Company Announcement

Bavarian Nordic Announces Initiation of a Global Phase 3 Clinical Trial of its RSV Vaccine Candidate in Older Adults

- First subject vaccinated in Phase 3 clinical trial of MVA-BN® RSV against respiratory syncytial virus (RSV) in older adults
- Trial will assess efficacy of MVA-BN RSV against lower-respiratory tract disease caused by RSV
- Multi-center trial planned to enroll approximately 20,000 volunteers in USA and Germany with topline results anticipated mid 2023

COPENHAGEN, Denmark, April 20, 2022 – Bavarian Nordic A/S (OMX: BAVA) announced today the dosing of the first subject in the Phase 3 VANIR clinical trial of its investigational respiratory syncytial virus (RSV) vaccine candidate, MVA-BN® RSV in older adults.

The VANIR trial is a global, randomized, double-blind Phase 3 trial of the recombinant MVA-BN RSV vaccine in 20,000 adults aged 60 years and older. The primary objective of the study will assess the efficacy of the vaccine candidate against lower-respiratory tract disease caused by RSV compared to placebo.

"RSV remains a significant cause of respiratory disease in older adults, and in severe cases, unfortunately leading to death. Despite an estimated burden on the healthcare system which is similar to that of influenza, no vaccines are available yet. The initiation of this pivotal trial of our vaccine candidate is a significant contribution to the global efforts to develop a safe and effective vaccine against RSV and represents an important step for Bavarian Nordic towards fulfilling our ambition to become one of the largest pure play vaccine companies," said Paul Chaplin, President and Chief Executive Officer of Bavarian Nordic.

The Phase 3 trial is being conducted at approximately 115 sites across the U.S. and Germany. The trial is designed to run through the RSV season 2022/2023 with topline results expected mid 2023 if the pre-defined number of lower-respiratory tract disease events has occurred.

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 older adults as well as immunocompromised individuals.

A prospective study in the U.S. has estimated the disease burden from RSV-induced infections and subsequent deaths to be similar to that of non-pandemic influenza in adults aged 65 years and older[1]. Accordingly, preventing RSV-induced infections is a top priority for governments and medical professionals globally. Currently there is no approved vaccine against RSV, thus representing a large and critical unmet medical need and a potential multi-billion-dollar vaccines market annually.

About MVA-BN RSV
Bavarian Nordic's vaccine candidate, MVA-BN RSV, is being developed for the prevention of respiratory syncytial virus (RSV) in older adults. 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 vaccine candidate is based on Bavarian Nordic's proven MVA-BN platform technology, which is employed in several approved vaccines.

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In 2021, Bavarian Nordic reported results from a clinical Phase 2 double-blinded, placebo-controlled human challenge trial (n=61), which enrolled healthy adult volunteers, 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. The study demonstrated a significant reduction in viral load subjects vaccinated with MVA-BN RSV (n=30) versus placebo (n=31), thus meeting the primary endpoint. In the subjects vaccinated with MVA-BN RSV, clinical symptoms typically associated with RSV infections were significantly reduced. Further, the vaccine demonstrated an efficacy of up to 79% in preventing symptomatic RSV infections[2].

Bavarian Nordic has also previously reported strong results from a Phase 2 trial of MVA-BN RSV in 421 older adults, 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 trial 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[3].

MVA-BN RSV has been granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration for active immunization for prevention of lower respiratory tract disease caused by RSV in adults aged 60 years or older.

About Bavarian Nordic
Bavarian Nordic is a fully integrated vaccine 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.

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