Bristol-Myers Squibb Signs Exclusive Agreement with Bavarian Nordic for PROSTVAC®, a Prostate-Specific Antigen-Targeting Cancer Immunotherapy

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Bavarian Nordic to receive up to $975 million, inclusive of $60 million upfront and potential exercise payment; potential development, regulatory and commercialization milestone payments; additional tiered double-digit royalties on future sales

KVISTGAARD, Denmark & NEW YORK--(BUSINESS WIRE)--Bavarian Nordic (OMX:BAVA) (OTC:BVNRY) and Bristol-Myers Squibb Company (NYSE:BMY) announced today an agreement that provides Bristol-Myers Squibb an exclusive option to license and commercialize PROSTVAC®, Bavarian Nordic’s investigational Phase 3 prostate-specific antigen (PSA)-targeting cancer immunotherapy in development for the treatment of asymptomatic or minimally symptomatic metastatic castration-resistant prostate cancer (mCRPC).

Under terms of the agreement, Bavarian Nordic will receive an upfront payment of $60 million. Bristol-Myers Squibb can exercise the option in its sole discretion within a designated time after data is available from the ongoing Phase 3 trial. Bavarian Nordic would be entitled to a payment of $80 million upon exercise of the option plus additional incremental payments starting at $50 million, but with a potential to exceed $230 million should the median overall survival benefit of PROSTVAC exceed the efficacy seen in Phase 2 results. Furthermore, Bavarian Nordic could receive regulatory milestone payments of $110 million, up to $495 million in sales milestones as well as tiered double-digit royalties on future sales of PROSTVAC. The parties have also agreed to enter into a supply contract, under which Bavarian Nordic will undertake the future commercial manufacturing of PROSTVAC.

An investigator sponsored Phase 2 study is currently in the planning stages to investigate the combination of Bristol-Myers Squibb’s YERVOY (ipilimumab) and PROSTVAC. The companies have also entered into an agreement by which they may conduct one or more exploratory combination studies of PROSTVAC and agents from Bristol-Myers Squibb’s immuno-oncology portfolio.

“While additional treatment options have become available, metastatic castration-resistant prostate cancer remains largely incurable,” said Michael Giordano, Head of Development, Oncology, Bristol-Myers Squibb. “Our agreement with Bavarian Nordic reflects our commitment to following the emerging science in immuno-oncology and supports our strategy to transform the treatment of cancer across multiple tumor types, lines of therapy and stages of disease.”

Bristol-Myers Squibb has an ongoing Phase 3 program for YERVOY in prostate cancer, and scientific rationale exists to evaluate PROSTVAC in combination with YERVOY, and other agents from Bristol-Myers Squibb’s immuno-oncology portfolio.

“We are proud to partner with Bristol-Myers Squibb whose excellence and leadership in immuno-oncology provides a strong foundation for advancing PROSTVAC, which has the potential to become an essential component in the treatment of prostate cancer,” said Paul Chaplin, Ph.D. and Chief Executive Officer of Bavarian Nordic. “Leveraging the capabilities of Bristol-Myers Squibb’s science, we look forward to exploring the full potential of PROSTVAC in the future treatment paradigm of prostate cancer.”

About PROSTVAC

PROSTVAC is a ready to use immuno-oncology agent that stimulates an immune response that attacks prostate cancer cells. Administered subcutaneously, PROSTVAC employs Bavarian Nordic’s active immunotherapy (vaccinia-fowlpox/TRICOM) technology platform. When PSA-TRICOM is presented to the immune system in the PROSTVAC regimen, cytotoxic T lymphocytes (CTLs) are generated that may recognize and kill PSA-expressing cancer cells and trigger an immune response to other tumor antigens. PROSTVAC is currently being evaluated in a global, randomized, double-blind, placebo-controlled phase 3 study (PROSPECT), that has fully enrolled at 1,298 patients with asymptomatic or minimally symptomatic metastatic castration-resistant prostate cancer (mCRPC). Previous clinical studies of PROSTVAC, either as single-agent therapy or in combination with anti-androgen therapies, radiation therapies or immune checkpoint inhibitors have indicated possible therapeutic synergies for these treatment combinations and PROSTVAC has been generally well-tolerated.

About Prostate Cancer
Prostate cancer is the second most frequently diagnosed cancer and the sixth most deadly cancer in men. Most deaths will be caused by metastatic castration-resistant prostate cancer, which occurs when the cancer becomes resistant to standard hormonal treatment and spreads from the prostate to other organs in the body.

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. For more information, please visit www.bavarian-nordic.com or follow us on Twitter at http://twitter.com/bavariannordic.

Bavarian Nordic Forward-Looking Statement

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.

About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information, please visit www.bms.com or follow us on Twitter at http://twitter.com/bmsnews.

Bristol-Myers Squibb Forward-Looking Statement

This press release contains “forward-looking statements” relating to the option and licensing agreement between Bavarian Nordic and Bristol-Myers Squibb and the discovery, development and commercialization of Bavarian Nordic’s investigational immunotherapy. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statement can be guaranteed. Among other risks, there can be no guarantee that BMS will exercise its option to license and commercialize PROSTVAC. In addition, PROSTVAC is subject to all the risks inherent in the drug development process, and there can be no assurance that its development will be successful. Forward-looking statements in the press release should be evaluated together with the many uncertainties that affect Bristol-Myers Squibb’s business, particularly those identified in the cautionary factors discussion in Bristol-Myers Squibb’s Annual Report on Form 10-K for the year ended December 31, 2014, its Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K. Bristol-Myers Squibb undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise.

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