

## **Bavarian Nordic Provides Update on Anticipated Timing of PROSPECT Study**

- PROSTVAC® overall survival data anticipated in the second half of 2017

**COPENHAGEN, Denmark, January 4, 2017** - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) today provided guidance for the current estimated timing of interim and final overall survival analysis from the PROSPECT study - a placebo controlled Phase 3 study designed to investigate the efficacy of PROSTVAC to prolong the survival of men with metastatic castration-resistant prostate cancer (mCRPC).

The company maintains its previous guidance that full data is expected within this year, albeit in the second half of 2017, with the third interim analysis likely to occur around mid-2017. This estimate is based on a decline in the number of average monthly events currently seen in the PROSPECT study.

“As there has been speculation that the third interim could occur during first quarter of 2017, we believe it is important to update the market on the current estimated timelines for readout of the Phase 3 study” said Paul Chaplin, President and CEO of Bavarian Nordic.

While the company remains blinded to all patient specific data, the latest estimates have been provided by the independent Data Monitoring Committee (DMC) following a routine analysis of the current survival data.

“While we will have to await the final read out of the PROSPECT study to establish the efficacy of PROSTVAC, we are encouraged that the current monthly event rate has declined. This is great news for the patients. Not only is this consistent with an improvement in the standard of care for patients with mCRPC, which has been observed in recent years, but could also be indicative of a therapeutic effect of PROSTVAC as well” said Paul Chaplin.

### **About the PROSPECT study**

PROSPECT is a global, randomized, double-blind, placebo-controlled phase 3 study being conducted under a Special Protocol Assessment (SPA) from the FDA. The objective of the study is to determine whether PROSTVAC alone or in combination with GM-CSF is effective in prolonging overall survival. The study has been fully enrolled with 1,297 asymptomatic or minimally symptomatic mCRPC patients as of January 2015. Patients were enrolled at more than 200 sites in 15 countries. Both the first and second interim analyses confirmed that the study would continue as planned. Final study data requires 534 events in both comparisons of treatment arms versus placebo, and the third interim analysis will occur at 427 events.

### **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 (OS) of patients with prostate cancer. A robust data package has been established that includes 18 ongoing or completed clinical studies, comprising more than 2,000 patients of which more than 1,100 patients have been actively treated with PROSTVAC, which has been generally well-tolerated. A randomized, placebo-controlled Phase 2 trial demonstrated the potential of PROSTVAC to extend the median overall survival by 8.5 months in patients with advanced prostate cancer. These results led to the initiation of the PROSPECT pivotal Phase 3 study.

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 Canada. Bavarian Nordic and its partner Janssen are developing an Ebola vaccine regimen, which has been fast-tracked, with the backing of worldwide health authorities, and a vaccine for the prevention and treatment of HPV. 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 [www.bavarian-nordic.com](http://www.bavarian-nordic.com) or follow us on Twitter [@bavariannordic](https://twitter.com/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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