

Company Announcement no. 28 / 2015

Bavarian Nordic Announces Initiation of Safety and Immunogenicity Study of Ebola Vaccine Regimen in Sierra Leone

- First study of the Ad26.ZEBOV/MVA-BN[®] Filo prime-boost vaccination regimen in an Ebola outbreak country
- Study being initiated on parallel track with multiple ongoing Phase 1 and 2 studies across U.S., Europe and Africa to support licensure of the vaccine regimen

COPENHAGEN, Denmark, October 9, 2015 - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) announced today the initiation of a new clinical study of the Ebola prime-boost vaccine regimen that combines Bavarian Nordic's MVA-BN[®] Filo vaccine with the Ad26.ZEBOV vaccine from Crucell Holland B.V., one of the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen). The study called 'EBOVAC-Salone' is being conducted in Sierra Leone's Kambia district, where some of the country's most recent Ebola cases have been reported. The first volunteers have received their initial vaccine dose.

The study, coordinated by the London School of Hygiene & Tropical Medicine and sponsored by Janssen, is designed to evaluate the safety and immunogenicity of the combination regimen. Volunteers will first be given the Ad26.ZEBOV dose to prime their immune system, and then the MVA-BN Filo dose at a later date to boost their immune response, with the goal of creating stronger and longer-lasting immunity. The first stage of the study, which has now been initiated, includes approximately 40 adults aged 18 years or older. In stage 2, approximately 400 individuals across different age groups will be vaccinated, including children and adolescents. Additional stages are being finalized in consultation with the Sierra Leonean authorities and international health agencies. Further details of the study can he found at http://clinicaltrials.gov/ct2/show/NCT02509494.

Paul Chaplin, President & Chief Executive Officer of Bavarian Nordic, said: "The initiation of EBOVAC-Salone marks an important milestone for our joint program with Janssen. It is a significant step forward in the development of a vaccine against Ebola. It is remarkable how far the program has moved, which has only been possible due to the commitment and dedication shown by both Janssen and our employees in terms of the progress we have made in manufacturing bulk vaccine for almost 2 million doses and initiating this study within a year of joining forces. The key attributes of both the MVA-BN and Ad26 technologies were initially recognized through NIH funding and subsequently the program has benefited from additional governmental funding. We believe our progress to date highlights the potential for a successful model of private-public partnerships in the development of products addressing unmet medical needs for the future."

The EBOVAC-Salone study is being initiated on a parallel track with multiple ongoing Phase 1 and 2 studies that are being conducted across the U.S., Europe and Africa as part of the accelerated development plan for the Ebola vaccine regimen. First-in-human Phase 1 clinical studies of the prime-boost vaccine regimen began in the United Kingdom and United States in January 2015, followed by several sites in Africa. In May 2015, Janssen presented positive preliminary data from the UK Phase 1 study to the U.S. Food and Drug Administration. A Phase 2 study, being carried out in the UK and France, started in July 2015 with a second multi-site Phase 2 study planned to shortly commence in several West and East African countries.

With nearly 14,000 people infected by Ebola, Sierra Leone accounts for the largest number of cases in any of the West African countries affected by the outbreak that has raged since 2014. In total, more than 28,000 people have been infected with the virus in the region and more than 11,000 people have died. Although only

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few new cases have been reported over the past months, Sierra Leone along with Guinea remains yet to be declared Ebola-free.

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About MVA-BN Filo

MVA-BN Filo is Bavarian Nordic's multivalent vaccine candidate designed to protect against Ebola Zaire, Ebola Sudan and Marburg viruses. The vaccine candidate was originally developed in collaboration with the U.S. National Institute of Allergy and Infectious Diseases, part of the U.S. National Institutes of Health (NIH) who also headed the preclinical investigation of the Ad26.ZEBOV/MVA-BN Filo prime-boost vaccine regimen.

MVA-BN Filo is developed using Bavarian Nordic's proprietary vaccine platform technology, MVA-BN, which is also employed in the Company's smallpox vaccine, IMVAMUNE[®] (approved in EU and Canada under the trade name IMVANEX[®]). To-date, Bavarian Nordic has produced and delivered 28 million doses of the smallpox vaccine for emergency use to the U.S. Strategic National Stockpile.

In October 2014, Bavarian Nordic and Janssen entered into a global license and a supply agreement for MVA-BN Filo. This was part of an overall commitment made by Johnson & Johnson to accelerate and significantly expand the production of the preventative Ebola vaccine program in development at its Janssen Pharmaceutical Companies. To date, Bavarian Nordic has produced and delivered the bulk equivalent of over one million doses of its vaccine to Janssen.

Funding acknowledgments

In January 2015, Europe's Innovative Medicines Initiative (IMI) awarded a consortium of leading global research institutions and non-government organizations working in conjunction with the Janssen Pharmaceutical Companies grants totaling more than €100 million from the Ebola+ program to support the development, manufacturing and deployment of the vaccine regimen. The EBOVAC1 and EBODAC consortia partners also include the London School of Hygiene & Tropical Medicine, University of Oxford, Inserm, Grameen Foundation and World Vision of Ireland. The EBOVAC-Salone study is funded under Innovative Medicines Initiative 2 Joint Undertaking grant agreement EBOVAC1 (grant no. 115854) and EBODAC (grant no. 115847), part of the Ebola+ program launched in response to the Ebola virus disease outbreak. This Innovative Medicines Initiative 2 Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation program and EFPIA.

The investigational Ebola vaccine regimen was discovered in a collaborative research program with the National Institutes of Health (NIH). This program received direct funding and preclinical services from the National Institute of Allergy and Infectious Diseases (NIAID), part of NIH, under Contract Numbers HHSN272200800056C, and HHSN272201000006I and HHSN272201200003I, respectively. The MVA-BN-Filo material used in phase 1 studies was produced under NIAID/Fisher BioServices contract #FBS-004-009 and NIH contract HHSN272200800044C.

About Bavarian Nordic

Bavarian Nordic is a biopharmaceutical company focused on the development and manufacturing of cancer immunotherapies and vaccines for infectious diseases. Through a long-standing collaboration with the U.S. Government, Bavarian Nordic has developed a portfolio of biological countermeasures, including the non-replicating smallpox vaccine, IMVAMUNE[®], which is stockpiled for emergency use by the U.S. and other governments. The vaccine is approved in the EU (under the trade name IMVANEX[®]) and in Canada. Bavarian Nordic and its partner Janssen are pioneering the development of an Ebola vaccine regimen, which has been

fast-tracked by authorities in response to the current situation in West Africa. Additionally, in collaboration with the National Cancer Institute, Bavarian Nordic has developed a portfolio of active cancer immunotherapies based on its versatile pox-virus based technologies, including PROSTVAC[®], which is currently in Phase 3 clinical development for the treatment of advanced prostate cancer. The company has partnered with Bristol-Myers Squibb for the potential commercialization of PROSTVAC. For more information visit <u>www.bavarian-nordic.com</u> or follow us on Twitter <u>@bavariannordic</u>.

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. 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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