Press Release

First Children Vaccinated in New Clinical Study Seeking to Expand the Indication for Bavarian Nordic's Mpox Vaccine

- Clinical study in children 2-11 years of age follows the recent EMA and WHO approvals of the MVA-BN mpox vaccine for adolescents 12-17 of age.

COPENHAGEN, Denmark, October 29, 2024 – Bavarian Nordic A/S (OMX: BAVA) announced today the initiation of a clinical study of the MVA-BN® mpox/smallpox vaccine in children 2 to 11 years of age.

The first children have now been vaccinated in the study, which is currently enrolling in the Democratic Republic of Congo (DRC) with plans also to include sites in Uganda. A total of 460 individuals are expected to participate in the study, which will compare the safety and immunogenicity of the vaccine between children aged 2 to 11 years of age to adults. The study (NCT06549530) is partially funded by the Coalition for Epidemic Preparedness Innovations (CEPI).

Results from this study could support an extension of the current approval of MVA-BN to include children from 2 years of age and older. Last month, the WHO prequalified the vaccine for adolescents 12 to 17 years of age, adopting the recent approval from the European Medicines Agency (EMA) for this age group.

Paul Chaplin, President & CEO of Bavarian Nordic, said: *"Children remain highly vulnerable to mpox infections in the ongoing outbreak in Africa, highlighting the importance and urgency to broaden the access to effective vaccines that can be safely administered to this young population. Following the recent approval of MVA-BN for adolescents, we are pleased to initiate this study, which could provide additional data to further extend the indication to also include children, and we thank CEPI and our partners in Africa for their support of this important work."*

Dr Nicole Lurie, Executive Director of Preparedness and Response at CEPI, said: *"The findings of this study will be crucial in shaping mpox vaccine strategies that could protect children and bring an end to this devastating and widespread outbreak, while also providing pivotal vaccine guidance in local endemic populations to tackle mpox outbreaks that could strike in the future."*

While this study represents the first investigation of MVA-BN as an mpox/smallpox vaccine for younger children, a recombinant version of MVA-BN (Mvabea®) was approved by EMA in 2020 as part of a prime-boost vaccine regimen[1] for the prevention of disease caused by Ebola virus in individuals 1 year of age and older. Clinical studies supporting this approval encompassed more than 3,300 individuals across Europe, USA, and Africa including over 800 children and adolescents 1 to 17 years of age in Africa[2]. The safety profile of Mvabea in children 1 to 17 years of age was generally similar to that observed in adults.

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 (from 12 years old) in individuals considered at risk for smallpox or mpox infection.

Bavarian Nordic A/S
Philip Heymans Alle 3
DK-2900 Hellerup
Tel. +45 33 26 83 83
www.bavarian-nordic.com
CVR-no. 16 27 11 87
LEI Code: 2138006JCDVYIN6INP51

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.

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

[1] Mvabea® was licensed in 2014 to Johnson & Johnson as part of a prime-boost vaccine regimen.
[2] https://www.ema.europa.eu/en/documents/assessment-report/mvabea-epar-public-assessment-report_en.pdf