Company Announcement

Bavarian Nordic Reports Positive Phase 3 Topline Results for Chikungunya Virus Vaccine in Adults and Adolescents

- Chikungunya vaccine candidate met all the co-primary endpoints of the Phase 3 study and was shown to be highly immunogenic in the majority of subjects 22 days post a single vaccination.
- A fast and durable response was confirmed with high levels of immunity at both 2 weeks and 6 months post a single vaccination.
- Regulatory submissions planned for 2024
- Conference call Monday, August 7 at 2 pm CEST / 8 am EDT

COPENHAGEN, Denmark, August 6, 2023 – Bavarian Nordic A/S (OMX: BAVA) announced today positive topline results from a randomized, double-blind, placebo-controlled Phase 3 clinical trial (NCT05072080) of its virus-like particle (VLP)-based chikungunya virus vaccine candidate, CHIKV VLP (PXVX0317) in adults and adolescents aged 12 to 64 years of age.

A total of 3,254 participants were enrolled and randomized to receive either a single intramuscular injection of CHIKV VLP, or placebo. The results up to day 22 post vaccination showed that CHIKV VLP was highly immunogenic in healthy adolescents and adults, as demonstrated by the strong induction of chikungunya neutralizing antibodies in 98% of vaccinees in the active group. The strong neutralizing antibody titres were equal to, or exceeded the threshold agreed with authorities as a marker of seroprotection, meeting primary objectives of the study.

Importantly, CHIKV VLP induced significant neutralizing antibodies in 97% of the subjects at 2 weeks post vaccination, confirming a rapid onset of protective levels of immunity. These responses were robust and durable, as 86% of the subjects had seroprotective levels of neutralizing antibodies 6 months post vaccination.

CHIKV VLP was well-tolerated in this adolescent and adult population and adverse events were mainly mild or moderate in nature.

“We are highly encouraged by the positive topline results now demonstrated in both Phase 3 studies of our chikungunya vaccine candidate. Our focus remains to finalize the studies and prepare for regulatory submissions next year,” said Paul Chaplin, President and CEO of Bavarian Nordic. “With a fast and durable response, our vaccine has the potential to be the best in class to prevent chikungunya infections in adolescents to elderly adults. Chikungunya that can often result in a severe and incapacitating disease affects large parts of the world, and with international travel on the rise again, our CHIKV vaccine offers a significant opportunity to address this large unmet medical need.”

In June 2023, Bavarian Nordic reported positive topline data from a similar Phase 3 study in healthy adults ≥65 years of age (NCT05349617), which demonstrated that CHIKV VLP induced chikungunya neutralizing antibodies in 87% of vaccinees 22 days after a single vaccination and was well-tolerated. Results from both studies will form the basis for submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in 2024 to support potential launch of the vaccine in 2025.

Conference call and webcast
The management of Bavarian Nordic will host an investor/analyst call Monday, August 7, 2023, at 2 pm CET (8 am EDT) to discuss the recent pipeline developments. Dial-in details and link to a live audiocast will become available at https://www.bavarian-nordic.com/investor/events.aspx?event=6815 in due time.

About chikungunya virus
Chikungunya is a mosquito-borne viral disease caused by the chikungunya virus (CHIKV). CHIKV disease typically presents with acute symptoms, including fever, rash, fatigue, headache, and often severe and incapacitating

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joint pain. While mortality is low, morbidity is high; nearly 50% of individuals with CHIKV disease have debilitating long-term symptoms that can intensify with age. In the past 20 years, the CHIKV has emerged in several previously non-endemic regions in Asia, Africa, southern Europe, and the Americas, often causing large unpredictable outbreaks. No effective treatments or vaccines are currently available[1].

About the chikungunya vaccine candidate CHIKV VLP
CHIKV VLP (PXVX0317) is an adjuvanted VLP-based vaccine in clinical development for active immunization against chikungunya disease, which is currently being evaluated in two pivotal Phase 3 trials: a multi-center, randomized, double blind, placebo-controlled study to evaluate the safety and immunogenicity of CHIKV VLP in 3,254 healthy individuals aged 12 to 64 years of age, and a randomized, double-blind, placebo-controlled study to evaluate the safety and immunogenicity of CHIKV VLP in 413 healthy adults ≥65 years of age.

CHIKV VLP has received Breakthrough Therapy designation and Fast Track designation from the FDA, and PRIME designation from EMA.

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 public health preparedness and have a strong portfolio of vaccines for travelers and endemic diseases. 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.

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[1] Bennett et al 2022. Lancet Infect Dis. doi: 10.1016/S1473-3099(22)00226-2