Company Announcement

3 March 2009

Bavarian Nordic has essentially agreed a pathway for the licensure of IMVAMUNE® with the FDA after successful end of Phase II meeting

Following the completion of the Phase II clinical development of IMVAMUNE®, a third-generation smallpox vaccine, Bavarian Nordic has held an end of Phase II meeting with the FDA to discuss the Phase III development. The meeting was a success and there was an open and highly constructive discussion with the FDA.

This meeting represented the first ever formal discussions with the agency to license a vaccine under the new legislation of the animal rule - a new regulatory path which allows the efficacy of products for indications like smallpox to be established in suitable animal efficacy models. This marks a major regulatory milestone in the successful development of IMVAMUNE®.

The animal efficacy models and phase III protocol have essentially been agreed with the agency – outlining a clear path for licensure of IMVAMUNE®. Once all protocols have been agreed with the FDA a Vaccines Related Biological Product Advisory Committee (VRBPAC) will be scheduled to ratify the license strategy. This exceptional review path will likely push the initiation of the Phase III studies into late 2010, leading to the submission of a BLA in 2013.

The outcome of the meeting has no impact on the delivery of vaccines to the Strategic National Stockpile (SNS) under the RFP-3 contract with the US government, which is still expected to be initiated in 2009.

In clinical trials to-date, IMVAMUNE® has shown to be safe and well tolerated in more than 2,400 people including more than 900 immune compromised people, either infected with HIV or diagnosed with atopic dermatitis. These clinical studies have demonstrated that IMVAMUNE® induces a fast and strong immune response, which is comparable to that induced by traditional smallpox vaccines. However, the efficacy of IMVAMUNE® cannot be established in the clinic, because smallpox no longer exist in the general population and will have to rely on the animal rule. To this end Bavarian Nordic has developed a number of efficacy models and has demonstrated IMVAMUNE® induces a comparable, if not superior, efficacy to that of traditional smallpox vaccines.

Anders Hedegaard, President & CEO of Bavarian Nordic, said: "*We are delighted with the outcome of the meeting with the FDA, as our plans to license IMVAMUNE® were essentially agreed with the FDA. Although the final protocols still have to be formally agreed with the agency there is now a clear path to registering IMVAMUNE®.*"

Asger Aamund
Chairman

Contact
Anders Hedegaard, President & CEO. Phone +45 23 20 30 64

Bavarian Nordic A/S Hejreskovvej 10A DK-3490 Kvistgaard Denmark Tel: +45 33 26 83 83 Fax: +45 33 26 83 80 www.bavarian-nordic.com CVR-no: 16 27 11 87

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.

About Bavarian Nordic
Bavarian Nordic A/S is a leading industrial biotechnology company developing and producing novel vaccines for the treatment and prevention of life-threatening diseases with a large unmet medical need. The company's business strategy is focused in three areas: biodefence, cancer and infectious diseases. Bavarian Nordic's proprietary and patented technology MVA-BN® is one of the world's safest, multivalent vaccine vectors. Bavarian Nordic has ongoing contracts with the US government for the late-stage development and procurement of the company's third-generation smallpox vaccine, IMVAMUNE®.

Bavarian Nordic is listed on NASDAQ OMX Copenhagen under the symbol BAVA.

For more information please visit www.bavarian-nordic.com

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