



Bavarian Nordic Submits Data to EMA to Extend Mpox and Smallpox Vaccine Approval to Children Aged 2-11 Years

- Submission based on topline data from clinical study, demonstrating a comparable safety profile and a non-inferior immune response for MVA-BN in children aged 2-11 years compared to adults.

COPENHAGEN, Denmark, March 27, 2026 - Bavarian Nordic A/S (OMX: BAVA) has submitted clinical data to the European Medicines Agency (EMA) to support the extension of the MVA-BN[®] mpox and smallpox vaccine indication to include children aged 2 to 11 years.

The submission is based on positive topline results from a Phase 2 clinical study ([NCT06549530](#)) in 227 children aged 2-11 years and 224 adults demonstrating non-inferiority of the immune responses as well as a similar safety profile, between both age groups after vaccination with two standard doses of the MVA-BN vaccine. The study was co-funded by the Coalition for Epidemic Preparedness Innovations (CEPI) and was conducted at sites in the Democratic Republic of Congo (DRC) and Uganda. Both countries reported cases of mpox in adults and children during the recent outbreak across Africa and the world.

Following review of the data by EMA, the Marketing Authorisation for MVA-BN could be extended to include use of the vaccine for individuals from 2 years of age later in 2026.

“The submission of data for children aged 2-11 years to EMA marks another leap in the advancement of our MVA-BN vaccine to protect populations broadly against mpox and smallpox,” said **Paul Chaplin, President and Chief Executive Officer of Bavarian Nordic**. “While the risk of mpox in Africa is now more moderate, children remain disproportionately affected by the disease, highlighting the importance to broaden the access to vaccines and therapies for this vulnerable population. Our collaboration with CEPI and local partners in Africa has been instrumental in generating the data to support this submission, and together we continue our endeavors to ensure access to the vaccine for other vulnerable populations.”

Dr Kristine Rose, Mpox Disease Programme Lead at CEPI, said: “Children have been significantly impacted during recent global outbreaks of mpox, with many facing a higher risk of severe disease compared to adults - especially when other health challenges, such as malnutrition, malaria or HIV, are present. This has led to ongoing suffering in the younger populations and continued transmission of the virus, underscoring the need to expand access to vaccines specifically for this age group. Bavarian Nordic’s submission to a WHO listed Authority like the EMA is an important step towards protecting children around the world as, following potential expansion of the vaccine to younger demographics, other regulators could follow suit.”

Professor Hypolite Muhindo Mavoko, University of Kinshasa, principal investigator of the study, said: “In the Democratic Republic of the Congo, children aged 2 to under 12 years represent nearly one-third of the population and are disproportionately affected by mpox complications. Because children interact closely with one another and within households, they can also contribute to ongoing transmission. Expanding vaccine access to this age group is therefore an important step to better protect vulnerable populations and strengthen outbreak control, while reducing the health and economic burden associated with mpox.”

About the mpox/smallpox vaccine

MVA-BN or Modified Vaccinia Ankara-Bavarian Nordic is the only non-replicating mpox vaccine approved in the U.S., Switzerland, Singapore, Mexico (marketed as JYNNEOS[®]), Canada (marketed as IMVAMUNE[®]), 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 population (from 12 years old) in individuals considered at risk for smallpox or mpox infection.

About Bavarian Nordic

Bavarian Nordic is a global vaccine company with a mission to improve health and save lives through innovative vaccines. We are a preferred supplier of mpox and smallpox vaccines to governments to enhance public health preparedness and have a leading portfolio of travel vaccines. 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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