Press Release

Bavarian Nordic Completes Enrollment in Global Phase 3 Trial of RSV Vaccine Candidate for Older Adults

- 20,000 adults aged 60 years and older have been enrolled according to plan
- Top-line results are anticipated in mid-2023

COPENHAGEN, Denmark, December 22, 2022 – Bavarian Nordic A/S (OMX: BAVA) announced today that the Company has completed the planned enrollment of subjects in the global, randomized, double-blind Phase 3 clinical trial of its investigational respiratory syncytial virus (RSV) vaccine candidate, MVA-BN® RSV in adults ≥60 years of age.

The trial was initiated in April 2022 and has now enrolled over 20,000 subjects within the expected time frame at 120 sites across the U.S. and Germany. The primary objective of the study will assess the efficacy of the vaccine candidate against lower-respiratory tract disease (LTRD) caused by RSV compared to placebo. Topline results are anticipated in mid-2023.

In parallel, Bavarian Nordic is also running a global Phase 3 trial of its COVID-19 booster vaccine candidate. Enrollment in this trial is progressing well and on target to allow for initial results to become available in early 2023 as previously communicated.

"The RSV Phase 3 trial is our largest single study to-date, and we are pleased to complete target enrollment within the projected timeframe. We would like to thank all the clinical trial sites and their personnel for their significant contribution to advancing our RSV vaccine candidate, and not least the many volunteers without whom innovation and progress in the development of novel vaccines would not be possible. Our RSV vaccine has shown great promise in clinical trials thus far confirming its significant potential to change the lives of adults at risk from RSV-related disease, and we look forward to seeing the results from the Phase 3 trial next year, " said Paul Chaplin, President and Chief Executive Officer of Bavarian Nordic.

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
MVA-BN RSV is based on Bavarian Nordic's proprietary vaccine platform technology, MVA-BN, and incorporates five distinct RSV antigens to stimulate a broad immune response against both RSV subtypes (A and B). In a clinical Phase 2 double-blinded, placebo-controlled human challenge trial, a significant reduction in viral load was reported in vaccinated subjects versus placebo and MVA-BN RSV demonstrated a vaccine efficacy of up to 79% in preventing symptomatic RSV infections[2].

MVA-BN RSV has been granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration as well as access to the European Medicines Agency's priority medicines (PRIME) scheme for active immunization for prevention of LTRD caused by RSV in adults ≥60 years of age.

About Bavarian Nordic

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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 mpox. The vaccine is also approved in Canada and Europe. 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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[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

[2] https://www.resvinet.org/uploads/2/2/2/7/22271200/abstract_booklet_rsvvw21.pdf