EMA/336632/2023

European Medicines Agency decision

P/0305/2023

of 11 August 2023

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for MVA-BN-RSV vaccine (construct MVA-mBN294B), (EMEA-003185-PIP01-22) 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 application submitted by Bavarian Nordic A/S on 30 June 2022 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 23 June 2023, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

A paediatric investigation plan for MVA-BN-RSV vaccine (construct MVA-mBN294B), 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 MVA-BN-RSV vaccine (construct MVA-mBN294B), 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 MVA-BN-RSV vaccine (construct MVA-mBN294B), 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 Bavarian Nordic A/S, Philip Heymans Alle 3, 2900 – Hellerup, Denmark.

EMA/PDCO/152344/2023
Amsterdam, 23 June 2023

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

EMEA-003185-PIP01-22

Scope of the application

Active substance(s):

MVA-BN-RSV vaccine (construct MVA-mBN294B)

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of lower respiratory tract disease caused by respiratory syncytial virus

Pharmaceutical form(s):

Suspension for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Bavarian Nordic A/S

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Bavarian Nordic A/S submitted for agreement to the European Medicines Agency on 30 June 2022 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 16 August 2022.

Supplementary information was provided by the applicant on 20 March 2023. The applicant proposed modifications to the paediatric investigation plan.

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 deferral in accordance with Article 21 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)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population.

   The Paediatric Committee member of Norway 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 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 lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV)

The waiver applies to:

- the paediatric population from birth to less than 2 months of age
- suspension for injection, intramuscular route;
- on the grounds that the specific medicinal product is likely to be ineffective.

2. Paediatric investigation plan

2.1. Condition:

Prevention of lower respiratory tract disease (LRTD) caused by RSV

2.1.1. Indication(s) targeted by the PIP

Prevention of lower respiratory tract disease (LRTD) caused by RSV

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

From 2 months of age 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	**Study 1 (Exploratory toxicity/efficacy study)** RSV challenge study in BALB/C mice to evaluate the potential for enhanced respiratory disease (ERD) induction in response to the MVA-BN-RSV vaccine. **Study 2 (Exploratory toxicity/efficacy study 2)** A vaccine dose de-escalating RSV challenge performed in cotton rats to evaluate the potential for ERD induction in response to the MVA-BN-RSV vaccine. **Study 3 (Reprotoxicity: [enhanced] pre- and postnatal development)** A GLP-compliant development and reproductive toxicity (DART) study in female NZW rabbits to evaluate the effects of MVA-BN-RSV on female fertility, foetal development, and postnatal development.

Clinical studies	**Study 4 (**RSV-MVA-010) Single blind, placebo controlled, partially randomised, age de-escalation and dose escalation study to evaluate the safety, tolerability, and immunogenicity of MVA-BN-RSV vaccine in infants and children from 2 months of age to less than 24 months of age. **Study 5 (**RSV-MVA-016) Randomised, open label study of co-administration of MVA-BN-RSV vaccine with routine vaccines in healthy infants at least 2 months of age. **Study 6 (**RSV-MVA-017) Randomised, double blind, placebo controlled study in infants from 2 months of age to less than 12 months of age to assess the efficacy of MVA-BN-RSV against lower respiratory tract disease (LRTD) caused by PCR confirmed RSV infection. **Study 7 (**RSV-MVA-012) Single blind, controlled study of the safety, reactogenicity and immunogenicity of MVA BN-RSV vaccine in children from 1 year of age to less than 18 years who are at high risk of severe RSV disease. **Study 8 (**RSV-MVA-018) Open label study of safety, reactogenicity and immunogenicity of MVA BN-RSV vaccine in immunocompromised children from 2 months of age to less than 18 years of age
Modelling and simulation studies	Not applicable
Other studies	Not applicable
Extrapolation plan	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 January 2035
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:

The product is not authorised anywhere in the European Community.