0457/2021 issued on 29 November 2021,

Having regard to the application submitted by Valneva Austria GmbH on 22 November 2023 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 23 November 2023, 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 live-attenuated La Reunion strain of chikungunya virus (VLA1553), powder and solvent for suspension for injection, intramuscular use, 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, Campus Vienna Biocenter 3, 1030 - Vienna, Austria.

EMA/PDCO/531985/2023
Amsterdam, 23 November 2023

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

EMEA-002873-PIP01-20-M01

Scope of the application

Active substance(s):

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

Invented name and authorisation status:

See Annex II

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 22 of Regulation (EC) No 1901/2006 as amended, Valneva Austria GmbH submitted to the European Medicines Agency on 22 November 2023 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0457/2021 issued on 29 November 2021.

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

The procedure started on 22 November 2023.

Scope of the modification

Some 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 member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver 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:

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	Description
Quality-related studies	Not applicable.
Non-clinical studies	Not applicable.
Clinical studies	**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 days following vaccination in healthy subjects from 1 year to less than 12 years of age. **Study 4 (VLA1553-222)**

Area	Description
	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. **Study 5 (VLA1553-323)** 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.
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 April 2030
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.