

Bavarian Nordic Initiates Phase 3 Study of Chikungunya Vaccine in Children

- First children vaccinated in clinical study seeking to expand the target population for the chikungunya vaccine.

COPENHAGEN, Denmark, June 12, 2025 - Bavarian Nordic A/S (OMX: BAVA) announced today the initiation of a Phase 3 clinical study of its single-dose, virus-like particle (VLP) chikungunya vaccine, CHIKV VLP in children 2 to 11 years of age.

This first trial of CHIKV VLP in a pediatric population aims to expand the target population for the vaccine, currently approved for persons 12 years of age and older in the US, EU and United Kingdom under the trade name VIMKUNYA®. The global, randomized, double-blind, placebo-controlled study ([NCT07003984](#)), sponsored by Bavarian Nordic, will evaluate the safety and immunogenicity of CHIK VLP vaccine in 720 children 2 to 11 years of age for two years. Primary results from the study are anticipated in the first half of 2028.

Paul Chaplin, President & CEO of Bavarian Nordic, said: *“Upon the successful approvals earlier this year of our chikungunya vaccine for persons aged 12 and older, we are pleased to initiate this Phase 3 study in children for whom there are currently no vaccines available to prevent against chikungunya. This study represents a significant part of our commitment to the further development of the vaccine to help ensure access for people of all ages.”*

About VIMKUNYA® Chikungunya vaccine (recombinant, adsorbed)

VIMKUNYA (CHIKV VLP) is the first and only virus-like particle (VLP) vaccine for the prevention of chikungunya disease in individuals aged 12 years and above. It is designed to induce a robust seroresponse, with protective immunity starting to develop as early as 1 week after vaccination. VIMKUNYA is the only single-dose vaccine against chikungunya disease available in a prefilled syringe. VIMKUNYA does not contain viral genetic material and is therefore non-infectious and unable to cause disease, ensuring a broad range of people can benefit from vaccination.

The vaccine was approved by the U.S. Food and Drug Administration (FDA) and the European Commission in February 2025^{1,2} and the United Kingdom in May 2025³.

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^{4,5}.

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 years⁶. 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 years⁷. In 2024, 620,000 cases of chikungunya and over 200

deaths were reported worldwide⁸. Recent data suggest that chikungunya is severely underreported and often misdiagnosed as dengue fever due to a similar symptom profile⁹.

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 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>

² 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>

³ Bavarian Nordic Receives Marketing Authorization for Chikungunya Vaccine for Persons Aged 12 and Older in the United Kingdom. <https://www.bavarian-nordic.com/media/media/news.aspx?news=7132>

⁴ Richardson JS, et al. Chikungunya Virus VLP Vaccine: Phase 3 Trial in Adolescents and Adults. medRxiv 2024.10.11.24315179.

⁵ Tindale LC, et al. Chikungunya Virus VLP Vaccine: Phase 3 Trial in Adults ≥65 Years of Age. medRxiv 2024.10.10.24315205.

⁶ Centers for Disease Control and Prevention. *Areas at Risk for Chikungunya*. <https://www.cdc.gov/chikungunya/data-maps/index.html>.

⁷ European Centre for Disease Prevention and Control. *Chikungunya virus disease*. <https://www.ecdc.europa.eu/en/chikungunya-virus-disease>.

⁸ 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>.

⁹ 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.