



Bavarian Nordic Receives Marketing Authorization in Europe for Chikungunya Vaccine for Persons Aged 12 and Older

- First chikungunya vaccine approved in Europe for persons as young as 12 years old.
- On track for launch in key European markets in the first half of 2025.

COPENHAGEN, Denmark, February 28, 2025 - Bavarian Nordic A/S (OMX: BAVA) today announced that the European Commission has granted marketing authorization in Europe for VIMKUNYA® for active immunization for the prevention of disease caused by chikungunya virus in individuals 12 years and older.

The virus-like particle (VLP) single-dose vaccine is the first chikungunya vaccine approved in Europe for persons as young as 12 years old. The approval, valid in all EU member states, as well as in Iceland, Liechtenstein, and Norway, marks the second approval of VIMKUNYA, following the approval by the U.S. Food and Drug Administration (FDA) earlier this month. Bavarian Nordic also recently submitted a Marketing Authorization Application (MAA) to the UK Medicines and Healthcare products Regulatory Agency (MHRA) with potential approval of the chikungunya vaccine in the UK in the first half of 2025.

Bavarian Nordic will launch VIMKUNYA in key European markets in the first half of 2025.

“We are highly encouraged by the European Commission’s accelerated decision to approve our chikungunya vaccine in Europe, which offers a differentiated profile for travelers, including those as young as 12 years,” said Paul Chaplin, President and CEO of Bavarian Nordic. *“As we expand our presence across Europe, this vaccine will help to further consolidate our leading position in travel vaccines, and we look forward to making the vaccine available in key markets during the first half of 2025.”*

The marketing authorization was granted by the European Commission upon recommendation by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) in January 2025 and was 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.

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 VIMKUNYA® Chikungunya vaccine (recombinant, adsorbed)

VIMKUNYA 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. VIMKUNYA will be available as a suspension for injection in a pre-filled syringe.

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. The most common side effects are injection site pain, fatigue, headache, and myalgia.

Full product information will be available from:

<https://www.ema.europa.eu/en/medicines/human/EPAR/vimkunya>

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.