



Bavarian Nordic Receives WHO Prequalification for Mpox Vaccine

- First mpox vaccine to obtain prequalification by the WHO
- Approval will help accelerate access to the vaccine for all African countries

COPENHAGEN, Denmark, September 13, 2024 - Bavarian Nordic A/S (OMX: BAVA) today announced that the Company has obtained prequalification from the World Health Organization (WHO) for IMVANEX® (MVA-BN®) as the first mpox vaccine to be added to the WHO prequalification list.

MVA-BN is indicated for active immunization against smallpox, mpox, and related orthopoxvirus infections and disease in all adults 18 years of age and older. According to recommendations from the WHO, MVA-BN may however be used “off-label” in infants, children and adolescents, and in pregnant and immunocompromised people in outbreak settings where the benefits of vaccination outweigh the potential risks¹.

A prequalification or secondary, an emergency use listing is a prerequisite for governments and organizations like Gavi, UNICEF and others to procure and distribute vaccines in African countries, and while the WHO’s intent was to evaluate mpox vaccines for an emergency use listing, the agency has assessed that MVA-BN meets the criteria for a full prequalification. This assessment is based on information submitted by Bavarian Nordic, including certifications, assessment reports and positive opinions issued by the European Medicines Agency (EMA), which is the regulatory agency of record for this vaccine.

Earlier this week, MVA-BN also received a provisional consent from New Zealand Medicines and Medical Devices Safety Authority, Medsafe and a full approval from the Mexican Federal Committee for Protection from Sanitary Risks, COFEPRIS.

Paul Chaplin, President & CEO of Bavarian Nordic, said: “We are highly encouraged that our mpox vaccine has received prequalification from the WHO, which is a testament to the strengths of our vaccine and the quality of data, we have generated through numerous studies, as well as in real life. While we continue to work with WHO and other regulatory bodies to expand the approval to include children, who are severely impacted by the mpox outbreak, we are pleased that this approval will help accelerate access to our vaccine for communities across the entire African continent and we applaud the WHO for their swift review and action to make this happen.”

About the mpox vaccine

MVA-BN or Modified Vaccinia Ankara-Bavarian Nordic is the only non-replicating mpox vaccine approved in the U.S., Switzerland and Singapore (marketed as JYNNEOS®), Canada (marketed as IMVAMUNE®), and the EU/EAA and United Kingdom (marketed as IMVANEX®). Originally developed as a smallpox vaccine in collaboration with the U.S. government to ensure the supply of a smallpox vaccine for the entire population, including immunocompromised individuals who are not recommended vaccination with traditional replicating smallpox vaccines, MVA-BN has been indicated for use in the general adult population in individuals considered at risk for smallpox or mpox infection.

Supported by data from a clinical study, conducted by the U.S. National Institutes of Health (NIH), Bavarian Nordic has recently filed a submission to the European Medicines Agency to extend the approval to adolescents 12-17 years of age and is also working with partners, including the Coalition for Epidemic Preparedness Innovations (CEPI) to evaluate the safety and efficacy of the vaccine in children 2-12 years of age.

Bavarian Nordic has been a long-term supplier of the vaccine to national stockpiles, and during the 2022-2023 mpox outbreak, the Company supported governments and supranational organizations by expanding access to the vaccine to more than 70 countries worldwide.

About Bavarian Nordic

Bavarian Nordic is a fully integrated vaccine company with a mission to protect and save lives through innovative vaccines. We are a global leader in smallpox and mpox vaccines, supplied to governments to enhance public health preparedness and have a strong portfolio of vaccines for travelers and endemic diseases. For more information visit www.bavarian-nordic.com.

Forward-looking statements

This announcement includes forward-looking statements that involve risks, uncertainties and other factors, many of which are outside of our control, that could cause actual results to differ materially from the results discussed in the forward-looking statements. Forward-looking statements include statements concerning our plans, objectives, goals, future events, performance and/or other information that is not historical information. All such forward-looking statements are expressly qualified by these cautionary statements and any other cautionary statements which may accompany the forward-looking statements. We undertake no obligation to publicly update or revise forward-looking statements to reflect subsequent events or circumstances after the date made, except as required by law.

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¹ Smallpox and mpox (orthopoxviruses): WHO position paper, August 2024 (<https://www.who.int/publications/i/item/who-wer-9934-429-456>)