

Bavarian Nordic Partners with Biological E Limited to Expand Global Access to Chikungunya Vaccine

• Contract manufacturing agreement marks the first step in collaboration to establish supply for expanded access to chikungunya vaccines in low- and middle-income countries.

COPENHAGEN, Denmark, February 25, 2025 - Bavarian Nordic A/S (OMX: BAVA) today announced a strategic partnership with Biological E. Limited (BE) to expand access to Bavarian Nordic's chikungunya vaccine in low-and middle-income (LMIC) countries.

Initially, the companies have entered into a contract manufacturing agreement to allow for scaling of capacity to enable future supply to endemic LMIC countries. This agreement comprises a technology transfer of the current drug product manufacturing process for the chikungunya vaccine, with option to transfer the drug substance process at a later stage. Bavarian Nordic retains its own manufacturing capacity for the forthcoming commercialization of the vaccine in Western markets.

Bavarian Nordic continues to explore opportunities in line with its strategy to provide global access to its chikungunya vaccine through license- and distribution partners for markets outside the US and Europe. The recent and first approval of the vaccine in the US as the first chikungunya vaccine for persons as young as 12 years and the positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use have demonstrated the feasability to expand regulatory approvals beyond these markets.

"We are pleased to announce our first collaboration to expand global access to our chikungunya vaccine and also our first partnership with Biological E, who have solid expertise and comprehensive experience in supplying vaccines for improving public health worldwide," said Paul Chaplin, President & CEO of Bavarian Nordic. "Expanding supply is a prerequisite for our ability to address the increasing need for solutions to prevent chikungunya in vulnerable populations in endemic regions, and we are dedicated to pursuing strong partnerships that can help us achieve this goal."

Ms. Mahima Datla, Managing Director, Biological E. Limited, said, "We are pleased to collaborate with Bavarian Nordic to help expand the availability of their chikungunya vaccine in low and middle-income countries. The scale of our manufacturing and successful track record in providing global access to vaccines is synergistically aligned with Bavarian Nordic, and we are committed to utilizing our advanced and efficient manufacturing technologies to meet health needs in endemic regions."

About CHIKV VLP vaccine

CHIKV VLP 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.

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.

In February 2025, the U.S. Food and Drug Administration (FDA) approved VIMKUNYA[™] (CHIKV VLP) as the first chikungunya vaccine for persons as young as 12 years. The approval 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. The vaccine was well-tolerated and vaccine-related adverse events were mainly mild or moderate in nature.

An EU approval is pending decision from the European Commision following a recommendation in January 2025 by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA).

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, 620,000 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 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.bavariannordic.com.

About Biological E

Biological E. Limited (BE) is the first private sector biological products company in India and the first pharmaceutical company in Southern India. BE supplies its vaccines to more than 130 countries and its therapeutic products are sold in India, the USA and Europe. BE currently has 10 WHO-approved vaccines and 10 FDA-approved generic injectables in its portfolio.

For further details, please visit www.biologicale.com

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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.

¹ Centers for Disease Control and Prevention. Areas at Risk for Chikungunya. <u>https://www.cdc.gov/chikungunya/data-</u> 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.