BAVARIAN NORDIC

*Company Announcement*

# Bavarian Nordic Reports Data from a Phase 3 Clinical Trial of its VLP-Based Chikungunya Virus Vaccine in Adults ≥65 Years of Age

- Study successfully met its primary endpoints
- Data from second pivotal Phase 3 study in people aged 12 to 64 years expected in the third quarter 2023

**COPENHAGEN, Denmark, June 20, 2023** – Bavarian Nordic A/S (OMX: BAVA) announced today the initial safety and immunogenicity results from a randomized, double-blind, placebo-controlled Phase 3 clinical trial of a virus-like particle (VLP)-based chikungunya virus (CHIKV) vaccine candidate CHIKV VLP (PXVX0317) in healthy adults ≥65 years of age. Results from a second Phase 3 study evaluating the safety and immunogenicity of CHIKV VLP in healthy adolescents and adults 12 to 64 years old will report data during the third quarter of 2023.

A total of 413 participants were enrolled and randomized 1:1 to receive either a single intramuscular injection of CHIKV VLP or placebo. The initial results up to Day 22 post vaccination showed that CHIKV VLP was immunogenic in healthy adults ≥65 years of age, as demonstrated by a strong induction of CHIKV neutralizing antibodies in 87% of vaccinees with neutralising antibody titres exceeding the threshold agreed with authorities as a marker of seroprotection, thus meeting the primary endpoints of the study. Importantly, seroprotective neutralizing antibodies were also observed in the majority of the subjects (82%) at Day 15 post the single vaccination, clearly demonstrating a fast onset of protection for the VLP-based CHIKV vaccine candidate.

CHIKV VLP was well-tolerated in this older adult population and with similar rates of adverse events observed between the active and the placebo group. The trial will continue for a 6-month follow-up for both safety and immunogenicity.

Paul Chaplin, President and CEO of Bavarian Nordic said: "We are pleased to report the first Phase 3 results for our CHIKV vaccine candidate that clearly show this vaccine is well tolerated and highly immunogenic in an older adult population. They also match what has previously been reported for younger adults in an earlier Phase 2 study, including a fast onset of protection. While we still await the results from the second and larger Phase 3 study in adolescents and adults later this year, these highly encouraging results provide a high degree of confidence for our CHIKV vaccine program."

**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 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 over 3,000 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



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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.

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