Press Release

Bavarian Nordic Announces Breakthrough Therapy Designation for its RSV Vaccine Candidate for the Prevention of Respiratory Syncytial Virus in Older Adults

COPENHAGEN, Denmark, February 14, 2022 – Bavarian Nordic A/S (OMX: BAVA) announced today that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation for the Company's vaccine candidate, MVA-BN RSV, for active immunization for prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV) in adults aged 60 years or older.

A Breakthrough Therapy Designation is designed to expedite the development and regulatory review of medicines that are intended to treat a serious condition. The designation has been granted upon the assessment of preliminary clinical evidence for MVA-BN RSV, indicating that the vaccine candidate may demonstrate substantial improvement over available therapy on a clinically significant endpoint[1]. The designation provides an option to work more closely with FDA for the development and review of MVA-BN RSV.

Paul Chaplin, President and CEO of Bavarian Nordic, said: "The development of an RSV vaccine is one of our main priorities that could help fulfil the significant unmet need for a preventative therapy, particularly for the elderly who may be at risk from serious complications from the disease. Our candidate has a clearly differentiated approach, as it employs five RSV-specific antigens with an aim to stimulate a broad antibody and cellular immune response against RSV. Based on the encouraging results demonstrated in a human challenge trial last year, we recently announced our plans to initiate a Phase 3 study this year and look forward to working closely with the FDA on our path towards licensure of the vaccine."

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.

It is estimated, that each year RSV-induced infections lead to approximately 177,525[2] 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 2021, 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

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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[3].

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[4].

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.

Bavarian Nordic plans to initiate a large Phase 3 trial of MVA-BN RSV in 2022.

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.

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[1] http://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy
[2] 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
[3] https://www.resvinet.org/uploads/2/2/2/7/22271200/abstract_booklet_rsvvw21.pdf
[4] Jordan E. et al. 2010. J. Infect, Dis. 28:223(6). 1062-1072