Company Announcement

Bavarian Nordic Provides Update on RSV Vaccine Program

- Phase 3 study failed to meet one of the success criteria of the primary objective
- RSV program to be discontinued

COPENHAGEN, Denmark, July 22, 2023 – Bavarian Nordic A/S (OMX: BAVA) today announced that its Phase 3 clinical trial of MVA-BN® RSV, a respiratory syncytial virus (RSV) vaccine candidate for adults ≥60 years of age did not meet all the primary endpoints of preventing lower respiratory tract disease (LRTD) from RSV.

The final study results showed that the vaccine candidate had a 59% efficacy in preventing at least 2 pre-defined LRTD symptoms meeting one of the efficacy criteria of the study. However, when measuring more severe LRTD based on at least 3 pre-defined symptoms, the vaccine candidate only demonstrated a 42.9% efficacy and missed the co-primary endpoint of the study.

Based on this outcome, Bavarian Nordic will discontinue its RSV program, including its partnership with Nuance Pharma to develop and launch the vaccine for selected Asian markets.

"We are disappointed that our RSV vaccine candidate was not successful in this pivotal trial," said Paul Chaplin, President and Chief Executive Officer of Bavarian Nordic. "While this outcome was unexpected and will impact our short-term growth expectations, we continue to have a unique commercial business and given the recent strong brand and market growth, this provides a solid foundation for profitable growth in the years to come."

A continued strong growth in the Company's travel vaccine business is expected to absorb the loss incurred from the lack of milestone payments of DKK 195 million, that are no longer expected under the Nuance partnership, and thus no impact on the financial guidance for 2023 is expected from the RSV program discontinuation.

About the Phase 3 trial
The global, randomized, placebo-controlled, double-blind Phase 3 VANIR clinical trial enrolled more than 20,000 adults ≥60 years of age, who were randomized 1:1 to receive either a single dose of MVA-BN RSV or placebo. The primary objective of the study was to assess the efficacy of the vaccine candidate against lower-respiratory tract disease (LTRD) caused by RSV.

About Bavarian Nordic
Bavarian Nordic is a fully integrated vaccines company focused on the research and development, manufacturing and commercialization of life-saving vaccines. We are a global leader in smallpox and mpox vaccines, which have been developed through our long-standing partnership with the U.S. Government to enhance the public health preparedness and have a strong portfolio of vaccines for travelers and endemic diseases. Using our live virus vaccine platform technology, MVA-BN® and in-licensed technologies, we have created a diverse portfolio of proprietary and partnered product candidates designed to save and improve lives by unlocking the power of the immune system. 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. All such forward-looking statements are expressly qualified by these cautionary statements and any other cautionary statements which may accompany the forward-looking statements. 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.

Bavarian Nordic A/S
Philip Heymans Alle 3
DK-2900 Hellerup
Tel. +45 33 26 83 83
www.bavarian-nordic.com
CVR-no. 16 27 11 87
LEI Code: 2138006JCDVYIN6INP51

Contacts
Europe: Rolf Sass Sørensen, Vice President Investor Relations, Tel: +45 61 77 47 43
US: Graham Morrell, Paddock Circle Advisors, graham@paddockcircle.com, Tel: +1 781 686 9600

Company Announcement no. 28 / 2023