



BAVARIAN NORDIC

*Company Announcement*

## **Bavarian Nordic Announces Initiation of Phase 2 Clinical Trial of RSV Vaccine**

- First Phase 2 study will evaluate prime-boost vaccine approach in elderly population

**COPENHAGEN, Denmark, October 18, 2016** - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) today announced the initiation of the first Phase 2 clinical study of MVA-BN<sup>®</sup> RSV, its novel, broad spectrum, vaccine candidate against RSV (respiratory syncytial virus).

The study, which is being conducted in USA, will enrol 400 healthy subjects, aged 55 or older who will be randomized into five groups of 80 subjects each. Subjects will receive two administrations four weeks apart of either low or high doses of MVA-BN RSV and/or placebo, in order to identify the optimal dose and schedule for future studies. More information on the trial can be found at <http://www.clinicaltrials.gov/ct2/show/NCT02873286>.

Top-line results from the study are anticipated around mid-2017 and will provide important information for a subsequent Phase 2b field efficacy study, which is planned for initiation later in 2017.

Paul Chaplin, President & Chief Executive Officer of Bavarian Nordic, said: “Advancing our RSV program into Phase 2 is an important milestone for Bavarian Nordic in our efforts to develop a vaccine which potentially offers broad protection against the virus. RSV remains an area of high unmet medical need with no approved vaccine available. This Phase 2 study represents an essential step in the successful development of any vaccine; to ensure we establish an ideal dose and dosing regimen, prior to exploring this candidate in larger studies. In this study we will evaluate both a single vaccination, as well as a prime-boost approach that will determine which regime induces prolonged immune responses against RSV “

MVA-BN RSV represents a new vaccine approach specifically designed to target five different RSV proteins to ensure a broad immune response against both RSV subtypes (A & B). Extensive preclinical studies have shown that MVA-BN RSV induces a balanced immune response comprised of both antibodies and T cells, in a similar fashion to the natural response to an RSV infection. These results were confirmed in a Phase 1 study in healthy adults, reported in May 2016, which showed that MVA-BN RSV significantly boosted antibodies and T cells against both RSV subtypes. The vaccine was well tolerated, with no unexpected or serious adverse reactions. The vast majority of events represented local and systemic reactions typical for vaccines.

### **About RSV**

Respiratory syncytial virus, or RSV, is the most common cause of bronchiolitis and pneumonia in infants and a significant cause of respiratory illness in older adults, resulting in a high number of hospitalizations. RSV infections are responsible each year for a similar number of deaths as the flu in children up to age 14, as well as in the elderly population. It is estimated that more than 64 million people are infected globally each year, yet unlike the flu, there is no vaccine to prevent RSV, presenting a large unmet medical need and market opportunity.

### **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<sup>®</sup>, 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<sup>®</sup>) and in Canada. Bavarian Nordic and its partner Janssen are developing an Ebola vaccine regimen, which has been fast-

Page 1 of 2

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<sup>®</sup>, 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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