Press Release

Bavarian Nordic Announces Grant of PRIME Eligibility from the European Medicines Agency for its RSV Vaccine Candidate for the Prevention of Respiratory Syncytial Virus in Older Adults

COPENHAGEN, Denmark, June 28, 2022 – Bavarian Nordic A/S (OMX: BAVA) announced today that the European Medicines Agency (EMA) has granted access to its priority medicines (PRIME) scheme for MVA-BN® RSV in active immunization for the prevention of lower respiratory tract disease (LRTD) caused by Respiratory Syncytial Virus (RSV) in adults ≥60 years of age. There are no approved vaccines for RSV, and access to PRIME has been granted upon an assessment that the available clinical data overall show the potential of MVA-BN-RSV to address the unmet medical need in the proposed target population.

PRIME is a scheme launched by EMA to enhance support for the development of medicines that target an unmet medical need. Through PRIME, EMA offers early support to medicine developers to optimize the generation of robust data on a medicine's benefits and risks and enable accelerated assessment of medicines applications. This will help patients to benefit as early as possible from therapies that may significantly improve their quality of life. According to EMA, only 1 in 4 requests for PRIME eligibility are granted.

For more information on the PRIME scheme, see https://www.ema.europa.eu/en/human-regulatory/research-development/prime-priority-medicines

Paul Chaplin, President and CEO of Bavarian Nordic, said: "Following the grant of a Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) earlier this year, we are proud to receive eligibility for PRIME access for our RSV vaccine candidate, enabling us to pursue accelerated development and review processes with the regulatory authorities in both U.S. and Europe. These grants highlight the potential of our vaccine to fulfil the significant unmet need for a preventative therapy, particularly for the elderly who may be at risk from serious complications from RSV. As we continue the enrolment into the global Phase 3 trial of the vaccine, we look forward to working closely with both EMA and the FDA on accelerating the pathway towards approval."

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[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.

Bavarian Nordic A/S
Philip Heymans Alle 3
DK-2900 Hellerup
Tel. +45 33 26 83 83
www.bavarian-nordic.com
CVR-no. 16 27 11 87
LEI Code: 2138006JCDVYIN6INP51

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 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[2].

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[3].

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

In February 2022, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation for 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.

In April 2022, Bavarian Nordic initiated a global, randomized, double-blind Phase 3 trial (VANIR) of MVA-BN RSV, planned to enroll 20,000 adults aged 60 years and older. The trial is being conducted at approximately 115 sites across the U.S. and Germany and 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 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 also approved for protection against smallpox and monkeypox in Canada, and as a smallpox vaccine in 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.

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

[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
[3] Jordan E. et al. 2010. J. Infect, Dis. 28:223(6). 1062-1072