Company Announcement

Bavarian Nordic Receives EMA Filing Acceptance and Validation of the MAA for its Chikungunya Vaccine

- EMA will now initiate its centralized review procedure under accelerated assessment for Bavarian Nordic's chikungunya vaccine

COPENHAGEN, Denmark, July 18, 2024 – Bavarian Nordic A/S (OMX: BAVA) today announced that the European Medicines Agency (EMA) has validated the marketing authorization application (MAA), which was submitted in June 2024 for CHIKV VLP, the Company's vaccine candidate for immunization to prevent disease caused by chikungunya virus infection in individuals 12 years of age and older. Validation of the application confirms the submission is complete and begins the EMA's centralized review procedure under accelerated assessment.

The accelerated assessment, which was granted by EMA's Committee for Medicinal Products for Human Use (CHMP) in February 2024, aims to reduce the timeframe for the CHMP to review a MAA, potentially supporting approval of the vaccine by the European Commission in the first half of 2025.

"The MAA submission and review marks a pivotal milestone for Bavarian Nordic in 2024, and we look forward to working closely with EMA throughout the evaluation process to make our chikungunya vaccine available to individuals 12 years of age and older at risk of chikungunya virus infection," said **Paul Chaplin, President and CEO of Bavarian Nordic**.

Bavarian Nordic also completed the submission of a Biologics License Application (BLA) for the CHIKV VLP vaccine to the U.S. Food and Drug Administration (FDA) in June 2024, potentially also supporting a US approval of the vaccine in the first half of 2025.

About CHIKV VLP vaccine
CHIKV VLP is an adjuvanted VLP-based vaccine candidate for active immunization to prevent disease caused by CHIKV infection. 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 based on the vaccine's major interest for public health and therapeutic innovation.

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 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

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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.

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[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.