



Bavarian Nordic Expands Capacity with U.S. Contract Manufacturer for Filling of Smallpox/Monkeypox Vaccines

- U.S. FDA approved facility operated by Grand River Aseptic Manufacturing will assist in filling of already manufactured bulk vaccine to expedite deliveries of monkeypox vaccines to the U.S.
- Agreement will significantly expand Bavarian Nordic's manufacturing capacity for the benefit of the U.S. and globally
- Expedited tech transfer has already started, allowing for manufacturing of first doses in 2022

COPENHAGEN, Denmark, August 18, 2022 - Bavarian Nordic A/S (OMX: BAVA) announced today that the Company has entered into an agreement with Grand River Aseptic Manufacturing (GRAM), a U.S. based contract manufacturer, for fill and finish of JYNNEOS smallpox/monkeypox vaccine. As announced on July 15, 2022, Bavarian Nordic received an additional order for 2.5 million doses the vaccine from the U.S. Biomedical Advanced Research and Development Authority (BARDA), a part of the Administration for Strategic Preparedness and Response (ASPR), which will be filled at GRAM using bulk vaccine already manufactured and invoiced under previous contracts with BARDA. Combined with previous orders, BARDA has requested a total of 5.5 million doses for delivery in 2022 and 2023.

The tech transfer of the production process to GRAM has already been initiated. The aim is to complete the tech transfer within three months - a process which could normally take up to nine months, thus enabling GRAM to start manufacturing later this year.

By adding the capacity of GRAM to fulfil a significant part of the orders from BARDA, Bavarian Nordic will be able to expedite delivery of vials to the U.S. while also freeing up capacity for other countries. The Company has already taken several steps to increase the filling capacity at its own manufacturing site in Denmark, now operating at double the capacity as before the monkeypox outbreak in May 2022 with an expectation to further increase over the coming months. Additionally, the Company's bulk manufacturing is now operational after a planned shutdown, allowing for production of new bulk vaccine. In parallel, the Company is exploring additional partnerships to further increase the manufacturing capacity in order to improve global access to the vaccine.

Bob Fenton, Coordinator of the White House National Monkeypox Response said: "Rapidly increasing the supply and safe delivery of monkeypox vaccine to Americans at the highest risk of contracting the virus is a top priority for President Biden. This partnership between Bavarian Nordic and GRAM will significantly increase the capacity to fill and finish government-owned doses - for the first time in the U.S. - and allow us to deliver our current and future supply more quickly to locations nationwide."

Paul Chaplin, President and CEO of Bavarian Nordic said: "We have been working diligently since the beginning of the monkeypox outbreak to expand our manufacturing capacity and the agreement with GRAM is an important step. With this agreement we will significantly expand our manufacturing capabilities into the United States allowing Bavarian Nordic to meet the growing worldwide demand."

About our vaccine contracts with the U.S. government

Since 2003, Bavarian Nordic has worked with the U.S. government on the development, manufacturing and supply of a non-replicating smallpox vaccine to ensure all populations can be protected from smallpox, including people with weakened immune systems who are at high risk of adverse reactions to traditional smallpox vaccines, which are based on replicating vaccinia virus strains. The Company has supplied nearly 30 million doses of the vaccine to the U.S., with the vast majority being delivered for emergency use - and now expired - before approval of the

vaccine by the FDA in 2019, which included an approval for the monkeypox indication as the only vaccine having obtained this to-date.

BARDA has supported the development of a freeze-dried version of the vaccine with longer shelf-life to replace the stockpile and in 2017 awarded the Company a ten-year contract for supply of freeze-dried vaccines. Under this contract Bavarian Nordic has produced bulk vaccine, corresponding to approximately 13 million doses. In May 2022, BARDA exercised the first contract options for conversion of the bulk vaccine to freeze-dried doses, anticipated for delivery in 2023-2025. In light of the current global monkeypox outbreak, BARDA has requested 5.5 million doses to be manufactured and delivered in 2022 and 2023 using the existing bulk vaccine, which will be filled in the current liquid-frozen formulation.

About Grand River Aseptic Manufacturing, Inc.

[Grand River Aseptic Manufacturing, Inc.](#), a prominent parenteral drug contract development and manufacturing organization with advanced technology, delivers customized solutions to meet clients' fill and finish needs from development through commercialization. With capabilities for biologics, small molecules and vaccines, Grand River Aseptic Manufacturing's elite equipment and staff supports pharmaceutical development and cGMP manufacturing, analytical testing, and regulatory filing.

About the Administration for Strategic Preparedness and Response

ASPR, an agency within the U.S. Department of Health and Human Services, leads the nation's medical and public health preparedness for, response to, and recovery from disasters and public health emergencies. Within ASPR, BARDA invests in the innovation, advanced research and development, acquisition, and manufacturing of medical countermeasures - vaccines, drugs, therapeutics, diagnostic tools, and non-pharmaceutical products - needed to combat health security threats.

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 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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