



BAVARIAN NORDIC

Company Announcement

23 February 2009

## Bavarian Nordic updates on Phase I/II studies with breast cancer vaccine

Bavarian Nordic today provided updated data from its clinical studies with its breast cancer vaccine, MVA-BN®-HER2, in development as therapy of metastatic breast cancer patients whose tumours over-express HER2. The study met its primary endpoint with regards to safety and by showing an immune response. Evidence of vaccine-induced anti-HER2 immune response was detected in approximately 70% of evaluated patients.

Clinically, the vaccine was well tolerated with no treatment-related severe adverse events. Currently, the disease has not progressed in 15 out of the 30 patients after a 6 month period. Also, in the group where vaccine was combined with chemotherapy, one complete response and one partial response were observed. These results confirm the positive interim data reported in 2008 and show that MVA-BN®-based, HER2 directed vaccination is a biologically active treatment for patients with HER2 positive breast cancer; however the overall immune response was moderate.

Additionally Bavarian Nordic has completed preclinical studies with an improved version of the MVA-BN®-HER2 vaccine. In those studies, the new vaccine induced up to 20-fold higher T-cell immune response as compared to the original version. Furthermore, it proved to be efficacious in additional tumour immunotherapy models in HER2 transgenic mice. The immunological situation regarding HER2 in those mice strongly resembles the situation in humans.

Based on those encouraging data from both clinical and preclinical studies Bavarian Nordic decided to advance the clinical development of MVA-BN®-HER2 in further clinical studies with the new and improved vaccine. Specifically, a new, single-site Phase I/II study in the US will be initiated by 2009 and evaluate 24 patients in both metastatic breast cancer as well as in an adjuvant therapy of breast cancer setting.

In order to strengthen Bavarian Nordic's patent portfolio in the cancer therapy field, the company has, for a minor payment, acquired from Pharmexa the families of patents that it had previously licensed.

Anders Hedegaard, President & CEO of Bavarian Nordic, said: *"I am pleased that we once again can confirm the unique safety profile of MVA-BN® and that we have been able to show immunogenicity in this patient group suffering from this severe disease. We are committed to bring this new and improved version of the HER2 vaccine further through clinical development."*

Asger Aamund  
Chairman

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#### **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<sup>®</sup> 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<sup>®</sup>.*

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

*For more information please visit [www.bavarian-nordic.com](http://www.bavarian-nordic.com)*