

Bavarian Nordic Receives European Commission Approval of Mpox/Smallpox Vaccine for Children Aged 2 to Less than 12 Years

- MVA-BN approval expanded to include children aged 2 to less than 12 years for protection against mpox, smallpox and disease caused by vaccinia virus
- Approval further strengthens MVA-BN's position in supporting global public health preparedness

COPENHAGEN, Denmark, August 7, 2026 - Bavarian Nordic A/S (OMX: BAVA) announced today that the European Commission has adopted the recent Committee for Medicinal Products for Human Use (CHMP) positive opinion recommending the approval of a type II variation for IMVANEX® (MVA-BN) smallpox and mpox vaccine, extending the current marketing authorization to include children 2 to less than 12 years of age.

The approval is based on data from a Phase 2 clinical study ([NCT06549530](#)) involving 227 children aged 2 to <12 years and 224 adults, demonstrating non-inferior immune responses and a similar safety profile in children compared to adults following vaccination with two standard doses of MVA-BN. The study was co-funded by the Coalition for Epidemic Preparedness Innovations (CEPI).

With this approval, MVA-BN is now authorized in the European Union for use in individuals aged 2 years and older, marking a significant expansion of access to a non-replicating vaccine designed to help protect vulnerable populations against mpox, smallpox and disease caused by vaccinia virus.

Paul Chaplin, President and Chief Executive Officer of Bavarian Nordic, said: "The European Commission's approval of MVA-BN for children aged 2 to less than 12 years represents an important advancement in our efforts to broaden access to protection against mpox and smallpox. Children have carried a disproportionate burden during recent mpox outbreaks, particularly in parts of Africa, underscoring the importance of making safe and effective vaccines available to this vulnerable population. We are grateful to the study participants, investigators, CEPI and our partners whose collaboration helped generate the data supporting this approval."

The approval adds to the growing body of clinical evidence supporting the use of MVA-BN across age groups and further strengthens Bavarian Nordic's commitment to supporting global public health preparedness and outbreak response.

About the mpox and 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/EEA European Economic Area 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 2 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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