EMADOC-1700519818-1880478

European Medicines Agency decision

EMA/PE/0000233803

of 21 March 2025

on the acceptance of a modification of an agreed paediatric investigation plan for Chikungunya virus virus-like particle 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/0159/2021 issued on 16 April 2021, and the decision P/0059/2024 issued on 7 March 2024,

Having regard to the application submitted by Bavarian Nordic A/S on 18 October 2024 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 31 January 2025, 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 and to the deferral.

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

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for Chikungunya virus virus-like particle, including changes to the deferral, 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 Bavarian Nordic A/S, Philip Heymans Alle 3, 2900 Hellerup Hovedstaden, Denmark.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

EMADOC-1700519818-1758850 Corr[1]
Amsterdam, 31 January 2025

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

EMA/PE/0000233803

Scope of the application

Active substance(s):

Chikungunya virus virus-like particle (CHIKV VLP)

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of chikungunya disease

Pharmaceutical form(s):

Suspension of injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Bavarian Nordic A/S

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Bavarian Nordic A/S submitted to the European Medicines Agency on 18 October 2024 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0159/2021 issued on 16 April 2021, and the decision P/0059/2024 issued on 7 March 2024.

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

The procedure started on 25 November 2024.

[1] 11 March 2025.

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 and to the deferral.

   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 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

Prevention of Chikungunya disease

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 (EBSI-CV-317-004)** Randomized, placebo-controlled, double-blind safety and immunogenicity study of Chikungunya virus virus-like particle vaccine/ aluminium hydroxide (CHIKV VLP) in adolescents from 12 years to less than 18 years of age (and adults). **Study 2 (EBSI-CV-317-006)** Randomized, double-blind, controlled, safety and immunogenicity superiority study of CHIKV VLP vaccine in children from 2 years to less than 12 years of age. **Study 3 (EBSI-CV-317-009)** Randomized, double-blind, controlled, safety and immunogenicity study of CHIKV VLP vaccine in children from birth to less than 2 years of age. **Study 4 (EBSI-CV-317-008)** Randomized, double-blind, long-term immunogenicity study in adolescents from 12 to less than 18 years of age (and adults) who were previously administered CHIKV VLP vaccine in study EBSI-CV-317-004 (PIP Study 1).

	Study 5 (EBSI-CV-317-007) *(new study added in procedure EMEA-002656-PIP01-19-M01)* Double blind, randomized, placebo-controlled, event-driven efficacy study to evaluate the efficacy, safety, and immunogenicity of an Adjuvanted Chikungunya virus virus-like particle vaccine (CHIKV VLP) for the prevention of Chikungunya disease in adolescents from 12 years to less than 18 years of age (and adults). Vaccination will be performed only during a Chikungunya virus (CHIKV) outbreak
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 2032
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:

1. Prevention of disease caused by chikungunya virus

Authorised indication(s):

VIMKUNYA is indicated for active immunisation for the prevention of disease caused by chikungunya virus (CHIKV) in individuals 12 years and older.

The use of this vaccine should be in accordance with official recommendations.

- Invented name(s): VIMKUNYA
- Authorised pharmaceutical form(s): Suspension for injection.
- Authorised route(s) of administration: intramuscular (IM) injection
- Authorised via centralised