Company Announcement

Bavarian Nordic Receives U.S. FDA Approval of Chikungunya Vaccine for Persons Aged 12 and Older

- First chikungunya vaccine approved for persons as young as 12 years old, addressing an unmet need for chikungunya prevention for younger travelers.
- On track for commercial launch in the U.S. in the first half of 2025.
- A Tropical Disease Priority Review Voucher was awarded to the Company upon approval.

COPENHAGEN, Denmark, February 14, 2025 – Bavarian Nordic A/S (OMX: BAVA) announced today that the U.S. Food and Drug Administration (FDA) has approved VIMKUNYA™ (Chikungunya Vaccine, Recombinant) for injection, the first virus-like particle (VLP) single-dose chikungunya vaccine in the U.S. for persons 12 years of age and older.

The FDA approved VIMKUNYA under Priority Review, 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. The vaccine was well-tolerated and vaccine-related adverse events were mainly mild or moderate in nature.[1] VIMKUNYA is a VLP vaccine, which means that it uses virus-like particles designed to mimic the chikungunya virus without the ability to infect cells, replicate or cause disease.

"*The approval of our chikungunya vaccine is a testament to our unwavering commitment to addressing unmet medical needs and protecting communities worldwide,*" said **Paul Chaplin, President and CEO of Bavarian Nordic**. "*As climate change continues to expand the reach of mosquito-borne illnesses like chikungunya, this milestone underscores the importance of cutting-edge solutions to safeguard travelers and vulnerable populations. We are proud to provide the first vaccine specifically approved for the prevention of chikungunya virus in individuals aged 12 and over, offering a critical tool to combat this emerging and growing health challenge.*"

Concurrent with the approval, the FDA awarded Bavarian Nordic a Priority Review Voucher (PRV) under the Tropical Disease PRV program, which the Company intends to monetize when appropriate.

Bavarian Nordic aims to provide commercial availability of VIMKUNYA in the U.S. in the first half 2025.

The vaccine recently received a positive opinion by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) and will also be launched in key European markets in the first half of 2025, pending adoption of a final decision on the marketing authorization by the European Commission.

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[2]. 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 years[3]. In 2024, 620,000 cases of chikungunya and over 200 deaths were reported worldwide[4]. Recent data suggest that chikungunya is severely underreported and often misdiagnosed as dengue fever due to a similar symptom profile[5].

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About VIMKUNYA™ (Chikungunya Vaccine, Recombinant)
VIMKUNYA is a vaccine for prevention of disease caused by chikungunya virus in people 12 years of age and older.

Additional clinical studies are required to confirm the clinical profile of VIMKUNYA, and confirmatory efficacy studies are also planned as part of the post-marketing commitments and requirements as agreed with the FDA.

VIMKUNYA is supplied as a single-dose 1-mL glass pre-filled syringe with 0.8 mL dose volume.

Important Safety Information
The following information is based on the U.S. Prescribing Information for VIMKUNYA. Please consult the full Prescribing Information for all the labelled safety information for VIMKUNYA.

You should not get VIMKUNYA if you are allergic to any of the ingredients of the vaccine or if you have had an allergic reaction following a previous dose of VIMKUNYA.

People with a lowered immune system, including people receiving medications that affect the immune system, may have a diminished response to VIMKUNYA. Tell your healthcare provider about all medications you are taking.

Fainting may occur with administration of injected vaccines including VIMKUNYA.

The most common side effects were pain at the injection site, fatigue, headache, and muscle pain. These are not all the possible side effects.

Tell your healthcare provider if you are pregnant, planning to become pregnant, or are breastfeeding.

Tell your healthcare provider about any side effects that concern you. To report SUSPECTED ADVERSE REACTIONS, contact Bavarian Nordic at 1-844-4BAVARIAN or the US Department of Health and Human Services by visiting www.vaers.hhs.gov/reportevent.html or call 1-800-822-7967.

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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Visit www.bavarian-nordic.com/media/chikungunya for additional media information.

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[1] VIMKUNYA Prescribing Information 2025
[2] Centers for Disease Control and Prevention. *Areas at Risk for Chikungunya*. https://www.cdc.gov/chikungunya/data-maps/index.html. Accessed February 14, 2025.
[3] European Centre for Disease Prevention and Control. *Chikungunya virus disease*. https://www.ecdc.europa.eu/en/chikungunya-virus-disease. Accessed February 14, 2025.
[4] European Centre for Disease Prevention and Control. *Chikungunya worldwide overview*. https://www.ecdc.europa.eu/en/chikungunya-monthly. Accessed February 14, 2025.
[5] 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.