EMA/288064/2023

European Medicines Agency decision

P/0284/2023

of 14 July 2023

on the acceptance of a modification of an agreed paediatric investigation plan for modified vaccinia Ankara - Bavarian Nordic virus (smallpox) (Imvanex), (EMEA-001161-PIP02-11-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/0038/2012 issued on 24 February 2012, and the decision P/0264/2022 issued on 13 July 2022 and the decision P/0539/2022 issued on 30 December 2022,

Having regard to the application submitted by Bavarian Nordic A/S on 20 February 2023 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 26 May 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.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[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 modified vaccinia Ankara - Bavarian Nordic virus (smallpox) (Imvanex), suspension for injection, subcutaneous use 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 Bavarian Nordic A/S, Philip Heymans Alle 3, 2900 – Hellerup, Denmark.

EMA/PDCO/87083/2023
Amsterdam, 26 May 2023

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

EMEA-001161-PIP02-11-M03

Scope of the application

Active substance(s):

Modified Vaccinia Ankara - Bavarian Nordic virus (smallpox)

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of smallpox, mpox and related orthopoxvirus infection and disease

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 20 February 2023 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, and the decision P/0264/2022 issued on 13 July 2022 and the decision P/0539/2022 issued on 30 December 2022.

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

The procedure started on 27 March 2023.

Scope of the modification

Some measures 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 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 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 related orthopoxvirus infection and disease

2.1.1. Indication(s) targeted by the PIP

Active immunisation against smallpox, mpox and related orthopoxvirus infection and disease

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	**Study 1:** 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 **Study 2:** Extrapolation from clinical recombinant MVA-BN-based measles vaccine and extrapolation from pre-clinical (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 **Study 3** Extrapolation from clinical recombinant MVA-BN-based measles vaccine and extrapolation from pre-clinical (newborn mice immunized with MVA-BN-smallpox vaccine) to pre-term and term infants from birth to less than 28 days of age

	Study 4 This study vas deleted with procedure EMEA-001161-PIP02-11-M02 and replaced with Study 5 and Study 6 below **Study 5** New study included in procedure EMEA-001161-PIP02-11-M02 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 related orthopoxvirus infection and disease. **Study 6** New study included in procedure EMEA-001161-PIP02-11-M02 Open label, multicentre immunogenicity and safety study of MVA-BN-smallpox vaccine in children from birth to less than 12 years of age for the prevention of smallpox, mpox and related orthopoxvirus infection and disease.

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 December 2024
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