Company Announcement

Bavarian Nordic Announces that Janssen has Received Positive CHMP Opinion for its Investigational Preventative Ebola Vaccine Regimen

COPENHAGEN, Denmark, May 29, 2020 – Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) announced today that its strategic partner Janssen Pharmaceutical Companies of Johnson & Johnson has received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) for its investigational Ebola vaccine regimen for the prevention of the Ebola Virus Disease caused by the Zaire ebolavirus species.

Two Marketing Authorisation Applications (MAAs) were submitted to the EMA in support of the vaccines in the two-dose regimen, which includes Ad26.ZEBOV as the first dose, based on Janssen's proprietary AdVac® viral vector technology, and MVA-BN Filo as the second dose, based on Bavarian Nordic's MVA-BN® technology, administered approximately eight weeks later. The goal of this two-dose approach is to induce long-term immunity against Ebola Virus Disease.

The regimen is specifically designed to support preventative vaccination in countries that are at risk of Ebola outbreaks, as well as for other at-risk groups such as healthcare workers, BSL4 lab workers, military deployed from other countries, airport staff and visitors to high-risk countries. Janssen is collaborating with the World Health Organization on vaccine pre-qualification to broaden access of its investigational Ebola vaccine regimen to those most in need and enable registration in African countries; European Commission (EC) approval of this regimen may help accelerate this process.

"The positive opinion issued by CHMP for the Ebola vaccine regimen brings us closer to the second European approval of a product based on our MVA-BN platform, validating a broader usage of the technology in the development of novel vaccines to address unmet medical needs," said Paul Chaplin, President and CEO of Bavarian Nordic. "We congratulate Janssen on this milestone and applaud their accelerated efforts to bring forward this Ebola vaccine to help protect people at risk of Ebola and prevent future outbreaks."

Pending the final approval by the European Commission of the MVA-BN Filo vaccine, Bavarian Nordic would be eligible to receive a milestone payment of USD 10 million under the license agreement with Janssen.

Background

Bavarian Nordic and Janssen entered an agreement in 2014, under which MVA-BN Filo was licensed to Janssen as part of their commitment to developing an Ebola vaccine regimen. Under the agreement, Bavarian Nordic also manufactured a significant amount of vaccines.

To date, approximately 60,000 people have been vaccinated with the Ebola vaccine regimen in clinical studies and vaccination initiatives. Janssen-sponsored Phase 1 studies have been reported in peer-reviewed journals including JAMA and the Journal of Infectious Diseases, and Phase 1, 2 and 3 data were recently presented at the 2019 European Congress of Clinical Microbiology & Infectious Disease (ECCMID). These studies indicate that the vaccine regimen is well tolerated, inducing robust and durable immune responses to the Zaire Ebolavirus strain. In May 2019, the WHO's Strategic Advisory Group of Experts (SAGE) on immunization recommended the use of the Janssen investigational Ebola vaccine regimen as part of efforts to contain the DRC outbreak and more than 50,000 people in the DRC and Rwanda were vaccinated.

About Bavarian Nordic

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Bavarian Nordic is a fully integrated biotechnology company focused on the development, manufacture 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. Strategic National Stockpile of a non-replicating smallpox vaccine, which has been approved by the FDA under the trade name JYNNEOS®, also for the protection against monkeypox. The vaccine is approved as a smallpox vaccine in Europe under the trade name IMVANEX® and in Canada under the trade name IMVAMUNE®. Our commercial product portfolio furthermore contains market-leading vaccines Rabipur®/RabAvert® against rabies and Encepur® against 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 investigational Ebola vaccine, licensed to Janssen. 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.

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Company Announcement no. 33 / 2020