

## Bavarian Nordic reports successful safety data from Phase II study with IMVAMUNE®

Bavarian Nordic has completed a clinical safety report from a large Phase II study with IMVAMUNE® in HIV infected subjects that confirms the excellent safety profile of IMVAMUNE®. Within the next few days the safety report of this study will be submitted to the FDA and this will trigger a USD 25 million milestone payment under the RFP-3 contract. The clinical safety report constitutes a major part of the data package that will be used to potentially support the use of IMVAMUNE® in a declared emergency.

In support of using IMVAMUNE® as a smallpox vaccine in individuals otherwise contraindicated to receive conventional vaccinia vaccines, Bavarian Nordic has performed a large Phase II study in HIV infected subjects with CD4 counts between 200 and 750 cells/µl to compare the safety to healthy subjects.

The safety report from this study, which represents an essential part of the EUA data package, includes safety data from over 300 HIV infected and 86 healthy subjects, all of whom had no history of prior smallpox vaccination. The low number of adverse events confirmed the favourable safety profile of IMVAMUNE® in vaccinia-naïve HIV infected subjects with varying degrees of immune suppression. Indeed, there was no difference in adverse events between the healthy and HIV infected subjects, even in the most immune compromised patients (CD4 counts  $\geq$  200-350 cells/µl). IMVAMUNE® has now been tested in more than 2,200 people in 11 completed or on-going clinical studies, which includes a large proportion (more than 750) of immune-compromised people i.e. HIV infected or diagnosed with Atopic Dermatitis (AD) who are excluded from vaccination with traditional smallpox vaccines.

The complete data set from this trial is expected to be reported in the second half of 2009. The final report will include data on immunogenicity as well as long-term (6-month) safety information and will contain data from subjects enrolled in an additional study arm funded by the NIH under RFP-2 (HIV infected subjects with a history of previous exposure to a conventional smallpox vaccine).

This announcement does not change Bavarian Nordic's previously announced financial guidance for 2008.

Kvistgård, 5 November 2008

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® 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](http://www.bavarian-nordic.com)*