



Bavarian Nordic Receives Positive CHMP Opinion for Chikungunya Vaccine for Persons Aged 12 and Older

- First chikungunya vaccine recommended by the CHMP for persons as young as 12 years old.
- The virus-like particle (VLP) single-dose chikungunya vaccine is expected to launch in key European markets in the first half of 2025, pending final marketing authorization.

COPENHAGEN, Denmark, January 31, 2025 - Bavarian Nordic A/S (OMX: BAVA) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending marketing authorization for VIMKUNYA® (CHIKV VLP vaccine) for active immunization for the prevention of disease caused by chikungunya virus in individuals 12 years and older.

After accelerated assessment, the CHMP's recommendation is primarily based on results from two phase 3 clinical trials which enrolled more than 3,500 healthy individuals 12 years of age and older and demonstrated a rapid immune response starting to develop within one week. 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. The vaccine was well-tolerated across both studies and vaccine-related adverse events were mainly mild or moderate in nature.

"The recommendation of our chikungunya vaccine for approval in Europe marks a huge milestone in our efforts to deliver protection against this debilitating disease and, once approved, would represent a significant contribution to expanding the availability of vaccines to a broader population, including adolescents aged 12-17 years," said **Paul Chaplin, President and CEO of Bavarian Nordic**. *"Chikungunya, like other mosquito-borne illnesses, represents an increasing public health risk across the globe due to factors such as climate change, and we look forward to making the vaccine available for travelers at risk later this year, while also continuing our efforts to expand access to endemic populations across the globe."*

The European Commission, which grants central marketing authorizations in the European Union (EU), will review the CHMP recommendation and is expected to make a final decision in the coming months. If granted, the marketing authorization of VIMKUNYA would be valid in all EU member states, as well as in Iceland, Liechtenstein, and Norway.

Based on the positive CHMP opinion, Bavarian Nordic will now also submit a Marketing Authorization Application (MAA) to the UK Medicines and Healthcare products Regulatory Agency (MHRA) under the International Recognition Procedure (IRP), with potential approval of the chikungunya vaccine in the UK in the first half of 2025.

The vaccine is also currently under priority review with the U.S. Food and Drug Administration (FDA), with a Prescription Drug User Fee Act (PDUFA) action date set for February 14, 2025.

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, approximately 480,000 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

CHIKV VLP 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 characterised, it is thought that the vaccine can induce protection from CHIKV infection by inducing neutralising antibodies against certain CHIKV proteins resulting in neutralisation of live virus. An adjuvant is added to increase the magnitude of vaccine-mediated immune responses.

Pending regulatory approval, CHIKV VLP vaccine will be supplied as a single-dose, pre-filled syringe.

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>. Accessed January 30, 2025.

² European Centre for Disease Prevention and Control. *Chikungunya virus disease*. <https://www.ecdc.europa.eu/en/chikungunya-virus-disease>. Accessed January 30, 2025.

³ European Centre for Disease Prevention and Control. *Chikungunya worldwide overview*. <https://www.ecdc.europa.eu/en/chikungunya-monthly>. Accessed January 30, 2025.

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.