



BAVARIAN NORDIC

Company Announcement no. 22 / 2015

Bavarian Nordic Initiates Phase 1 Clinical Trial of MVA-BN[®] in Respiratory Syncytial Virus (RSV)

COPENHAGEN, Denmark - August 18, 2015 - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) today announced the initiation of a Phase 1 clinical study of its MVA-BN[®] RSV vaccine candidate against respiratory syncytial virus (RSV), the first study to evaluate the vaccine candidate in humans.

The study, which is being conducted in USA, will evaluate the safety, tolerability and immunogenicity of a recombinant MVA-BN-based RSV vaccine in 63 healthy adults, ages 18-65. Subjects will be enrolled into three groups to receive different doses of MVA-BN RSV. One group will enroll subjects of 50-65 years of age who will receive a higher dose of MVA-BN RSV in order to evaluate the immune responses in an elderly population, which is a key target for the vaccine. Volunteers in each group will be randomized to receive two vaccinations of MVA-BN RSV vaccine or placebo. More information on the trial can be found at <https://clinicaltrials.gov/ct2/show/NCT02419391>.

Paul Chaplin, President & Chief Executive Officer of Bavarian Nordic, said: "The addition of RSV to our clinical pipeline significantly expands the commercial potential of our MVA-BN vaccine platform technology. RSV is an exciting opportunity as it represents an area of high unmet medical need with no approved vaccine available. Based on the broad protection seen in our preclinical data, we believe that MVA-BN has the potential to address this opportunity. Once data from this initial study are available, we plan to aggressively pursue the development of this promising vaccine candidate in all potential risk populations, including elderly and young children."

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

About RSV

RSV is the most common cause of lower respiratory tract infection in infants and children worldwide, resulting in a high number of hospitalizations. By 2 years of age virtually all infants have had an RSV infection. In addition, RSV causes serious disease in elderly and immune compromised individuals, and results in a comparable number of deaths in the elderly population as influenza. Currently, there is no approved RSV vaccine available for any of these populations. It is estimated that more than 64 million people are infected globally each year, thus representing a blockbuster market opportunity for a safe and effective vaccine.

About MVA-BN[®] RSV

Bavarian Nordic's recombinant MVA-BN-based RSV vaccine candidate has been shown to induce a balanced humoral and cellular immune response against both RSV subtypes in preclinical models. Furthermore, the candidate has been shown to be highly efficacious in preclinical models, including in studies sponsored by the NIH.

About MVA-BN®

MVA-BN (Modified Vaccinia Ankara - Bavarian Nordic) is a proprietary and patented vaccine platform technology of Bavarian Nordic, originally developed through a successful public-private partnership with the U.S. Government. MVA-BN is a robust and adaptable platform suitable for addressing a wide variety of infectious diseases.

In addition to developing MVA-BN as a safer smallpox vaccine (approved in the EU and Canada) essential to protecting the immune-compromised population, and through a partnership with Janssen as an Ebola vaccine, Bavarian Nordic has conducted more than a dozen preclinical and clinical studies of recombinant MVA-BN-based vaccines. More than 7,600 individuals, nearly 1,000 of whom are immunocompromised, have been vaccinated with MVA-BN-based vaccines, showing the platform displays high immunogenicity and a favorable safety profile.

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, 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 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. 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.