

## Bavarian Nordic Initiates Rolling Submission of Biologics License Application with FDA for its Chikungunya Vaccine Candidate

**COPENHAGEN, Denmark, April 29, 2024** - Bavarian Nordic A/S (OMX: BAVA) today announced that it has initiated the rolling submission process with the U.S. Food and Drug Administration (FDA) for a Biologics License Application (BLA) for the licensure of its CHIKV VLP vaccine candidate for immunization against chikungunya virus infection in individuals 12 years of age and older.

Bavarian Nordic will submit additional data over the coming months, aiming to complete the BLA submission before the end of the first half of 2024 to support a potential FDA approval of the vaccine in the first half of 2025.

“We are pleased to advance our chikungunya vaccine candidate into the registration phase and look forward to working with the regulators in our efforts to bring this novel product to the market. We have generated robust data in adolescents, adults and older adults, suggesting a strong and durable antibody response against the chikungunya virus and a fast onset of protection, which supports our belief that we can establish our vaccine as the preferred choice in this emerging market,” said Paul Chaplin, President and CEO of Bavarian Nordic.

The CHIKV VLP vaccine candidate received Breakthrough Therapy designation and Fast Track designation from the FDA in October 2020 and April 2018, respectively, and PRIME designation from the EMA in September 2019. These designations are designed to facilitate the development or expedite review of medicines that either target an unmet medical need or may demonstrate substantial improvement over available therapy. In February 2024, the Committee for Medicinal Products for Human Use (CHMP) under EMA granted accelerated assessment for the MAA for the CHIKV VLP vaccine candidate, which Bavarian Nordic plans to submit by mid-2024.

### About chikungunya

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 relatively 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.

### About Bavarian Nordic

Bavarian Nordic is a fully integrated vaccine company with a mission to protect and save lives through innovative vaccines. We are a global leader in smallpox and mpox vaccines, supplied to governments 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](http://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.

### Contacts

Europe: Rolf Sass Sørensen, Vice President Investor Relations, [rss@bavarian-nordic.com](mailto:rss@bavarian-nordic.com), Tel: +45 61 77 47 43

US: Graham Morrell, Paddock Circle Advisors, [graham@paddockcircle.com](mailto:graham@paddockcircle.com), Tel: +1 781 686 9600

Company Announcement no. 09 / 2024