Bavarian Nordic Announces First Patient Treated in a Phase 2 Study Evaluating its Immunotherapy Candidate CV-301 in Bladder Cancer

KVISTGAARD, Denmark, April 28, 2014 - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) announced today the first patient has now been treated in a randomized, prospective Phase 2 study of its active immunotherapy candidate CV-301 in bladder cancer.

In the study, sponsored by the National Cancer Institute, 54 patients with high grade non-muscle invasive bladder cancer whose cancer has progressed after initial BCG (Bacillus Calmette-Guerin) treatment will be treated with BCG alone or in combination with CV-301. BCG has been approved in many countries to prevent the recurrence of superficial bladder tumors.

The study’s primary endpoint is to determine if there is an improvement in disease-free survival for patients receiving BCG treatment and CV-301 immunotherapy compared to those receiving BCG treatment alone. It is the hypothesis that the combined administration of BCG and CV-301 may augment the BCG-induced cytotoxic T lymphocyte response against bladder cancer cells expressing MUC-1 and/or CEA and potentially reverse BCG failure in patients that progressed following a prior induction course of the therapy. Lead investigator for the study is Piyush K. Agarwal, M.D., Head, Bladder Cancer Section, National Cancer Institute, NIH.

An abstract on this study, entitled “A Randomized, Prospective, Phase II Study to Determine the Efficacy of Bacillus Calmette-Guerin (BCG) given in combination with PANVAC versus BCG given alone in Adults with High Grade Non-Muscle Invasive Bladder Cancer (NMIBC) who failed at least 1 Induction Course of BCG,” has been accepted for presentation in the Trials in Progress section at the 2014 ASCO Annual Meeting in Chicago, IL from May 30 to June 3. Abstract #TPS4590. Poster Board: #157B. Presenter: Sam Joseph Brancato, M.D.

James B. Breitmeyer, President of Bavarian Nordic’s Cancer Immunotherapy Division said: “We are very pleased that development of our cancer immunotherapy candidates is expanding further into new indications and new combination approaches. We are hopeful that combination therapy with CV-301 will yield positive results for bladder cancer patients who currently face limited treatment options.”

Anders Hedegaard, President & CEO.

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About CV-301
CV-301 (formerly developed as PANVAC) is an immunotherapy product candidate for the treatment of multiple cancers. It originates from the same poxvirus technology platform as PROSTVAC.

Both PROSTVAC and CV-301 are prime-boost vaccines sequentially combining two different poxviruses (vaccinia and fowlpox). Collectively, these two product candidates, along with earlier generations of these vaccines, have been the subject of over 30 clinical trials with more than 1,100 patients actively treated for prostate, breast, lung, colorectal, gastric, pancreatic, ovarian and other cancers. These extensive clinical studies suggest
that the product candidates are well-tolerated with the ability to induce specific immune responses directed against the relevant tumor-associated antigens.

While PROSTVAC incorporates a single antigen over-expressed in prostate cancer (PSA), CV-301 incorporates two antigens (CEA and MUC-1) that are over-expressed in other major cancers, including breast, colon, bladder and other cancers, which makes CV-301 potentially applicable in various cancers.

About bladder cancer
In developed countries, more than 250,000 people are diagnosed every year with bladder cancer. Approximately one third of the patients present with high-grade non-muscular invasive bladder cancer, which is extremely difficult to treat due to high recurrence and progression rates. The standard of care is a single induction of intravesical BCG treatment followed by maintenance therapy. Unfortunately, high recurrence rates of 50% lead to a significant unmet need.

Bladder cancer is well known to respond to immunotherapy, and BCG was the first modern immunotherapy to be approved in many countries to prevent the recurrence of superficial bladder tumors. BCG is a vaccine against tuberculosis that is prepared from attenuated (weakened) live bovine tuberculosis bacillus that has lost its virulence in humans. BCG immunotherapy is effective in up to 2/3 of the cases at this stage. The mechanism by which BCG prevents recurrence is unknown, but may involve a localized immune reaction which clears residual cancer cells.

Although a second induction course can be used in patients who fail a single induction course of BCG, only 35% of patients who failed an initial induction course will experience 12 month disease-free survival after receiving a second induction course. For those patients failing a second induction course, radical cystectomy with pelvic lymphadenectomy is the recommended treatment, although it has a high morbidity rate and a small but real mortality rate. Therefore, there is an unmet need for localized treatment for patients who fail an initial induction course of BCG that can potentially improve upon the poor results of a second induction course of BCG.

About Bavarian Nordic
Bavarian Nordic is an international biotechnology company developing and manufacturing novel cancer immunotherapies and vaccines for infectious diseases. Lead product candidates are PROSTVAC®, an immunotherapy product candidate for advanced prostate cancer that is the subject of an ongoing pivotal Phase 3 clinical trial and IMVAMUNE®, a non-replicating smallpox vaccine candidate in Phase 3 development, which is being developed and supplied for emergency use to the U.S. Strategic National Stockpile under a contract with the U.S. Government. The vaccine is approved in Canada under the trade name IMVAMUNE and in the European Union under the trade name IMVANEX®.

Bavarian Nordic's shares are listed on NASDAQ OMX Copenhagen under the symbol BAVA (Reuters: BAVA.CO, Bloomberg: BAVA.DC). The company has a sponsored Level 1 ADR program listed in the US (OTC) under the symbol BVNRY.

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. 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.