Press Release

Bavarian Nordic Receives U.S. and EU Approvals of its Fill and Finish Vaccine Manufacturing Facility

- U.S. approval follows successful pre-approval inspection of the facility by the U.S. FDA
- EU approval obtained after submission of application to EMA in June 2022

COPENHAGEN, Denmark, July 27, 2022 – Bavarian Nordic A/S (OMX: BAVA) announced today that the Company has received approvals from the U.S. and EU regulatory authorities to manufacture JYNNEOS®/IMVANEX® smallpox and monkeypox vaccine at the Company's fill and finish facility in Denmark. With the approvals of the final drug production – the process by which the vaccine is formulated and filled into vials – the Company is now allowed to deliver drug product manufactured at its own site to the U.S. and EU market.

An expedited pre-approval inspection (PAI) was conducted by the U.S. Food and Drug Administration (FDA) at the facility at the beginning of July 2022. The inspection included the final drug production of JYNNEOS®, which was previously performed at a contract manufacturer. The inspection was successfully completed with no observations made, which has led to the approval of Bavarian Nordic as the new drug product manufacturer of JYNNEOS.

The approval by the European Medicines Agency (EMA) was granted upon assessment by the Committee for Medicinal Products for Human use (CHMP) of a type II-variation application submitted in June 2022, which, similar to the FDA approval, acknowledges Bavarian Nordic as the new drug product manufacturer of the IMVANEX vaccine, in supplement to the inspection, and approval earlier granted, by the Danish Medicines Agency,

The expedited approvals have been made possible through close interactions between Bavarian Nordic and the regulatory authorities on the data package and the submission strategy and marks the final step for the Company in fulfilling the strategy to become a best-in-class vaccine manufacturer, controlling the entire value chain from manufacturing, filling, packaging and release to distribution of vaccines.

Paul Chaplin, President and CEO of Bavarian Nordic said: "We are proud to announce the successful completion of the FDA's inspection and subsequent approval of our state-of-the-art fill and finish facility along with EMA's approval. This achievement, which underscores the excellence of our manufacturing site and our ability to deliver high quality vaccines for improving and saving lives, was made possible through the dedication and commitment of our talented employees. We are thankful to both FDA and EMA for accelerating their review, during this monkeypox outbreak, which now has been named a public health emergency of international concern by the WHO, and we look forward to continuing our work with health authorities around the globe to ensure supply of vaccines against monkeypox."

About Bavarian Nordic
Bavarian Nordic is a fully integrated vaccines company focused on the development, manufacturing and commercialization of life-saving vaccines. We are a global leader in smallpox vaccines and have been a long-term supplier to the U.S. Government of a non-replicating smallpox vaccine, which has been approved by the FDA, also for the protection against monkeypox. The vaccine is also approved in Europe and Canada. Our commercial product portfolio furthermore contains market-leading vaccines against rabies and tick-borne encephalitis. Using our live virus vaccine platform technology, MVA-BN®, we have created a diverse portfolio of proprietary and partnered product candidates designed to save and improve lives by unlocking the power of the immune system, including an Ebola vaccine, which is licensed to the Janssen Pharmaceutical Companies of

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Johnson & Johnson. We are also committed to the development of a next generation COVID-19 vaccine. For more information visit www.bavarian-nordic.com.

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