

EMA/550224/2021

European Medicines Agency decision P/0429/2021

of 29 October 2021

on the acceptance of a modification of an agreed paediatric investigation plan for Ebola Zaire vaccine (rVSVΔG-ZEBOV-GP, live) (Ervebo), (EMEA-001786-PIP01-15-M02) 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 European Medicines Agency's decision P/0095/2017 issued on 11 April 2017 and the decision P/0316/2020 issued on 14 August 2020,

Having regard to the application submitted by Merck Sharp & Dohme (Europe) Inc. on 3 June 2021 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

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

¹ OJ L 378, 27.12.2006, p.1.

² OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for Ebola Zaire vaccine (rVSVΔG-ZEBOV-GP, live) (Ervebo), solution for injection, intramuscular use, 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 Merck Sharp & Dohme (Europe), Inc., Clos du Lynx 5, 1200 – Brussels, Belgium.

EMA/PDCO/345852/2021
Amsterdam, 10 September 2021

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-001786-PIP01-15-M02

Scope of the application

Active substance(s):

Ebola Zaire Vaccine (rVSVΔG-ZEBOV-GP, live)

Invented name:

Ervebo

Condition(s):

Prevention of Ebola disease

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Merck Sharp & Dohme (Europe) Inc.

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Merck Sharp & Dohme (Europe) Inc. submitted to the European Medicines Agency on 3 June 2021 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0095/2017 issued on 11 April 2017 and the decision P/0316/2020 issued on 14 August 2020.

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

The procedure started on 12 July 2021.

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 and to the deferral in the scope set out in the Annex I of this opinion.

The Norwegian Paediatric Committee member 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

1.1. Condition:

Prevention of Ebola disease

The waiver applies to:

- the paediatric population from birth to less than 1 year;
- solution for injection, intramuscular use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2. Paediatric investigation plan

2.1. Condition:

Prevention of Ebola disease

2.1.1. Indication(s) targeted by the PIP

Prevention of Ebola disease

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 1 year of age to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution 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	2	Study 1 V920-016: Partnership for Research on Ebola VACcination (PREVAC) Randomized, double-blind, placebo-controlled study to evaluate the immunogenicity and safety of 1 or 2 doses of rVSVΔG-ZEBOV-GP in healthy children (and adults) from 1 year of age. Study 2

		V920-015 Safety and Immunogenicity HIV+ subject study Randomized, double-blind, placebo-controlled study to evaluate the safety and immunogenicity of 1 or 2 doses of V920 in HIV-infected adolescents (and adults) from 13 years of age.
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:	Yes
Date of completion of the paediatric investigation plan:	By December 2023
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Prevention of Ebola virus disease

Authorised indication(s):

- Ervebo is indicated for active immunization of individuals 18 years of age or older to protect against Ebola Virus Disease (EVD) caused by Zaire Ebola virus.

Authorised pharmaceutical form(s):

Solution for injection

Authorised route(s) of administration:

Intramuscular use