



Bavarian Nordic Announces Acceptance of Marketing Authorization Application for Chikungunya Vaccine in the UK for Persons Aged 12 and Older

COPENHAGEN, Denmark, March 7, 2025 - Bavarian Nordic A/S (OMX: BAVA) announced today that the UK Medicines and Healthcare products Regulatory Agency (MHRA) has validated the marketing authorization application and accepted to start the review of the Company's single-dose chikungunya vaccine, CHIKV VLP vaccine, for active immunization for the prevention of disease caused by chikungunya virus in individuals 12 years and older.

The application was submitted to MHRA in February 2025 under the international recognition procedure based on the positive opinion adopted by the Committee for Medicinal Products for Human Use of the European Medicines Agency in January 2025. CHIKV VLP vaccine was approved by the U.S. Food and Drug Administration (FDA) and the European Commission in February 2025 under the trade name VIMKUNYA®, and could potentially obtain approval in the UK later in the first half of 2025.

Bavarian Nordic recently expanded its global commercial presence to include a dedicated UK-based organization to manage its travel health portfolio, also comprising vaccines for rabies, typhoid and cholera. The Company is also a supplier of mpox vaccines to the UK Health Security Agency (UKHSA).

"Following the approvals of our chikungunya vaccine in the US and EU last month, we are excited about the opportunity to expand its availability to European countries later this year." said **Paul Chaplin, President and CEO of Bavarian Nordic**. *"With our recent organizational expansion into the UK, we are strongly positioned to leverage synergies across our growing travel health portfolio in the launch of the chikungunya vaccine for travelers, including those aged 12-17 years, pending approval by the MHRA."*

About chikungunya

Chikungunya is a mosquito-borne disease caused by the chikungunya virus (CHIKV). In the past 20 years, the virus has emerged across several regions in Asia, Africa, and the Americas, including many popular travel destinations, often causing large unpredictable outbreaks. Since its discovery, CHIKV has been identified in more than 110 countries, with evidence of transmission confirmed in more than 50 countries over the past five years¹. Chikungunya typically presents with acute symptoms, including fever, rash, fatigue, headache, and often severe and incapacitating joint pain. Most patients recover, but 30-40% of those affected may develop chronic symptoms that can last for months or even years². In 2024, 620,000 cases of chikungunya and over 200 deaths were reported worldwide³. Recent data suggest that chikungunya is severely underreported and often misdiagnosed as dengue fever due to a similar symptom profile⁴.

About CHIKV VLP vaccine

CHIKV VLP vaccine is an adjuvanted VLP recombinant protein vaccine for active immunization for the prevention of disease caused by chikungunya virus (CHIKV) in individuals 12 years and older.

Because VLPs contain no virus genetic material, the vaccine cannot infect cells, reproduce or cause disease.

While the mechanism of action of CHIKV VLP vaccine still needs to be further characterized, it is thought that the vaccine can induce protection from CHIKV infection by inducing neutralizing antibodies against certain CHIKV proteins resulting in neutralization of live virus. An adjuvant is added to increase the magnitude of vaccine-mediated immune responses.

The US and EU approvals of VIMKUNYA (CHIKV VLP vaccine) were based on results from two phase 3 clinical trials which enrolled more than 3,500 healthy individuals 12 years of age and older. The studies met their primary endpoints, with results showing that 21 days after vaccination, the vaccine induced neutralizing antibodies in up

to 97.8% of the vaccinated individuals and demonstrated a rapid immune response starting to develop within one week. The vaccine was well-tolerated and vaccine-related adverse events were mainly mild or moderate in nature.

About Bavarian Nordic

Bavarian Nordic is a global vaccine company with a mission to improve health and save lives through innovative vaccines. We are a preferred supplier of mpox and smallpox vaccines to governments to enhance public health preparedness and have a leading portfolio of travel vaccines. 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 Centers for Disease Control and Prevention. *Areas at Risk for Chikungunya*. <https://www.cdc.gov/chikungunya/data-maps/index.html>.

² European Centre for Disease Prevention and Control. *Chikungunya virus disease*. <https://www.ecdc.europa.eu/en/chikungunya-virus-disease>.

³ European Centre for Disease Prevention and Control. *Chikungunya worldwide overview*. <https://www.ecdc.europa.eu/en/chikungunya-monthly>.

⁴ 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.