EMA/197737/2019

European Medicines Agency decision

P/0117/2019

of 28 March 2019

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver 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] (EMEA-002308-PIP01-17) 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 application submitted by Janssen Cilag International N.V. on 20 April 2018 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 1 March 2019, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

(4) It is therefore appropriate to adopt a decision granting a waiver.

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

Has adopted this decision:

Article 1

A 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], suspension for injection, intramuscular use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral 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], suspension for injection, intramuscular use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A waiver 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], suspension for injection, intramuscular use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

This decision is addressed to Janssen Cilag International N.V., Turnhoutseweg 30, B-2340 – Beerse, Belgium.

EMA/PDCO/154617/2019
London, 1 March 2019

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a waiver and a deferral

EMEA-002308-PIP01-17

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]

Condition(s):

Prevention of Ebola virus disease (EVD)

Pharmaceutical form(s):

Suspension for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Janssen Cilag International N.V.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Janssen Cilag International N.V. submitted for agreement to the European Medicines Agency on 20 April 2018 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 29 May 2018.

Supplementary information was provided by the applicant on 31 October 2018. The applicant proposed modifications to the paediatric investigation plan and requested a deferral.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients;
   - to grant a deferral in accordance with Article 21 of said Regulation.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed 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 annex 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) [AC52150EBL2004 Partnership for Research on Ebola Vaccination (PREVAC)]. *This study is the same as Study 1 of EMEA-001786-PIP01-15 and subsequent modifications thereof.* *This study is the same as 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 July 2021
Deferral for one or more measures contained in the paediatric investigation plan:	Yes