

Bavarian Nordic Reports Positive Topline Data for Mpox/Smallpox Vaccine in Pediatric Population

- Primary endpoint was met in 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.
- Results will support filing for label extension with EMA in 2026.

COPENHAGEN, Denmark, October 7, 2025 - Bavarian Nordic A/S (OMX: BAVA) today reported topline results from a clinical study of its MVA-BN® mpox/smallpox vaccine in children 2 to 11 years of age.

The study ([NCT06549530](#)) enrolled 460 individuals in two cohorts: children aged 2-11 years and adults aged 18-50 years with the purpose of comparing safety and immunogenicity of two standard doses of the MVA-BN vaccine between the pediatric and the adult populations. 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.

Topline results from the study, comprising 451 individuals evaluable for the primary endpoint, showed that the immune response in children (n=227) two weeks after the second vaccination with MVA-BN was non-inferior to the adult group (n=224), with the highest immune responses observed in the youngest subgroup of children aged 2-5 years. While the safety and immunogenicity generated from this study in adults were comparable to historical data with MVA-BN, the immune response in children was 2.5 times higher than in the adult group as demonstrated by neutralizing antibody titers. The vaccine was generally well tolerated in the pediatric population, with a safety profile similar to adults and no unexpected signals.

Pending final results from the study, Bavarian Nordic plans to submit the data to the European Medicines Agency (EMA) in 2026 to support an extension of the vaccine's approval to include children aged 2 years and older. MVA-BN is currently approved by the European Commission for individuals aged 12 years and older.

The findings could also expand the use of the vaccine to children in countries severely affected by the current mpox outbreak surging in Africa, with cases also reported in other countries around the world.

Paul Chaplin, President & CEO of Bavarian Nordic, said: *"Mpox remains a major public health threat, particularly in Africa, where the disease is widespread. While vaccination efforts have significantly improved, certain populations remain highly vulnerable, including younger children. With the support from CEPI and local partners in Africa, we have now shown MVA-BN to be well-tolerated and to generate a robust and clinically relevant immune response in this population, bringing us one step closer to approval of our vaccine for children aged 2-11 years. This will significantly strengthen the profile of the vaccine and provides an even stronger tool in the public health response to current and future mpox outbreaks."*

Nina Wressnigg, Head of Clinical Development Science at CEPI, said: *"Mpox has been raging across Africa for over a year and remains a declared continental health emergency. Although MVA-BN has been licensed for emergency use in children in the Democratic Republic of the Congo - the worst affected country - many other countries lack this access causing children to continue to bear the brunt of the suffering, marked by severe illness and possible loss of life. These new topline data provide additional positive findings that could expand licensure to children in more countries to control the ongoing outbreak."*

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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