EMA/382663/2021

European Medicines Agency decision

P/0334/2021

of 19 August 2021

on the acceptance of a modification of an agreed paediatric investigation plan for multivalent, live, recombinant, non-replicating in human cells, Modified Vaccinia Ankara vectored vaccine, expressing the EBOV Mayinga glycoprotein, the Sudan virus Gulu GP, the Marburg virus Musoke GP, and the Taï Forest virus nucleoprotein [MVA-BN-Filo] (Mvabea), (EMEA-002308-PIP01-17-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 726/2004[1],

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 Agency[2],

Having regard to the European Medicines Agency's decision P/0117/2019 issued on 28 March 2019 and the decision P/0138/2020 issued on 17 April 2020,

Having regard to the application submitted by Janssen Cilag International NV on 18 March 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 25 June 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 multivalent, live, recombinant, non-replicating in human cells, Modified Vaccinia Ankara vectored vaccine, expressing the EBOV Mayinga glycoprotein, the Sudan virus Gulu GP, the Marburg virus Musoke GP, and the Taï Forest virus nucleoprotein [MVA-BN-Filo](Mvabea), suspension 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 Janssen Cilag International NV, Turnhoutseweg 30, B-2340 - Beerse, Belgium.

EMA/PDCO/188696/2021
Amsterdam, 25 June 2021

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

EMEA-002308-PIP01-17-M02

Scope of the application

Active substance(s):

Multivalent, live, recombinant, non-replicating in human cells, Modified Vaccinia Ankara vectored vaccine, expressing the EBOV Mayinga glycoprotein, the Sudan virus Gulu GP, the Marburg virus Musoke GP, and the Taï Forest virus nucleoprotein [MVA-BN-Filo]

Invented name:

Mvabea

Condition(s):

Prevention of Ebola virus disease

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Suspension for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Janssen Cilag International NV

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Janssen Cilag International NV submitted to the European Medicines Agency on 18 March 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/0117/2019 issued on 28 March 2019 and the decision P/0138/2020 issued on 17 April 2020.

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

The procedure started on 27 April 2021.

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 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 virus disease (EVD)

The waiver applies to:

- the paediatric population from birth to less than 1 year of age;
- suspension 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 virus disease (EVD)

2.1.1. Indication(s) targeted by the PIP

Prevention of Ebola virus disease (EVD)

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

From 1 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

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	3	**Study 1** Randomised, observer-blind, placebo-controlled trial to evaluate safety, tolerability and immunogenicity of different prime-boost regimens of Monovalent, live, recombinant, replication-incompetent adenoviral serotype 26 (Ad26)-vectored vaccine expressing the full length glycoprotein (GP) of the Ebola virus (EBOV) Mayinga variant [Ad26.ZEBOV] and Multivalent, live, recombinant, non-replicating in human cells, Modified Vaccinia Ankara (MVA)-vectored vaccine, expressing the EBOV Mayinga

		glycoprotein (GP), the Sudan virus (SUDV) Gulu GP, the Marburg virus (MARV) Musoke GP, and the Taï Forest virus (TAFV) nucleoprotein (NP) [MVA-BN-Filo] in healthy children from 4 to less than 18 years of age (and adults) [VAC52150EBL2002] *This study is the same as Study 1 of EMEA-002307-PIP01-17 and subsequent modifications thereof.* **Study 2** Double-blind, randomised, unrelated vaccine-controlled trial to evaluate safety and immunogenicity of Ad26.ZEBOV and MVA-BN-Filo in healthy children from 1 to less than 18 years of age (and adults) [VAC52150EBL3001- Stage 2]. *This study is the same as Study 2 of EMEA-002307-PIP01-17 and subsequent modifications thereof.* **Study 3** Double-blind, randomised, placebo-controlled trial to evaluate safety and immunogenicity of three different Ebola vaccine strategies in healthy children from 1 to less than 18 years of age (and adults) [VAC52150EBL2004 Partnership for Research on Ebola Vaccination (PREVAC)]. *This study is the same as Study 1 of EMEA-001786-PIP01-15 and subsequent modifications thereof and Study 3 of EMEA-002307-PIP01-17 and subsequent modifications thereof.*
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 March 2022
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 disease caused by Ebola virus (Zaire ebolavirus species)

Authorised indication(s):

- Mvabea, as part of the Zabdeno, Mvabea vaccine regimen, is indicated for active immunisation for prevention of disease caused by Ebola virus (Zaire ebolavirus species) in individuals ≥1 year of age

Authorised pharmaceutical form(s):

Suspension for injection

Authorised route(s) of administration:

Intramuscular route