

Company Announcement

# Independent Data Monitoring Committee Recommends Discontinuation of Bavarian Nordic's Phase 3 Study of PROSTVAC in Metastatic Prostate Cancer

• Conference call scheduled for 2:00 PM CEST / 8:00 AM EDT tomorrow, Friday, September 15

COPENHAGEN, Denmark, September 14, 2017 - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) today announced that an independent Data Monitoring Committee (DMCB) has determined, based on a preplanned interim analysis, that continuation of the Phase 3 PROSPECT study of PROSTVAC® in patients with metastatic castration-resistant prostate cancer (mCRPC) is futile.

"We are extremely disappointed for patients that this study of PROSTVAC as monotherapy was not successful," said Paul Chaplin, President & Chief Executive Officer of Bavarian Nordic. "On behalf of Bavarian Nordic, I want to express our gratitude to the PROSPECT investigators, patients and families who participated in this trial. While this is certainly not the desired outcome, we remain steadfast believers in the power of combination treatments, including immunotherapies, to transform the future of cancer therapies."

The contents of this announcement do not affect the Company's expectations for the financial results for 2017.

#### Conference call and webcast

The management of Bavarian Nordic will host a conference call tomorrow, Friday, September 15 at 2 PM CEST (8 AM EDT) to discuss the outcome of the interim analysis. Dial-in numbers and link to a live and archived webcast of the conference call will become available at <a href="http://www.bavarian-nordic.com/investor/events.aspx?event=5307">http://www.bavarian-nordic.com/investor/events.aspx?event=5307</a> during the morning.

## About the PROSPECT study

PROSPECT was a global, randomized, double-blind, placebo-controlled Phase 3 study conducted under a Special Protocol Assessment (SPA) from the FDA. The objective of the study was to determine whether PROSTVAC alone or in combination with GM-CSF could prolong overall survival in men with asymptomatic or minimally symptomatic mCRPC. The study enrolled 1,297 patients at more than 200 sites in 15 countries.

## **About PROSTVAC**

PROSTVAC (rilimogene galvacirepvec/rilimogene glafolivec, or "rilimogene") is a prostate specific antigen (PSA)-targeted immunotherapy candidate designed to enhance or stimulate the body's immune response, specifically T cells that will home to and kill prostate cancer cells, altering the course of the disease and improving overall survival of patients with prostate cancer. PROSTVAC employs two poxviruses (vaccinia and fowlpox) in a prime-boost vaccine regimen. A robust data package has been established that includes 19 ongoing or completed clinical studies, comprising more than 2,000 patients, the majority of which have been actively treated with PROSTVAC, which has been generally well-tolerated.

PROSTVAC is being developed in collaboration with the National Cancer Institute under a Cooperative Research and Development Agreement.

#### **About Bavarian Nordic**

Bavarian Nordic is a fully integrated biotechnology company focused on the development, manufacturing and commercialization of cancer immunotherapies and vaccines for infectious diseases, based on the Company's live virus vaccine platform. Through long-standing collaborations, including a collaboration with the U.S. government, Bavarian Nordic has developed a portfolio of vaccines for infectious diseases, including the non-replicating smallpox vaccine, IMVAMUNE®, which is stockpiled for emergency use by the United States and other governments. The vaccine is approved in the European Union (under the trade name IMVANEX®) and in

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Hejreskovvej 10A Tel. +45 33 26 83 83 DK-3490 Kvistgård CVR-no. 16 27 11 87 Canada. Bavarian Nordic and its strategic partner Janssen are developing an Ebola vaccine regimen, and therapeutic vaccines for HPV, HBV and HIV. Additionally, in collaboration with the National Cancer Institute, Bavarian Nordic has developed a portfolio of active cancer immunotherapies, 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 <a href="https://www.bavarian-nordic.com">www.bavarian-nordic.com</a> or follow us on Twitter <a href="https://www.bavarian-nordic.com">@bavariannordic</a>.

#### 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.

## Contacts

Rolf Sass Sørensen Vice President Investor Relations (EU)

Tel: +45 61 77 47 43

Seth Lewis

Vice President Investor Relations (US)

Tel: +1 978 341 5271

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