

Bavarian Nordic Receives Marketing Authorization for Chikungunya Vaccine for Persons Aged 12 and Older in the United Kingdom

COPENHAGEN, Denmark, May 2, 2025 - Bavarian Nordic A/S (OMX: BAVA) announced today that the UK Medicines and Healthcare products Regulatory Agency (MHRA) has granted marketing authorization in the United Kingdom (UK) for VIMKUNYA® (recombinant, adsorbed) for active immunization for the prevention of disease caused by chikungunya virus in individuals 12 years and older.

The vaccine was approved following MHRA review under the international recognition procedure, which is a targeted assessment that recognizes approvals from certain other regulatory bodies, in this case the recent approval by the European Commission. Bavarian Nordic is targeting launch of the vaccine in the UK during the summer of 2025.

“Chikungunya mostly represents a risk for UK citizens traveling overseas to affected regions in the Americas, Africa and Asia, but as recent research has shown, invasive mosquitos known to carry the disease have established themselves in many parts of Southern Europe and are moving further north due to climate change¹,” said Paul Chaplin, President and CEO of Bavarian Nordic. “The mosquitos cannot be stopped, but with preventative measures such as vaccines, we can mitigate the impact of emerging diseases like chikungunya for those at risk, and we look forward to launching our vaccine in the UK later this year.”

The UK approval of VIMKUNYA marks the third approval of Bavarian Nordic’s chikungunya vaccine, which was approved by the U.S. Food and Drug Administration (FDA) and the European Commission in February 2025.^{2,3} Bavarian Nordic has also submitted an application to Health Canada, potentially supporting approval of the chikungunya vaccine in the first half of 2026.

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 years⁴. Chikungunya typically presents with acute symptoms, including fever, rash, fatigue, headache, and often severe and incapacitating joint pain. Most patients recover within 1-2 weeks, but 30-40% of those affected may develop chronic arthritis that can last for months or even years⁵. In 2024, 620,000 cases of chikungunya and over 200 deaths were reported worldwide⁶. Recent data suggest that chikungunya is severely underreported and often misdiagnosed as dengue fever due to a similar symptom profile⁷.

About VIMKUNYA® Chikungunya vaccine (recombinant, adsorbed)

VIMKUNYA is a single dose, prefilled, adjuvanted VLP recombinant protein vaccine for active immunization for the prevention of disease caused by chikungunya virus (CHIKV) in individuals 12 years and older.

The US, EU and UK approvals of VIMKUNYA (CHIKV VLP vaccine) were all 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, (97.8% in individuals 12 years to 64 and 87.3% in over 65 year olds). The key secondary endpoint of seroresponse rate at day 8 post vaccination was 46.6% and 96.8% at day 15 in the 12-64 year old population and 82.3% at day 15 for the over 65 population. The vaccine was well-tolerated and vaccine-related adverse events were mainly mild or moderate in nature. The most common side effects were pain at the injection site, fatigue, headache, and muscle pain.

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 European Centre for Disease Prevention and Control. *Increasing risk of mosquito-borne diseases in EU/EEA following spread of Aedes species*. <https://www.ecdc.europa.eu/en/news-events/increasing-risk-mosquito-borne-diseases-eueea-following-spread-aedes-species>

² Bavarian Nordic Receives U.S. FDA Approval of Chikungunya Vaccine for Persons Aged 12 and Older. <https://www.bavarian-nordic.com/media/media/news.aspx?news=7053>

³ Bavarian Nordic Receives Marketing Authorization in Europe for Chikungunya Vaccine for Persons Aged 12 and Older. <https://www.bavarian-nordic.com/media/media/news.aspx?news=7056>

⁴ Centers for Disease Control and Prevention. *Areas at Risk for Chikungunya*. <https://www.cdc.gov/chikungunya/data-maps/index.html>.

⁵ European Centre for Disease Prevention and Control. *Chikungunya virus disease*. <https://www.ecdc.europa.eu/en/chikungunya-virus-disease>.

⁶ European Centre for Disease Prevention and Control. *Chikungunya virus disease case notification rate per 100 000 population, January 2024-December 2024*. <https://www.ecdc.europa.eu/en/publications-data/chikungunya-virus-disease-case-notification-rate-100-000-population-january-2024>.

⁷ 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.