



BAVARIAN NORDIC

Company Announcement

Bavarian Nordic Announces Top-line Results from Phase 2 Clinical Trial of BN-Brachyury in Chordoma

- Study showed signs of clinical activity, but failed to meet the primary endpoint of the Phase 2 study
- Two ongoing phase 1 trials are exploring the intravenous administration of two different MVA-based brachyury-targeting investigational products in chordoma.

COPENHAGEN, Denmark, December 18, 2020 - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) today announced top-line results from a Phase 2 clinical study evaluating the targeted immunotherapy candidate, BN-Brachyury in the treatment of advanced chordoma, a rare cancer occurring in the base of the skull and spine. While the study failed to meet its primary endpoint, it provided evidence of clinical activity.

The Phase 2 study enrolled 29 patients, which were treated with a combination of the prime-boost vaccine candidate, BN-Brachyury and the current standard of care, radiation therapy. Whereas radiation has been shown to inflame the tumor, thereby releasing cancer antigens, BN-Brachyury has been designed to teach T cells to attack and kill brachyury-expressing tumor cells. Patients were monitored over a period of 12 months after radiation therapy, a timeframe during which historical controls show an objective response rate (ORR) of less than 5% with radiation alone. The overall goal of the study was to achieve four patients with objective responses, corresponding to an ORR of approximately 14% for all patients enrolled.

Two patients achieving objective responses were observed in the study, as measured by the predefined conventional assessment criteria (RECIST) according to the study protocol. In addition, 19 patients have stable disease, while the rest progressed, or left the study before the assessment was performed. The RECIST criteria assumes tumors are spherical and assesses their size by measuring the tumor diameter. This method may, however, underestimate the chordoma tumor shrinkage, as a retrospective analysis of six of the patients enrolled into the study revealed four of these patients had an objective response when tumor shrinkage was evaluated by a volumetric assessment. These intriguing signs of clinical efficacy are also supported by two chordoma patients that have recorded either a volumetric objective response, or a symptomatic response following the intravenous administration of BN-Brachyury in a separate on-going trial.

While no further studies of BN-Brachyury administered subcutaneously are planned, the signs of clinical efficacy that have been observed support brachyury as a potentially important immunotherapy target, particularly for chordoma. The Company is now looking to adapt ongoing trials to investigate MVA-based vaccines encoding brachyury administered intravenously - a promising approach designed to utilize broader aspects of the immune response while improving T cell activation and function.

“Chordoma is known for its refractoriness to all treatments investigated so far. The observation of some hints of efficacy with our immunotherapy approach is encouraging enough for us to continue with our efforts to develop a new treatment for this highly unmet medical need,” said Paul Chaplin, President and Chief Executive Officer of Bavarian Nordic.

About Bavarian Nordic

Bavarian Nordic is a fully integrated vaccines company focused on the development, manufacture 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. of a non-replicating smallpox vaccine, which has been approved by the FDA under the trade name JYNNEOS®, also for the protection against monkeypox. The vaccine is approved as a smallpox vaccine in Europe under the trade name IMVANEX® and in Canada under the trade name IMVAMUNE®. Our commercial

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product portfolio furthermore contains the market-leading vaccine Rabipur®/RabAvert® against rabies and Encepur® against 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, MVABEA®, which is licensed to Janssen. 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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