

Bavarian Nordic Receives FDA Orphan Drug Designation for BN-Brachyury for the Treatment of Chordoma

- Phase 2 Study in Metastatic Chordoma to Initiate in second half of 2018

COPENHAGEN, Denmark, May 2, 2018 - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) announced today that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to the Company's novel cancer vaccine BN-Brachyury for the treatment of chordoma.

Chordoma is a rare type of cancer that develops along the spine, with presentation occurring at one of three main sites: sacrum, mobile spine, or the clivus (skull base). It shares many characteristics with sarcomas, but is often characterized as a bone tumor. Chordomas are complicated tumors to treat, due to the proximity to and/or involvement with critical structures such as the brainstem, spinal cord, and important nerves and arteries. Nuclear Brachyury (T) expression has emerged as a "sensitive and fairly specific" diagnostic marker for chordoma¹. A growing body of literature suggests that it contributes significantly to chordoma pathogenesis.

A phase 2 study in patients with metastatic chordoma will initiate in the second half of 2018, enrolling up to 25 patients, with a goal of increasing overall response rates for patients receiving the BN-Brachyury vaccine in combination with radiation therapy. In early 2018, the Company initiated an open-label Phase 1 trial to evaluate the safety and tolerability of the BN-Brachyury vaccine. This trial is currently enrolling up to 10 patients with metastatic or unresectable, locally advanced malignant solid tumors. The primary endpoint of the study is safety and tolerability, and secondary endpoints include immunologic responses, as measured by an increase in brachyury-specific T-cells and other tumor-associated antigens.

"We are very happy to obtain orphan status for our chordoma program, given the severe lack of effective therapies for this population of patients. Chordoma is a unique tumor where the brachyury protein is universally overexpressed; which presents us with an exceptional opportunity to use our vaccine in a optimally targeted manner. We plan to initiate our phase 2 study in the fall of this year and to rapidly progress this program through proof of concept," said Paul Chaplin, President and CEO of Bavarian Nordic.

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.

Chordoma is diagnosed in just one in one million people per year. That means that about 300 patients are diagnosed with chordoma each year in the United States, and about 700 in all of Europe. At any given time, it is estimated that fewer than one in 100,000 people are living with chordoma.

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 a prime (MVA-BN) and a booster dose (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 IMVAMUNE® non-replicating smallpox vaccine to the U.S. Strategic National Stockpile and other government stockpiles. The vaccine is approved in the European Union (under the trade name IMVANEX®) and in Canada. Registration studies are currently underway in the U.S. In addition to our long-standing collaboration with the U.S. government on the development of IMVAMUNE® and other 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](https://twitter.com/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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ⁱ Miettinen M, Wang Z, Lasota J, Heery C, Schlom J, Palena C. Nuclear Brachyury Expression Is Consistent in Chordoma, Common in Germ Cell Tumors and Small Cell Carcinomas, and Rare in Other Carcinomas and Sarcomas: An Immunohistochemical Study of 5229 Cases. Am J Surg Pathol. 2015;39(10):1305-1312.