Company Announcement

Bavarian Nordic Commits to Initiating Phase 3 Trial of RSV Vaccine Candidate and to Strengthening its Capital Base

- Bavarian Nordic to initiate Phase 3 with RSV vaccine candidate in first half of 2022 subject to a successful equity capital raise
- EBITDA expectations for 2021 slightly lowered, as Phase 3 preparations are now being intensified

COPENHAGEN, Denmark, December 6, 2021 – Bavarian Nordic A/S (OMX: BAVA) a fully integrated vaccines company, formally announces its commitment to initiate a Phase 3 clinical trial of its RSV vaccine candidate, MVA-BN® RSV. Bavarian Nordic intends to fund the trial through an equity raise, of up to 10% of its registered share capital.

Strategic update on RSV vaccine candidate

Bavarian Nordic remains committed to the vision of becoming a leading pure-play vaccine company by 2025 through a combination of organic growth and/or acquisitions, and MVA-BN RSV holds the potential to become a key contributor to this vision. There is a significant unmet need for an RSV vaccine, as the number of RSV-induced infections are very similar to influenza and lead to an estimated 177,525[1] hospitalizations and 14,000[1] deaths annually in adults 65 years and older alone in the United States. The total estimated hospitalization costs attributed to RSV in older adults in the United States exceeds USD 1 billion[1].

Bavarian Nordic remains at the forefront of the development of a vaccine against RSV. In September 2021, the Company reported that MVA-BN RSV had met its primary endpoint in a Phase 2 human challenge study, demonstrating a statistically significant reduction in viral load in vaccinated versus control (placebo) treated volunteers. Further, the vaccine demonstrated an efficacy of up to 79% in preventing symptomatic RSV infections.

Paul Chaplin, President and CEO of Bavarian Nordic, commented: "The progress of our COVID-19 vaccine has further de-risked the profile of Bavarian Nordic and allows us to make important strategic decisions with respect to our promising RSV vaccine candidate. Time-to-market is of the essence, so we have decided to initiate a self-funded Phase 3 RSV trial, subject to the completion of a successful equity capital raise. RSV is a potential multi-billion-dollar vaccine market annually and by securing the necessary financing to advance MVA-BN RSV on our own, we preserve maximum strategic flexibility and accelerate the time-to-market."

Bavarian Nordic has engaged a contract research organization and expects to initiate a pivotal RSV Phase 3 trial in the first half of 2022. The Phase 3 trial is expected to enroll up to 20,000 subjects and run over the course of one year, spanning multiple geographies. The total estimated cost of the study is approximately USD 250 million, including follow-up phases in 2023 and 2024. Bavarian Nordic plans to finance this through an equity capital raise of up to 10% of its registered share capital. The capital raise is expected to be launched in the near term, subject to a conducive market environment.

Revised guidance for 2021

With the decision to initiate the Phase 3 trial in 2022, Bavarian Nordic will incur additional costs of approximately DKK 30 million already in 2021 and hence is adjusting the expected EBITDA guidance correspondingly to approximately DKK 70 million. The guided year-end cash position remains unchanged and excludes any potential proceeds from a capital raise.

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Conference call and webcast
The management of Bavarian Nordic will host a conference call today at 2 pm CET (8 am EST) to present the plans for the RSV vaccine, along with a presentation of the Phase 2 results for the COVID-19 vaccine reported yesterday. This will be 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=6437. 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 4569358.

About Respiratory Syncytial Virus (RSV)
RSV is a common virus that usually causes mild, cold-like symptoms, but in serious cases can lead to severe lung infections, including bronchiolitis and pneumonia, which ultimately can lead to death. At-risk individuals typically include infants and elderly / immunocompromised individuals.

RSV infection can be dangerous for older people. It is estimated, that each year RSV-induced infections lead to approximately 177,525[1] hospitalizations and 14,000[1] deaths in adults aged 65 years and older in the US, similar to influenza. Accordingly, preventing RSV-induced infections is a top priority for governments and medical professionals globally. Currently there is no approved vaccine against RSV. As such, RSV constitutes a large and critical unmet medical need and a potential multi-billion-dollar vaccines market annually.

About MVA-BN RSV
MVA-BN RSV, Bavarian Nordic's vaccine candidate for the prevention of RSV, is being developed for use in elderly individuals. The vaccine incorporates five distinct 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 other RSV vaccine candidates currently in development.

In September, Bavarian Nordic reported strong results from a clinical Phase 2 double-blinded, placebo-controlled trial, which 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.

Bavarian Nordic has also previously reported strong results from a Phase 2 trial of MVA-BN RSV in 421 elderly subjects aged 55 years and older, 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 subjects 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, also for the protection against monkeypox. The vaccine is approved as a smallpox vaccine in Europe and Canada. Our commercial product portfolio furthermore contains market-leading vaccines against rabies and 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, 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. 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.

Financial advisors
Citi and Nordea have been mandated as Joint Global Coordinators and Joint Bookrunners in connection with the planned equity capital raise.

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[1] Falsey AR, Hennessey PA, Formica MA, Cox C, Walsh EE. Respiratory syncytial virus infection in elderly and high-risk adults. N Engl J Med. 2005 Apr 28;352(17):1749–59