Press Release

Bavarian Nordic Announces the Initiation of Clinical Trials of Mpox Vaccine in Infants and Pregnant Women

- First studies to evaluate MVA-BN in infants under 2 years of age and pregnant and breastfeeding women.
- The multi-partner research project is aimed at expanding access to mpox vaccines for vulnerable populations.

COPENHAGEN, Denmark, June 26, 2025 – Bavarian Nordic A/S (OMX: BAVA) announced today the initiation of the first of two clinical trials designed to support approval and use of the MVA-BN® mpox/smallpox vaccine in vulnerable populations: infants under 2 years of age and pregnant and breastfeeding women

The first participants have been vaccinated in a study (NCT06844487), evaluating the safety and immunogenicity of MVA-BN in 344 infants aged 4-24 months. Recruitment has also started in a second study (NCT06844500), which is planned to enrol 359 women (pregnant or breastfeeding), also to be evaluated for safety and immunogenicity of MVA-BN. Both studies are conducted in the Democratic Republic of Congo (DRC), the epicentre of the ongoing mpox outbreak, where infants and pregnant women remain highly vulnerable to mpox.

Paul Chaplin, President & CEO of Bavarian Nordic, said: "Through partnerships we have made significant advances already by expanding access to our mpox vaccine for children and adolescents. These new studies will fill the gap by providing important data about the use of MVA-BN in infants and pregnant women, and we applaud the study partners as well as the funding partners, EDCTP3 and CEPI for supporting this important work which could help support a label expansion for MVA-BN to include the most vulnerable populations."

Both studies are part of the PregInPoxVac research project, led by the University of Antwerp and the University of Kinshasa. The project is further supported by partners in Kenya (ACE Research) and Italy (Penta Foundation), funded by the European Union Global Health EDCTP3, the Coalition for Epidemic Preparedness Innovations (CEPI), and Bavarian Nordic.

In addition, Bavarian Nordic is sponsoring a trial of MVA-BN in children aged 2-11 years, which has received funding support from CEPI. Topline results from this trial (NCT06549530) are anticipated in the third quarter of 2025. Once full results become available, these could potentially support regulatory approval of MVA-BN for younger children.

About the mpox vaccine

MVA-BN or Modified Vaccinia Ankara-Bavarian Nordic is the only non-replicating mpox vaccine approved in the U.S., Switzerland, Singapore and Mexico (marketed as JYNNEOS®), Canada (marketed as IMVAMUNE®), and 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 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.

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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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