EMA/516932/2023

European Medicines Agency decision

P/0495/2023

of 1 December 2023

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-M03) 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/0095/2017 issued on 11 April 2017, the decision P/0316/2020 issued on 14 August 2020 and the decision P/0429/2021 issued on 29 October 2021,

Having regard to the application submitted by Merck Sharp & Dohme (Europe) Inc. on 21 July 2023 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 13 October 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 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, 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 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., Boulevard du Souverain 25, 1170 – Brussels, Belgium.

EMA/PDCO/371546/2023
Amsterdam, 13 October 2023

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

EMEA-001786-PIP01-15-M03

Scope of the application

Active substance(s):

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

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of Ebola disease

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Merck Sharp & Dohme (Europe) Inc.

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 21 July 2023 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, the decision P/0316/2020 issued on 14 August 2020 and the decision P/0429/2021 issued on 29 October 2021.

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

The procedure started on 11 September 2023.

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 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

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	Description
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**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	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:	Yes
Date of completion of the paediatric investigation plan:	By July 2024
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:

Condition(s) and authorised indication(s)

1. Prevention of Ebola virus disease

Authorised indication(s):

- Ervebo is indicated for active immunisation of individuals 1 year of age or older to protect against Ebola Virus Disease (EVD) caused by Zaire Ebola virus.
  - Invented name(s): Ervebo
  - Authorised pharmaceutical form(s): Solution for injection
  - Authorised route(s) of administration: Intramuscular use
  - Authorised via centralised procedure