



BAVARIAN NORDIC

Company Announcement

Bavarian Nordic Announces License and Supply Agreement with Nuance Pharma on the Development and Commercialization of Respiratory Syncytial Virus (RSV) Vaccine for Adults in China and Selected Asian Markets

- Bavarian Nordic to receive up to USD 225 million in upfront and milestone payments in addition to tiered, double-digit royalties
- Nuance Pharma obtains rights to commercialize MVA-BN[®] RSV in Chinese Mainland, Hong Kong, Macau, Taiwan, South Korea and Southeast Asia and will be responsible for all costs, including development and regulatory
- Bavarian Nordic will manufacture and supply commercial doses post launch

COPENHAGEN, Denmark, March 21, 2022 - Bavarian Nordic A/S (OMX: BAVA) (“the Company”) announced today, that it has entered into an exclusive license and supply agreement with Nuance Pharma, a Shanghai-based specialty pharmaceutical company, on the development and commercialization of MVA-BN[®] RSV against respiratory syncytial virus (RSV) in adults in Chinese Mainland, Hong Kong, Macau, Taiwan, South Korea and certain Southeast Asian countries¹. The agreement entails clinical development, including a Phase 3 trial to support regulatory approval of MVA-BN RSV in China, which will be conducted separately from the Company’s own Phase 3 trial planned for initiation later in the first half of 2022 to support a U.S. Biologics License Application.

Under the terms of the agreement, Bavarian Nordic will receive an upfront payment of USD 12.5 million and is eligible to receive future milestone payments of up to USD 212.5 million that are triggered upon achievement of certain clinical, regulatory, and commercial milestones, in addition to tiered, double-digit royalties on future net sales.

Nuance Pharma will assume all costs and responsibility for the clinical development, regulatory filings, and commercialization of the vaccine in territories covered by the agreement. Subject to Chinese regulatory authority (National Medical Products Administration, NMPA) approval, Phase 1 and Phase 3 trials are planned for the vaccine approval in China.

The parties have also entered into a supply agreement by which Bavarian Nordic will assume future commercial manufacturing and supply of the vaccine.

“We are pleased to partner with Nuance Pharma in our efforts to bring our late-stage RSV vaccine candidate to market. Their regional presence combined with a strong leadership and focus on respiratory diseases provides a unique first-to-market opportunity for MVA-BN RSV to fulfil the unmet need for a vaccine to prevent severe disease from RSV infections in the aging Chinese population. With our plans to initiate a self-funded Phase 3 trial of MVA-BN RSV in the USA and Germany later in the first half of 2022, we remain committed to the development and commercialization of the vaccine globally,” said Paul Chaplin, President and CEO of Bavarian Nordic.

“Nuance is thrilled to enter into this agreement with Bavarian Nordic on MVA-BN RSV, to set a new standard in the prevention of RSV, and to address the critical unmet medical needs of the highly vulnerable elderly patients. MVA-BN RSV represents an ideal fit for Nuance’s portfolio, given our focus in the respiratory space in China and the Asian markets. This is an opportune moment for us to be developing and commercializing MVA-BN RSV in the Territory, riding the wave of appreciably heightened awareness to the benefits of vaccination in the COVID-era,” commented Mark G. Lotter, CEO and Co-Founder of Nuance Pharma.

While the upfront milestone payment was not included in the 2022 financial guidance it is still too early to change the guidance given the current market uncertainty.

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 older². 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.

The Chinese target population for an RSV vaccine is estimated to be nearly 400 million people aged 60 years or older with an estimated annual growth rate of 3%.

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.

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 in vaccinated subjects (n=30) versus placebo (n=31), thus meeting the primary endpoint. In the vaccinated subjects, clinical symptoms typically associated with RSV infections were significantly reduced. Further, the vaccine demonstrated an efficacy of up to 79% in preventing symptomatic RSV infections³.

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 vaccination⁴.

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 Nuance Pharma

Nuance Pharma is a patient-centric and innovation focused biopharmaceutical company, with both clinical and commercial stage assets. Founded by Mark Lotter in 2014, with the mission to address critical unmet medical needs in China and Asia Pacific, Nuance has built a late clinical stage innovative portfolio, while maintaining a self-sustainable commercial operation. Focusing on specialty care, Nuance's portfolio represents a differentiated combination of commercial stage and innovative pipeline assets across respiratory, pain management, emergency care, and iron deficiency anemia. Through partnerships with global leading biopharma companies, Nuance has built a leading late-stage portfolio in respiratory and pain management, as well as a commercial stage portfolio in emergency care and iron deficiency anemia.

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 Brunei, Myanmar, Cambodia, Timor-Leste, Indonesia, Laos, Malaysia, the Philippines, Singapore, Thailand and Vietnam.

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.resvnet.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