Bavarian Nordic Announces Initiation of Phase 2 Trial of BN-Brachyury for the Treatment of Chordoma

- First dose has been administered in the multiple-center study
- BN-Brachyury for the treatment of chordoma received FDA Orphan Drug Designation in May 2018

COPENHAGEN, Denmark, November 1, 2018 - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) today announced that the first patient has been dosed in a Phase 2 study evaluating its novel, targeted cancer immunotherapy, BN-Brachyury, and radiation in patients with advanced chordoma.

Chordoma is a rare cancer that occurs in the bones of the skull base and spine, resulting in approximately 1,000 new cases being diagnosed in the United States and Europe annually. The brachyury protein has been shown to be universally overexpressed in chordoma tumors, while not being found in most normal tissue. The presence of brachyury in epithelial solid tumors has been highly correlated with metastatic disease, multi-drug resistance and decreased survival rates. BN-Brachyury’s prime-boost vaccination regimen has been optimized to include the gene for brachyury, as well as costimulatory molecules (TRICOM) known to increase immune activation. Prior data suggests that BN-Brachyury can safely target brachyury and induce brachyury-specific T-cell immune responses.

“While upfront surgical resection or definitive radiation can result in cure for some patients, we know that the majority of patients with this disease are not cured. Those who are not cured will almost all go on to have advanced disease, for which there are no therapeutic options known to result in defined clinical benefit,” said Chris Heery, M.D., the Chief Medical Officer of Bavarian Nordic and member of the Medical Advisory Board of the Chordoma Foundation. “The almost universal expression of brachyury in chordoma makes it a prime candidate for our targeted immunotherapy. The initiation of the Phase 2 study serves as a significant step in the evaluation of BN-Brachyury as an effective treatment for patients with this rare disease.”

The Phase 2, multiple-site trial will assess the effectiveness of BN-Brachyury and radiation therapy in patients with advanced chordoma. The study is expected to enroll up to 29 patients, in a two-stage design. If the threshold of activity is reached in stage 1, the study will proceed to stage 2 and full enrollment. Patients will be administered a primer of the highly attenuated, non-replicating vaccinia virus MVA-BN-Brachyury, followed by a booster of the recombinant fowlpox virus FPV-Brachyury and radiation therapy. The study aims to determine if the combination therapy results in a clinically meaningful objective response rate (ORR) within 12 months of radiation therapy, a timeframe during which historical controls show an ORR of less than 5% with radiation alone.

“For more than a decade, we have supported patients and research centers across the United States and Europe in their quest to find and develop better treatment options for this devastating cancer,” said Josh Sommer, Founder and Executive Director of the Chordoma Foundation. “Although there has been a dramatic increase in chordoma research over the years, the rarity and complexity of the disease has left it relatively underserved. Bavarian Nordic’s cancer immunotherapy, BN-Brachyury, is a welcome, needed and promising advancement in the treatment of patients with advanced chordomas.”

In May 2018, the FDA granted orphan drug designation to BN-Brachyury for the treatment of chordoma. The FDA’s Office of Orphan Drug Products grants orphan status to support development of medicines for safe and effective treatment, diagnosis or prevention of rare diseases or disorders that affect fewer than 200,000 people in the United States. Orphan drug designation may provide certain benefits, including a seven-year period of market exclusivity if the drug is approved, tax credits for qualified clinical trials and an exemption from FDA application fees.
For more information on trial, please visit: https://www.clinicaltrials.gov/ct2/show/NCT03595228

**About BN-Brachyury**

BN-Brachyury is a novel prime-boost cancer immunotherapy candidate, developed in collaboration with the National Cancer Institute (NCI). The product candidate consists of two different vaccine components; MVA-BN and fowlpox or FPV, which have been modified to express brachyury and to encode three costimulatory molecules, known as TRICOM. Brachyury is a tumor-associated antigen that is overexpressed in major solid tumor indications, as well as several rare, ultra-orphan cancer indications, and is reported to play a key role in the metastasis and progression of tumors. Tumors that overexpress brachyury are believed to be highly resistant to standard therapies, including radiation and chemotherapy, and are associated with decreased survival rates.

**About Bavarian Nordic**

Bavarian Nordic is a fully integrated biotechnology company focused on the development of innovative and safe therapies against cancer and infectious diseases. Using our live virus vaccine platform technology, MVA-BN®, we have created a diverse portfolio of proprietary and partnered product candidates intended to improve the health and quality of life for children and adults. We supply our MVA-BN® non-replicating smallpox vaccine to the U.S. Strategic National Stockpile and other government stockpiles. The vaccine is approved in the European Union and in Canada (under the trade names IMVANEX® and IMVAMUNE® respectively). In addition to our long-standing collaboration with the U.S. government on the development of medical countermeasures, our infectious disease pipeline comprises a proprietary RSV program as well as vaccine candidates for Ebola, HPV, HBV and HIV, which are developed through a strategic partnership with Janssen. Additionally, in collaboration with the National Cancer Institute, we have developed a portfolio of active cancer immunotherapies, designed to alter the disease course by eliciting a robust and broad anti-cancer immune response while maintaining a favorable risk-benefit profile. Through multiple industry collaborations, we seek to explore the potential synergies of combining our immunotherapies with other immune-modulating agents, e.g. checkpoint inhibitors. For more information visit www.bavarian-nordic.com or follow us on Twitter @bavariannordic.

**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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