



BAVARIAN NORDIC

Company Announcement

Bavarian Nordic Reports Positive Result from ongoing Phase 2 Trial Evaluating BN-Brachyury in Chordoma

COPENHAGEN, Denmark, June 5 2019 - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) announced today that the Data and Safety Monitoring Board (DSMB) confirmed a partial response in one of the first chordoma patients recruited and treated with the combination of BN-Brachyury and radiation treatment at the first evaluation timepoint. As this meets the initial pre-defined threshold of activity for the first stage of the Phase 2 trial, recruitment will be expanded to enroll another 19 patients, while the first 10 patients continue to be treated and evaluated.

The proof-of-concept Phase 2 trial was designed to determine if the combination of BN-Brachyury and radiation therapy, the current standard of care, results in a clinically meaningful objective response rate (ORR), measured as a percentage of patients with a decrease in tumor size within 12 months of radiation therapy. This is a timeframe during which historical controls show an ORR of less than 5% with radiation alone.

The first stage of the study enrolled 10 patients between November 2018 and January 2019. The study will now advance into stage 2, expanding enrollment to a total of 29 patients with an overall goal of achieving 4 patients with objective responses, corresponding to an ORR of ~14% for all patients enrolled for the study to be considered successful.

“We are excited to share these first Phase 2 data from our current immuno-oncology pipeline, and also the first data suggesting clinical activity of combining our targeted immunotherapy with standard of care,” said Paul Chaplin, President and Chief Executive Officer of Bavarian Nordic. “We are encouraged by the rapid progression of this trial, which may offer final results sooner than anticipated and hope this initial finding is confirmed in a larger number of patients and that BN-Brachyury may improve treatment options for patients with chordoma.”

For more information on how to take part in this trial, please visit the website of the Chordoma Foundation, who is working to advance new therapies to improve the lives of chordoma patients, and is also actively supporting Bavarian Nordic in the study: <https://www.chordomafoundation.org/clinical-trials/bn-brachyury-phase-2/>

About chordoma

Chordoma is a rare cancer that universally overexpresses brachyury and occurs in the base of the skull and spine. There are approximately 1,000 new cases of chordoma diagnosed in the U.S. and E.U. annually, and 10,000 people living with the disease. Current treatments have resulted in limited success against chordoma, with a historical objective response rate of less than 5% with radiation alone.

About BN-Brachyury

Bavarian Nordic’s novel immuno-oncology candidate, BN-Brachyury, targets a key prognostic indicator of several common (e.g. colorectal, prostate, small cell lung, and triple negative breast cancer) and rare or orphan (e.g. chordoma, thyroid, neuroendocrine) cancers. Brachyury is a transcription factor that is believed to play a prominent role the metastasis and progression of tumors. Expression of brachyury is highly correlated with metastatic disease, poor overall survival, multi-drug resistance, and decreased survival rates. BN-Brachyury utilizes a prime-boost vaccination regimen that has been optimized to include the gene for brachyury and other molecules known to increase immune activation. Patients will receive a primer of MVA-BN Brachyury followed by booster doses of the recombinant fowlpox virus. A previous phase 1 trial demonstrated that MVA-BN-Brachyury could safely target brachyury and induce brachyury-specific T-cell immune responses.

BN-Brachyury has received orphan drug status from the FDA.

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About Bavarian Nordic

Bavarian Nordic is a fully integrated biotechnology company focused on the development of innovative 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 unlock the power of the immune system to improve public health with a focus on high unmet medical needs. We supply our MVA-BN non-replicating smallpox vaccine to the U.S. SNS 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](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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