Company Announcement

Bavarian Nordic Completes BLA Submission to U.S. FDA for its Chikungunya Vaccine Candidate

- First regulatory submission completed for CHIKV VLP seeking approval of the vaccine candidate for immunization against chikungunya virus infection in individuals 12 years of age and older
- Represents first BLA for a chikungunya vaccine for adolescents

COPENHAGEN, Denmark, June 17, 2024 – Bavarian Nordic A/S (OMX: BAVA) today announced the completion of the rolling submission process which was initiated in April 2024 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. Pending acceptance from the FDA, the BLA could support a potential approval of the vaccine in the first half of 2025.

The BLA submission includes results from two phase 3 clinical trials in more than 3,600 healthy individuals 12 years of age and older, demonstrating that the CHIKV VLP vaccine was highly immunogenic, as demonstrated by the strong induction of chikungunya neutralizing antibodies against chikungunya 21 days after vaccination, with antibody titers equal to or above the threshold agreed with authorities as a marker of seroprotection. The CHIKV VLP vaccine was well-tolerated across both studies and vaccine-related adverse events were mainly mild or moderate in nature.

Bavarian Nordic also intends to submit a Marketing Authorisation Application (MAA) with the European Medicines Agency (EMA) by the end of the first half 2024. The MAA has already been granted accelerated assessment, which means the CHIKV VLP vaccine could potentially obtain approval by the European Commission in the first half of 2025.

“The completion of the BLA submission marks a significant milestone in the development of our CHIKV VLP vaccine and represents an important contribution to the development of preventative solutions for individuals 12 years of age and older at risk of chikungunya virus from bites by infected mosquitos. With the near-term anticipated MAA submission to EMA, we are looking towards potential approval of the vaccine in the first half of 2025 and subsequent launch in both the US and EU,” said **Paul Chaplin, President and CEO of Bavarian Nordic**.

About CHIKV VLP
CHIKV VLP is an adjuvanted VLP-based vaccine candidate for active immunization against chikungunya disease. Pending regulatory approval, the single-dose vaccine will be made in a pre-filled syringe, designed to ease administration by saving vaccinators' time and reducing the risk of administrative errors.

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.

About chikungunya
Chikungunya is a mosquito-borne viral disease caused by the chikungunya virus (CHIKV), which belongs to the group of arboviruses like dengue virus. 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

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

Asia, Africa, southern Europe, and the Americas, often causing large unpredictable outbreaks. Recent data[1] suggest that chikungunya is severely underreported and often misdiagnosed as dengue fever due to lack of proper testing.

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.

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, Tel: +45 61 77 47 43
US: Graham Morrell, Paddock Circle Advisors, graham@paddockcircle.com, Tel: +1 781 686 9600

Company Announcement no. 18 / 2024

[1] Ribas Freitas AR, Pinheiro Chagas AA, Siqueira AM, Pamplona de Góes Cavalcanti L. How much of the current serious arbovirus epidemic in Brazil is dengue and how much is chikungunya? Lancet Reg Health Am. 2024 Apr 30;34:100753. doi: 10.1016/j.lana.2024.100753. PMID: 38711542; PMCID: PMC11070701.