



Bavarian Nordic Submits Data to EMA to Extend Mpox/Smallpox Vaccine Approval to Adolescents

- Interim results from clinical study show non-inferiority of immune responses from mpox/smallpox vaccination in adolescents and similar safety profile compared to adults, supporting the extension of current approval in Europe later in 2024.

COPENHAGEN, Denmark, August 16, 2024 - Bavarian Nordic A/S (OMX: BAVA) has submitted clinical data to the European Medicines Agency (EMA) to support the extension of the IMVANEX® (MVA-BN®) smallpox and mpox vaccine indication to include adolescents 12 to 17 years of age.

While currently only indicated for adults 18 years and older, the vaccine was granted an Emergency Use Authorization for use in adolescents by the FDA during the 2022 global mpox outbreak. It remains the only FDA and EMA-approved mpox vaccine.

The submission is based on interim results from a clinical study ([NCT05740982](#)), sponsored by the U.S. National Institutes of Health's (NIH) National Institutes of Allergy and Infectious Diseases (NIAID), in 315 adolescents 12-17 years of age and 211 adults aged 18 years and older, 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.

Following review of the data by EMA, the Marketing Authorisation for IMVANEX could be extended to include use of the vaccine for adolescents during the fourth quarter of 2024.

Bavarian Nordic is also preparing for a clinical trial to assess the immunogenicity and safety of MVA-BN in children from 2-12 years of age, aiming to further extend the indication of the vaccine into younger populations. The trial, partially funded by the Coalition for Epidemic Preparedness Innovations (CEPI), is planned for initiation in the Democratic Republic of Congo and Uganda later this year, potentially also supporting a regulatory approval of MVA-BN in African countries, where mpox is endemic.

“Children and adolescents are disproportionately affected by mpox in the ongoing outbreak in Africa, highlighting the importance and urgency to broaden the access to vaccines and therapies for this vulnerable population. We applaud the NIH for their work on this study and are pleased to report data that support the use of our vaccine in adolescents, adding to the growing pool of evidence that MVA-BN is well tolerated and able to generate a relevant immune response in adolescent and adult populations,” said **Paul Chaplin, President and Chief Executive Officer of Bavarian Nordic**.

About the smallpox/mpox vaccine

MVA-BN or Modified Vaccinia Ankara-Bavarian Nordic is a non-replicating smallpox vaccine and the only mpox vaccine approved in the U.S. and Switzerland (marketed as JYNNEOS®), Canada (marketed as IMVAMUNE®), and the EU/EEA and United Kingdom (marketed as IMVANEX®). Originally developed 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 (18 years and older) in individuals considered at risk for smallpox or mpox. During the 2022-2023 mpox outbreak, the vaccine was granted an Emergency Use Authorization by the U.S. FDA for both pre- and post-exposure use in adolescents.

Bavarian Nordic has been a long-term supplier of the vaccine to the U.S. and Canada as well as several other countries as part of their national biological preparedness. During the 2022-2023 mpox outbreak, Bavarian Nordic has

furthermore 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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