Press Release

Bavarian Nordic Receives Acceptance from Health Canada for Review of the New Drug Submission for its Chikungunya Vaccine

COPENHAGEN, Denmark, July 22, 2025 – Bavarian Nordic A/S (OMX: BAVA) announced today that Health Canada has accepted for review the Company's application for licensure of the single-dose, virus-like particle (VLP) chikungunya vaccine candidate, CHIKV VLP, for immunization to prevent disease caused by chikungunya virus infection in individuals 12 years of age and older. The application screening acceptance by the Directorate confirms that the New Drug Submission is complete and begins a standard review procedure, potentially supporting approval of the vaccine in the first half of 2026.

The New Drug Submission is based on the data, which also supported the recent US, EU and UK approvals of the vaccine, including 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[1,2].

Paul Chaplin, President and CEO of Bavarian Nordic, said: *"The regulatory submission and acceptance by Health Canada represents yet another highlight in our efforts to expand access to our chikungunya vaccine across the globe. Pending approval, this vaccine will further strengthen our offering for Canadians seeking protection against serious diseases when traveling the world."*

About CHIKV VLP
CHIKV VLP is a 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. Pending regulatory approval, CHIKV VLP vaccine will be available in a prefilled syringe.

CHIKV VLP 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[3,4] and the United Kingdom in May 2025[5] under the trade name VIMKUNYA®[6].

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 years[7]. 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 years[8]. In 2024, 620,000 cases of chikungunya and over 200 deaths were reported worldwide[9]. Recent data suggest that chikungunya is severely underreported and often misdiagnosed as dengue fever due to a similar symptom profile[10].

About Bavarian Nordic

Bavarian Nordic A/S
Philip Heymans Alle 3
DK-2900 Hellerup
Tel. +45 33 26 83 83
www.bavarian-nordic.com
CVR-no. 16 27 11 87
LEI Code: 2138006JCDVYIN6INP51

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.

Contact investors:

Europe: Rolf Sass Sørensen, Vice President Investor Relations, rss@bavarian-nordic.com, Tel: +45 61 77 47 43
US: Graham Morrell, Gilmartin Group, graham@gilmartinir.com, Tel: +1 781 686 9600

Contact media:

Nicole Seroff, Vice President Corporate Communications, nise@bavarian-nordic.com, Tel: +45 53 88 06 03

---

[1] Richardson JS, et al. Chikungunya Virus VLP Vaccine: Phase 3 Trial in Adolescents and Adults. medRxiv 2024.10.11.24315179.
[2] Tindale LC, et al. Chikungunya Virus VLP Vaccine: Phase 3 Trial in Adults ≥65 Years of Age. medRxiv 2024.10.10.24315205.
[3] Bavarian Nordic Receives U.S. FDA Approval of Chikungunya Vaccine for Persons Aged 12 and Older. https://www.bavarian-nordic.com/investor/news/news.aspx?news=7053
[4] Bavarian Nordic Receives Marketing Authorization in Europe for Chikungunya Vaccine for Persons Aged 12 and Older. https://www.bavarian-nordic.com/investor/news/news.aspx?news=7056
[5] Bavarian Nordic Receives Marketing Authorization for Chikungunya Vaccine for Persons Aged 12 and Older in the United Kingdom. https://www.bavarian-nordic.com/investor/news/news.aspx?news=7132
[6] Marketed as VIMKUNYA™ in the US. Marketed as VIMKUNYA® in EU and the United Kingdom.
[7] Centers for Disease Control and Prevention. *Areas at Risk for Chikungunya*. https://www.cdc.gov/chikungunya/data-maps/index.html.
[8] European Centre for Disease Prevention and Control. *Chikungunya virus disease*. https://www.ecdc.europa.eu/en/chikungunya-virus-disease.
[9] 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.
[10] 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.