



## Bavarian Nordic Completes Case Accrual for RSV Phase 3 Clinical Trial

- Pivotal Phase 3 trial of MVA-BN<sup>®</sup> RSV has accrued enough cases required for efficacy analysis
- Topline results expected around mid-2023

**COPENHAGEN, Denmark, April 11, 2023** - Bavarian Nordic A/S (OMX: BAVA) announced today that the Phase 3 clinical trial of MVA-BN<sup>®</sup> RSV, the Company's investigational vaccine for the prevention of respiratory syncytial virus (RSV) in adults  $\geq 60$  years of age, has now accrued the number of cases required to complete the primary efficacy analysis, which is expected around mid-2023. Adjudicated data have confirmed enough cases with both 2+ symptoms and 3+ symptoms as required in the trial.

The global, randomized, placebo-controlled, double-blind Phase 3 VANIR clinical trial has enrolled more than 20,000 participants across more than 100 centers in 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.

"We are encouraged by reaching the required number of cases in the study in only one season, which provides a robust basis for completing the efficacy analysis later this year on our path towards registration of the vaccine. 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, and we are committed to bringing this vaccine to the market to help minimize the burden from RSV-related disease in the older population," 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. By the age of 2 years, most infants have experienced their first RSV infection, followed by frequent reinfections throughout life, because RSV infections do not induce a sustainable, long-lasting protective immunity.

Infants, older adults and immunocompromised individuals are most susceptible to serious complications from infection with RSV. An estimated 5.2 million cases of RSV occurred in high-income countries among adults aged  $\geq 60$  years in 2019, leading to 470,000 hospitalizations and 33,000 in-hospital deaths<sup>1</sup>, thus representing a significant burden to the healthcare system. Currently there is no approved vaccine against RSV.

### 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 88.5% when active RSV infection was confirmed by cell culture<sup>2</sup>.

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  $\geq 60$  years of age.

### About Bavarian Nordic

Bavarian Nordic is a fully integrated vaccines company focused on the research and development, manufacturing and commercialization of life-saving vaccines. We are a global leader in smallpox and mpox vaccines, which have been developed through our long-standing partnership with the U.S. Government to enhance the public health preparedness. Our commercial product portfolio furthermore contains market-leading vaccines against rabies and tick-borne encephalitis. Using our live virus vaccine platform technology, MVA-BN<sup>®</sup> and in-licensed technologies, 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 late-stage development programs

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for an RSV vaccine for older adults and a next generation COVID-19 vaccine. For more information visit [www.bavarian-nordic.com](http://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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<sup>1</sup> Savic, M.; Penders, Y.; Shi, T.; Branche, A.; Pirçon, J.-Y. Respiratory syncytial virus disease burden in adults aged 60 years and older in high-income countries: A systematic literature review and meta-analysis. *Influenza Other Respir Viruses* 2023, 17, e13031.

<sup>2</sup> <https://www.medrxiv.org/content/10.1101/2022.12.02.22283030v1.full.pdf>