Company Announcement

Bavarian Nordic Announces Submission of European Marketing Authorisation Applications for Investigational Ebola Vaccine Regimen

COPENHAGEN, Denmark, November 7, 2019 – Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) today announced that its partner Janssen Pharmaceutical Companies of Johnson & Johnson have submitted Marketing Authorisation Applications (MAAs) to the European Medicines Agency (EMA) seeking licensure for an investigational Ebola vaccine regimen for the prevention of Ebola Virus Disease (EVD) caused by Zaire ebolavirus. Two MAAs have been submitted in parallel supporting each vaccine in the two-dose regimen (Ad26.ZEBOV, MVA-BN® Filo). In September 2019, the EMA's Committee for Medicinal Products for Human Use (CHMP) granted an Accelerated Assessment, which will shorten the review time for these applications.

The vaccine regimen includes Ad26.ZEBOV as the first dose, which is based on Janssen's AdVac® technology, and MVA-BN® Filo as the second dose, which is based on Bavarian Nordic's MVA-BN® technology and is administered approximately eight weeks later. The MAAs are supported by data from Phase 1, 2 and 3 clinical studies evaluating the safety and immunogenicity of the vaccine regimen in adults and children, preclinical studies, and immunobridging analyses. To date, more than 6,500 volunteers across the U.S., Europe and Africa have participated in over 10 clinical studies of the vaccine.

Janssen also has ongoing discussions with the U.S. Food and Drug Administration (FDA) to define the required data set for filing of the Ebola vaccine regimen under the FDA's Animal Rule licensure pathway and is also working in collaboration with the World Health Organization (WHO) to enable registration of the Ebola vaccine regimen in African countries.

On October 31, 2019, Janssen announced it will provide up to 500,000 regimens of its investigational vaccine to the Democratic Republic of Congo (DRC) for use in a new clinical trial organized by the DRC government and global health stakeholders in an effort to contain the country's Ebola outbreak.

"We congratulate Janssen on this important milestone in the development of a much-needed vaccine to fight Ebola, and we are proud to support the process to ensure a successful regulatory review," said Paul Chaplin, President and CEO of Bavarian Nordic. "We are excited about the prospects of yet another approved product coming from our pipeline, building on our validated MVA-BN platform technology."

Upon EMA approval 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

In 2014, in response to the Ebola epidemic in West Africa, Johnson & Johnson accelerated the development of a preventive Ebola vaccine regimen with multiple global partners across the U.S., Europe and Africa. The regimen (Ad26.ZEBOV, MVA-BN-Filo) uses a combination of two vaccines based on AdVac® technology from Janssen, and MVA-BN® technology from Bavarian Nordic. The first dose primes the immune system, and the second aims to enhance the duration of the immune response. These vaccines both use a viral vector approach, where a virus is genetically modified so that it cannot replicate but is used to safely express key proteins of the target virus, in this case Ebola virus. To date, more than 6,500 individuals across the U.S., Europe and Africa have participated in multiple Janssen-sponsored and partner-led clinical studies. The available clinical data suggest that the vaccine regimen has a favorable safety profile, is well tolerated, and induces robust and durable immune responses against the Ebola virus Zaire strain. – the cause of the DRC outbreak.

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Under the agreement with Janssen in 2014, Bavarian Nordic licensed MVA-BN Filo to Janssen and manufactured a significant amount of vaccines, currently stockpiled by Janssen.

The vaccine regimen was developed in a collaborative research program with the NIH and received direct funding and preclinical services from the National Institute of Allergy and Infectious Diseases, part of NIH, under Contract Numbers HHSN272200800056C, and HHSN272201000006I and HHSN272201200003I, respectively. Further funding for the Ebola vaccine regimen has been provided in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, BARDA under Contract Numbers HHSO100201700013C and HHSO100201500008C.

About Bavarian Nordic
Bavarian Nordic is a fully integrated biotechnology company focused on the development of innovative therapies against infectious diseases and cancer. Using our live virus vaccine platform technology, MVA-BN®, we have created a diverse portfolio of proprietary and partnered product candidates intended to unlock the power of the immune system to improve public health with a focus on high unmet medical needs. In addition to our long-standing collaboration with the U.S. government on the development and supply of medical countermeasures, including the only FDA-approved, non-replicating smallpox vaccine, our infectious disease pipeline comprises a proprietary RSV program as well as vaccine candidates for Ebola, HPV, HBV and HIV, which are developed through a strategic partnership with Janssen. Additionally, we have developed a portfolio of active cancer immunotherapies, designed to alter the disease course by eliciting a robust and broad anti-cancer immune response while maintaining a favorable benefit-risk profile. For more information visit www.bavarian-nordic.com or follow us on Twitter @bavariannordic.

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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