



BAVARIAN NORDIC

Press Release

## Investigational Ebola Vaccine from Janssen and Bavarian Nordic to Support Outbreak Response in Democratic Republic of the Congo

COPENHAGEN, Denmark, October 31, 2019 - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) today announced that its partner Janssen Pharmaceutical Companies of Johnson & Johnson will donate up to 500,000 doses of its investigational Ebola vaccine regimen to support vaccination efforts in the Democratic Republic of the Congo (DRC). The vaccine regimen consists of the Ad26.ZEBOV vaccine from Janssen and the recombinant MVA-BN<sup>®</sup> Filo vaccine from Bavarian Nordic.

The DRC is currently experiencing the world's second-largest Ebola outbreak on record and has been declared a [Public Health Emergency of International Concern](#) (PHEIC) by the World Health Organization (WHO). The DRC government recently announced the country's decision to introduce Janssen's investigational vaccine as part of an expanded public health response to fight the Ebola outbreak, thus following the [recent recommendations](#) from WHO's Strategic Advisory Group of Experts (SAGE) on Immunization.

As part of the DRC's expanded public health response, a new clinical study of the vaccine regimen will be implemented, targeting individuals at risk of Ebola infection who live in areas close to the current outbreak zone, with the goal of preventing the further geographic spread of the virus.

"Since the beginning of our collaboration with Janssen, we have been working diligently to support the advanced development of this novel vaccine regimen as part of the global response towards Ebola, and we applaud Janssen for maintaining the readiness to act promptly in this severe situation. Fighting the disease has shown to be a complex task, and the development of a vaccine which offers durable protection is a key step towards achieving this goal. We also applaud the recommendation from WHO to deploy the vaccine, which is yet another validation of our vaccine technology as a suitable platform for development of novel countermeasures," said Paul Chaplin, President and CEO of Bavarian Nordic.

The study will be implemented by the Institut National de Recherche Biomédicale (INRB) and the DRC Ministry of Health, supported by Médecins Sans Frontières (MSF), Epicentre and the London School of Hygiene & Tropical Medicine (LSHTM), under the leadership of the Principal Investigator Professor Jean-Jacques Muyembe, INRB Director and head of the DRC multisector Ebola response committee. The trial will be sponsored by LSHTM, and funded by the Coalition for Epidemic Preparedness CEPI, the European Union, the UK Department for International Development, Wellcome and the Paul G. Allen Family Foundation. Janssen is donating supplies of its investigational vaccine regimen for the study.

### 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<sup>®</sup> technology from Janssen, and MVA-BN<sup>®</sup> 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.

Under the agreement with Janssen in 2014, Bavarian Nordic licensed MVA-BN Filo to Janssen and manufactured a significant amount of vaccines for the stockpile, which is now being deployed in the DRC.

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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<sup>®</sup>, 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](http://www.bavarian-nordic.com) or follow us on Twitter [@bavariannordic](https://twitter.com/bavariannordic).

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