EMA/107989/2012

European Medicines Agency decision

P/0038/2012

of 24 February 2012

on the agreement of a paediatric investigation plan and on the granting of a deferral for modified Vaccinia Ankara - Bavarian Nordic virus (smallpox), (EMEA-001161-PIP02-11) 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8670
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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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 Bavarian Nordic A/S on 8 August 2011 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 10 February 2012, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 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.

(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.

[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 modified Vaccinia Ankara - Bavarian Nordic virus (smallpox), suspension for injection, subcutaneous 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 modified Vaccinia Ankara - Bavarian Nordic virus (smallpox), suspension for injection, subcutaneous 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

This decision is addressed to Bavarian Nordic A/S, Hejreskovvej 10A, 3490 - Kvistgaard, Denmark.

Done at London, 24 February 2012

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/922366/2011

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

EMEA-001161-PIP02-11

Scope of the application

Active substance(s):

Modified Vaccinia Ankara - Bavarian Nordic virus (smallpox)

Condition(s):

Prevention of smallpox infection

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 16(1) of Regulation (EC) No 1901/2006 as amended, Bavarian Nordic A/S submitted for agreement to the European Medicines Agency on 8 August 2011 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 14 September 2011.

Supplementary information was provided by the applicant on 21 November 2011.

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@e□a.europa.eu □**ebsite** www.ema.europa.eu

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 18 of said Regulation,
   - to grant a deferral in accordance with Article 21 of said Regulation.

   The Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed 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 annex(es) and appendix.

London, 10 February 2012

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

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

1. Waiver

Not applicable

2. Paediatric Investigation Plan

2.1. Condition: Prevention of smallpox infection

2.1.1. Indication(s) targeted by the PIP

Active immunisation against smallpox infection and disease in the paediatric population including HIV patients and patients with atopic dermatitis.

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. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	4	**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 from birth to less than 28 days old. **Study 4:** Open label, non-controlled, multicenter immunogenicity and safety study

Area	Number of studies	Description
		of MVA-BN-smallpox vaccine in children from birth to less than 12 years of age. (POX-MVA-035)

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	No later than 26 weeks after the declaration of a smallpox outbreak.
Deferral for one or more studies contained in the paediatric investigation plan:	Yes