



BAVARIAN NORDIC

Company Announcement

Bavarian Nordic Reports Positive Results from Human Challenge Trial of its RSV Vaccine Candidate

- Study achieved the primary endpoint by demonstrating a statistically significant reduction in viral load in vaccinated versus control (placebo) treated volunteers
- Demonstrated up to a 79% efficacy in reducing symptomatic RSV infections
- Management will host a conference call today at 2 pm CET (8 am EST) to review the results

COPENHAGEN, Denmark, September 1, 2021 - Bavarian Nordic A/S (OMX: BAVA) announced today results from a human challenge trial of the RSV vaccine candidate, MVA-BN® RSV. The phase 2 double-blinded, placebo-controlled trial enrolled healthy adult volunteers, 18-50 years of age who were randomized to receive either a single vaccination of MVA-BN RSV or placebo. Volunteers were challenged intranasally with an RSV type A strain 28 days after vaccination. A total of 61 subjects were evaluable.

The study demonstrated a significant reduction in viral load in vaccinated subjects (n=30) versus placebo (n=31), thus meeting the primary endpoint of this pivotal study. At the same time, the vaccinated subjects showed a significant reduction in clinical symptoms typically associated with RSV infections. The MVA-BN RSV vaccine demonstrated a vaccine efficacy of up to 79% in preventing symptomatic RSV infections.

No vaccine-related serious adverse events were observed, and the vaccine was well tolerated, consistent with the safety profile previously reported in phase 1 and phase 2 clinical studies.

Paul Chaplin, President and CEO of Bavarian Nordic, commented: “We are pleased to report these highly encouraging results, that are equivalent to, or even better than those of competitor candidates and which confirm the potential of our RSV vaccine candidate. MVA-BN RSV has been designed to simulate a broad immune response against RSV by incorporating not only one, but five different antigens of the virus, thereby offering the advantage of a broad protection against RSV that will likely be required to prevent hospitalization with severe disease caused by RSV. The COVID-19 pandemic has clearly demonstrated the susceptibility and severity of respiratory viruses in vulnerable populations, and we remain committed to bring this novel vaccine to the market to fulfil the high unmet medical need in the elderly population, which is estimated to be on par with influenza.”

Pending further analysis of the current RSV infection rates, discussions with regulatory authorities about the Phase 3 design, and funding/partnering considerations, the Company will determine the immediate next steps and expects to communicate these during fourth quarter of 2021.

Conference call and webcast

The management of Bavarian Nordic will host a conference call today at 2 pm CET (8 am EST) to review the trial results followed by a Q&A session. A listen-only version of the call can be accessed via <https://www.bavarian-nordic.com/investor/events.aspx?event=6392>. To join the Q&A session, use one of the following dial-in numbers: Denmark: +45 32 72 04 17, UK: +44 (0) 844 481 9752, USA: +1 646-741-3167. Participant code is 7370558.

About Respiratory Syncytial Virus (RSV)

RSV is a common virus that usually causes mild, cold-like symptoms, but in serious cases can cause severe lung infections, including bronchiolitis and pneumonia. Those at risk are typically young infants and the elderly as well as people with weakened immune systems. RSV-induced infections result in a similar number of

hospitalizations and deaths in the elderly population, as influenza. According to the CDC¹, approximately 177,000 elderly U.S. citizens are hospitalized annually, due to RSV-induced infections, and about 14,000 of them die. With no approved vaccines, RSV remains a high unmet medical need, particularly in children and the elderly.

About MVA-BN RSV

MVA-BN RSV, Bavarian Nordic's product candidate for the prevention of RSV, is being developed for an elderly population. The vaccine incorporates five different RSV antigens to stimulate a broad immune response against both RSV subtypes (A and B), thus mimicking the immune response observed following a natural response to an RSV infection. The incorporation of five antigens differentiates MVA-BN RSV from any other RSV vaccine candidates in development.

Bavarian Nordic has previously concluded a phase 2 trial of MVA-BN RSV in 421 elderly subjects, demonstrating that the vaccine was well tolerated and induced both broad and durable antibody and T-cell responses against RSV, as well as mucosal immune responses that may be important for protection against RSV. The phase 2 program in elderly included a revaccination of subjects after one year, following which the immune responses were rapidly and significantly increased, notably in subjects with the weakest immunity prior to the booster vaccination.

The vaccine candidate is based on Bavarian Nordic's proprietary MVA-BN[®] platform technology, also used in the Company's approved vaccines for smallpox and Ebola.

About Bavarian Nordic

Bavarian Nordic is a fully integrated vaccines company focused on the development, manufacturing and commercialization of life-saving vaccines. We are a global leader in smallpox vaccines and have been a long-term supplier to the U.S. Government of a non-replicating smallpox vaccine, which has been approved by the FDA under the trade name JYNNEOS[®], also for the protection against monkeypox. The vaccine is approved as a smallpox vaccine in Europe under the trade name IMVANEX[®] and in Canada under the trade name INVAMUNE[®]. Our commercial product portfolio furthermore contains the market-leading vaccine Rabipur[®]/RabAvert[®] against rabies and Encepur[®] against tick-borne encephalitis. Using our live virus vaccine platform technology, MVA-BN[®], we have created a diverse portfolio of proprietary and partnered product candidates designed to save and improve lives by unlocking the power of the immune system, including an Ebola vaccine, MVABEA[®], which is licensed to the Janssen Pharmaceutical Companies of Johnson & Johnson. We are also committed to the development of a next generation COVID-19 vaccine based on an in-licensed capsid virus-like particle technology. The vaccine candidate, ABNCoV2, is currently being investigated in clinical trials. For more information visit www.bavarian-nordic.com.

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

Europe: Rolf Sass Sørensen, Vice President Investor Relations, Tel: +45 61 77 47 43

US: Graham Morrell, Paddock Circle Advisors, graham@paddockcircle.com, Tel: +1 781 686 9600

Company Announcement no. 29 / 2021

¹ <https://www.cdc.gov/rsv/research/us-surveillance.html>