



Bavarian Nordic and CEPI Partners to Advance Mpox Vaccination in Africa

- African trial could potentially support licensure of mpox vaccine in endemic countries and expansion of current regulatory approvals to include children
- CEPI has awarded USD 6.5 million in funding to support the Phase 2 clinical trial which is projected to start later in 2024

COPENHAGEN, Denmark / OSLO, Norway, May 30, 2024 - Bavarian Nordic A/S (OMX: BAVA) and the Coalition for Epidemic Preparedness Innovations (CEPI) today announced a partnership to advance the development of Bavarian Nordic's mpox vaccine in children in Africa.

CEPI has awarded USD 6.5 million¹ to support a Phase 2 clinical study evaluating the immunogenicity and safety of the MVA-BN[®] non-replicating vaccine in children from 2 years to less than 12 years of age compared to adults aged 18-50 years of age for the prevention of smallpox, mpox and related orthopoxvirus infections. Subject to regulatory approvals, the study plans to enroll a total of approximately 460 healthy individuals in endemic regions without previous mpox infection or poxvirus vaccination, who will receive two doses of the MVA-BN vaccine. Bavarian Nordic will be the sponsor of the trial which will be conducted in one or more African countries with planned initiation later in 2024.

The new trial follows the publication of a [continental plan](#) by Africa CDC and African Ministries of Health to strengthen mpox preparedness and response efforts, as well as the World Health Organization's (WHO) [framework](#) for enhancing prevention and control of mpox.

Results from this study could provide assurance of the use of this vaccine in children, and thus support an extension of the current regulatory approvals for use of the vaccine in adults to also include children 2-12 years of age. Importantly, the study will also generate evidence on the vaccine in endemic African populations and could potentially support regulatory approval of MVA-BN in endemic countries.

“We now understand that children suffer disproportionately from mpox, a concerning and neglected disease that has spread rapidly in recent years” said **Dr Richard Hatchett, CEO of CEPI**. “To address the risk that children face in DR Congo and other areas where the disease is endemic, CEPI is supporting this important trial which will provide key mpox vaccine safety and immunogenicity data in children. The findings of this study will be crucial in shaping mpox vaccine strategies to help protect children and potentially to bringing an end to the widespread outbreak in the DR Congo as well as mpox outbreaks that may strike in the future.”

“We are very pleased to join forces with CEPI in their continued efforts to provide equitable access to a much-needed vaccine against mpox for endemic populations, and we are firmly committed to working with the local authorities to develop solutions for vulnerable populations, including children who sadly represent the vast majority of those affected by the ongoing mpox outbreak in the DR Congo.” Said **Paul Chaplin, President and Chief Executive Officer of Bavarian Nordic**.

About mpox in the DRC and other African countries

Multiple countries in Central and East Africa are currently tackling the largest and deadliest known mpox outbreak to date. Over 6,500 mpox cases and 345 deaths [have been reported](#) in the DR Congo this year alone, with children accounting for the majority of infections and deaths. Cases have also been confirmed in the Congo, Cameroon, Central African Republic and Liberia.

Mpox was first identified in the DR Congo in 1970. In most cases, mpox symptoms—typically fever and headache, followed by painful lesions—disappear within a few weeks. However, for some, mpox can lead to medical

complications, such as bronchopneumonia, sepsis, encephalitis, loss of vision, and even death. The mpox strain behind the current outbreak, known as Clade I, is estimated to be fatal in around 8-12% of cases.

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 infection. 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 CEPI

CEPI was launched in 2017 as an innovative partnership between public, private, philanthropic and civil organisations. Its mission is to accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats so they can be accessible to all people in need. CEPI has supported the development of more than 50 vaccine candidates or platform technologies against multiple known high-risk pathogens or a future Disease X. Central to CEPI's pandemic-beating five-year plan for 2022-2026 is the '100 Days Mission' to compress the time taken to develop safe, effective, globally accessible vaccines against new threats to just 100 days.

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.

Contacts

Europe: Rolf Sass Sørensen, Vice President Investor Relations, rss@bavarian-nordic.com, Tel: +45 61 77 47 43
US: Graham Morrell, Paddock Circle Advisors, graham@paddockcircle.com, Tel: +1 781 686 9600

CEPI:

press@cepi.net

+44 7387 055214

¹ Approximate funding figure. Final budget still pending.