



BAVARIAN NORDIC

Company Announcement

Bavarian Nordic Announces Initiation of Phase 2 Trial Evaluating the Combination Therapy of CV301 and Atezolizumab in Bladder Cancer

- Bavarian Nordic-sponsored study has commenced dosing
- Study marks the second of three planned Phase 2 combination studies of CV301 with checkpoint inhibitors in solid tumors

COPENHAGEN, Denmark, September 18, 2018 - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) today announced that the first patient has been dosed in a Phase 2 study evaluating the combination therapy of its cancer immunotherapy, CV301, and Roche's checkpoint inhibitor, atezolizumab (TECENTRIQ®), for the treatment of patients with locally advanced or metastatic urothelial bladder cancer.

Bavarian Nordic's CV301 targets tumor-associated antigens, CEA and MUC1, which are overexpressed on multiple solid tumors, including bladder cancer. Preclinical data has shown that vaccination resulted in the induction of tumor specific T-cells that infiltrated the tumor resulting in the upregulation of PD-L1 on tumor cells. The upregulation of PD-L1 is a marker indicating the tumor is under attack from T-cells, presenting an opportunity for a greater response in patients who might otherwise not benefit from treatment with a checkpoint inhibitor alone.

CV301 is administered in an innovative manner designed to generate a potent and durable T-cell response. Patients receive an enhanced priming regimen of the highly attenuated, non-replicating vaccinia virus MVA-BN-CV301 in 4 different injection sites on days 1 and 22, followed by boosters of the recombinant fowlpox virus FPV-CV301 at tapering intervals throughout the two years they are receiving atezolizumab.

The Phase 2, single-arm, multi-institutional clinical trial is designed to study the combination of CV301 with atezolizumab as a first-line treatment for patients with urothelial bladder cancer who are not eligible for cisplatin-containing chemotherapy (Cohort 1) and as a second-line treatment for patients who have previously been treated with cisplatin-based chemotherapies. The study is expected to enroll 68 patients, using a two-stage design within each cohort.

Stage 1 is planned to enroll approximately 40% of the subjects, with a threshold of around 25% of the subjects needing to achieve an objective response before enrolling the rest of the patients in Stage 2. Key secondary measures will also be evaluated, including: progression free survival (PFS), overall survival (OS) and duration of response.

"Today represents another large step forward in the development of our CV301 program and understanding its potential in bladder cancer," said Paul Chaplin, President and CEO of Bavarian Nordic. "We are hopeful that the preclinical data demonstrating a synergistic effect of CV301 with checkpoint inhibition will translate into a new, much-needed treatment option for patients living with this disease."

For more information on the trial, please visit: <https://clinicaltrials.gov/ct2/show/study/NCT03628716>

About CV301

CV301 is an active immunotherapy candidate that targets two tumor-associated antigens, CEA and MUC1, long known to be overexpressed in most solid tumors. The poxvirus-based prime/boost vaccine incorporates a modified version of vaccinia (MVA-BN, a proprietary technology of Bavarian Nordic) as a priming dose, followed by multiple fowlpox boosts, and encodes the TRICOM costimulatory molecules. Preclinical data shows that antigen specific vaccination results in T cell infiltration into areas of antigen expression and upregulation of PD-

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L1 on antigen expressing tumor cells. The upregulation of PD-L1 is a marker indicating the tumor is under attack from T-cells, presenting an opportunity for a greater response in patients who might otherwise not benefit from treatment with a checkpoint inhibitor alone.

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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