



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-1852052

## European Medicines Agency decision

EMA/PE/0000223819

of 28 January 2025

on the acceptance of a modification of an agreed paediatric investigation plan for modified vaccinia Ankara – bavarian nordic live virus (Imvanex) 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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on the acceptance of a modification of an agreed paediatric investigation plan for modified vaccinia Ankara – bavarian nordic live virus (Imvanex) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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<sup>1</sup>,

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<sup>2</sup>,

Having regard to the European Medicines Agency's decision P/0038/2012 issued on 24 February 2012, the decision P/0264/2022 issued on 13 July 2022, the decision P/0539/2022 issued on 30 December 2022 and the decision P/0284/2023 issued on 14 July 2023,

Having regard to the application submitted by Bavarian Nordic A/S on 9 September 2024 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 13 December 2024, 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 and on the refusal of a waiver.
- (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.
- (4) It is therefore appropriate to adopt a decision refusing a waiver.

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<sup>1</sup> OJ L 378, 27.12.2006, p.1, as amended.

<sup>2</sup> OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

**Article 1**

Changes to the agreed paediatric investigation plan for modified vaccinia Ankara – bavarian nordic live virus (Imvanex), 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**

A waiver for modified vaccinia Ankara – bavarian nordic live virus (IMVANEX), the details of which are set out in the opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby refused.

**Article 3**

This decision is addressed to Bavarian Nordic A/S, Philip Heymans Alle 3, 2900 – Hellerup, Hovedstaden, Denmark.



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-1707668 Corr<sup>1</sup>  
Amsterdam, 13 December 2024

## Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA/PE/0000223819

### Scope of the application

#### Active substance(s):

Modified vaccinia Ankara – Bavarian Nordic live virus (MVA-BN - smallpox vaccine)

#### Invented name and authorisation status:

See Annex II

#### Condition(s):

Prevention of smallpox, mpox and diseases caused by vaccinia virus

#### Pharmaceutical form(s):

Suspension for injection

#### Route(s) of administration:

Subcutaneous use

#### Name/corporate name of the PIP applicant:

Bavarian Nordic A/S

### Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Bavarian Nordic A/S submitted to the European Medicines Agency on 9 September 2024 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0038/2012 issued on 24 February 2012, the decision P/0264/2022 issued on 13 July 2022, the decision P/0539/2022 issued on 30 December 2022 and the decision P/0284/2023 issued on 14 July 2023.

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

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<sup>1</sup> 22 January 2025



The procedure started on 14 October 2024.

## **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;
- to refuse the granting of a waiver for some of the subsets of the paediatric population and the above mentioned condition(s) as it does not meet the grounds detailed in Article 11(1) of said Regulation.

The Paediatric Committee members of Liechtenstein and Norway agree with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan 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

Not applicable.

## 2. Paediatric Investigation Plan

### 2.1. Condition

Prevention of smallpox, mpox and diseases caused by vaccinia virus

#### 2.1.1. Indication(s) targeted by the PIP

Active immunisation against smallpox, mpox and diseases caused by vaccinia virus

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

From birth to less than 18 years of age

#### 2.1.3. Pharmaceutical form(s)

Suspension for injection

#### 2.1.4. Measures

Area	Description
Quality	Not applicable.
Non-clinical	Not applicable.
Clinical	<p><b>Study 1:</b></p> <p>Extrapolation from modified vaccinia Ankara - Bavarian Nordic virus (MVA-BN - smallpox vaccine) adult studies to children and adolescents aged 12 years to less than 18 years of age.</p> <p><b>Study 2:</b></p> <p>Extrapolation from clinical recombinant MVA-BN-based measles vaccine and from pre-clinical data (juvenile rats immunized with MVA-BN-based measles vaccine) to infants 28 days to less than 6 months of age and to children 6 months to less than 11 years of age.</p> <p><b>Study 3</b></p> <p>Extrapolation from clinical recombinant MVA-BN-based measles vaccine and extrapolation from pre-clinical data (newborn mice immunized with MVA-BN-smallpox vaccine) to pre-term and term infants from birth to less than 28 days of age.</p>

	<p><b>Study 4</b></p> <p>This study was deleted with procedure EMEA-001161-PIP02-11-M02 and replaced with Study 5 and Study 6 below.</p> <p><b>Study 5</b></p> <p>New study included in procedure EMEA-001161-PIP02-11-M02.</p> <p>Open label, comparative, multicentre immunogenicity and safety study of MVA-BN - smallpox vaccine in children from 12 years to less than 18 years of age compared to young adults for the prevention of smallpox, mpox and diseases caused by vaccinia virus.</p> <p><b>Study 6</b></p> <p>New study included in procedure EMEA-001161-PIP02-11-M02.</p> <p>Open label, multicentre immunogenicity and safety study of MVA-BN - smallpox vaccine in children from 2 years of age to less than 12 years of age for the prevention of smallpox, mpox and diseases caused by vaccinia virus (compared to adults).</p> <p><b>Study 7</b></p> <p>New study included in procedure EMA/PE/0000223819.</p> <p>Open-label, randomised immunogenicity and safety study of MVA-BN - smallpox vaccine in children from 6 months to less than 2 years of age for the prevention of smallpox, mpox and diseases caused by vaccinia virus (compared to adults).</p> <p><b>Study 8</b></p> <p>New study included in procedure EMA/PE/0000223819.</p> <p>Open-label, randomised immunogenicity and safety study of MVA-BN - smallpox vaccine in children from birth to less than 6 months of age for the prevention of smallpox, mpox and diseases caused by vaccinia virus.</p>
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### 3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By September 2030
Deferral for one or more studies 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 smallpox infection

Authorised indication(s):

- Active immunisation against smallpox in adults
  - Invented name(s): Imvanex
  - Authorised pharmaceutical form(s): suspension for injection
  - Authorised route(s) of administration: subcutaneous use
  - Authorised via centralised procedure