Update on vaccine development Bavarian Nordic

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Bavarian Nordic **at a glance**

*A preferred partner to governments and supranational organizations on vaccines for **public preparedness***

*Leading commercialized portfolio of **travel vaccines***

Since 2020, we have successfully transformed Bavarian Nordic into one of the largest pure-play vaccine companies with global presence and more than 1,600 employees.

USA
Clinical Development, Regulatory and commercial functions

Switzerland
Manufacturing, global marketing and sales functions

Germany
Research and development, sales and commercial functions

Denmark
Headquarters
Manufacturing

Other countries
Commercial and administrative functions: Belgium, Canada, France, Italy, Portugal, Spain, Sweden and United Kingdom

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Products and pipeline

Commercial products

- Mpox & smallpox — IMVANEX®, JYNNEOS®, IMVAMUNE®
- Chikungunya — Vimkunya®
- Rabies — Rabipur®
- Tick-borne encephalitis (TBE) — Encepur®
- Cholera — Vaxchora® (Cholera Vaccine, Live, Oral)
- Typhoid — Vivotif® (Typhoid Vaccine Live Oral Ty21a)

Pipeline

	Phase 1	*Phase 2*	*Phase 3*
MVA-BN WEV *Equine encephalitis*	✓	2025	
Epstein-Barr virus	2026		
Lyme disease	2026		

VIMKUNYA®

Chikungunya vaccine (recombinant, absorbed)

- Virus-like particle (VLP) technology
- Pre-filled syringe
- 3-year shelf life

- **Indication:** prevention of disease caused by chikungunya virus in individuals 12 years of age and older

- **Contraindications:** hypersensitivity to the vaccine components

- *PRIME Designation (2019), Fast Track (2018) and Breakthrough Therapy Designation (2020) granted*
- *Rolling BLA submission and EU MAA submission (June 2024); both reviewed under accelerated pathways*

14 February
FDA Approval, United States

28 February
EC Approval, European Union

19 February
MHRA submission, United Kingdom

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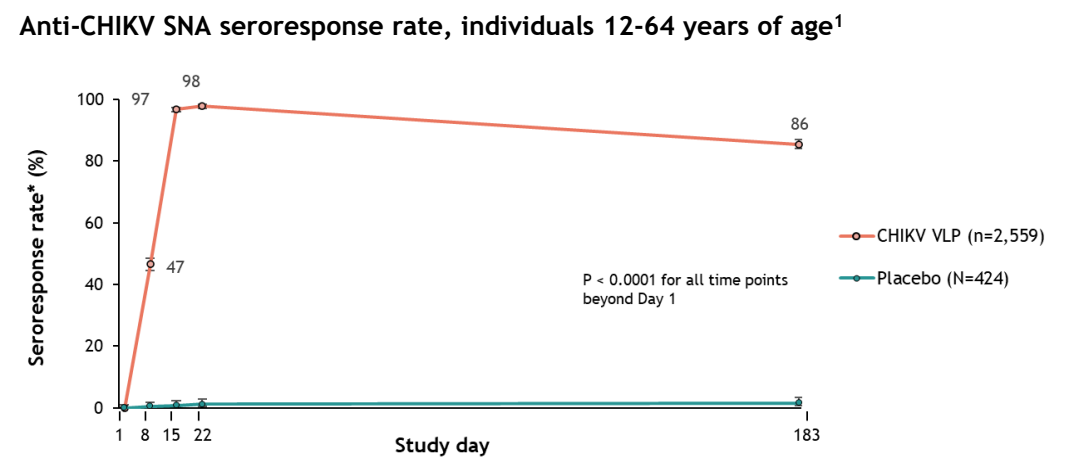
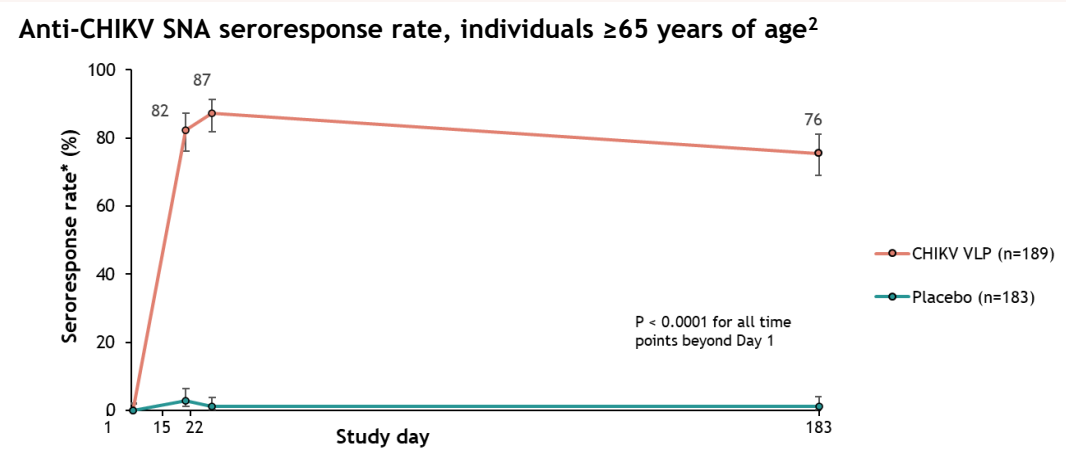
FDA: U.S. Food and Drug Administration; EC: European Commission: MAA: Marketing Authorisation Application
VIMKUNYA, US Prescribing Information. Available at: Link. Accessed March 2025

Rapid induction of robust seroresponse





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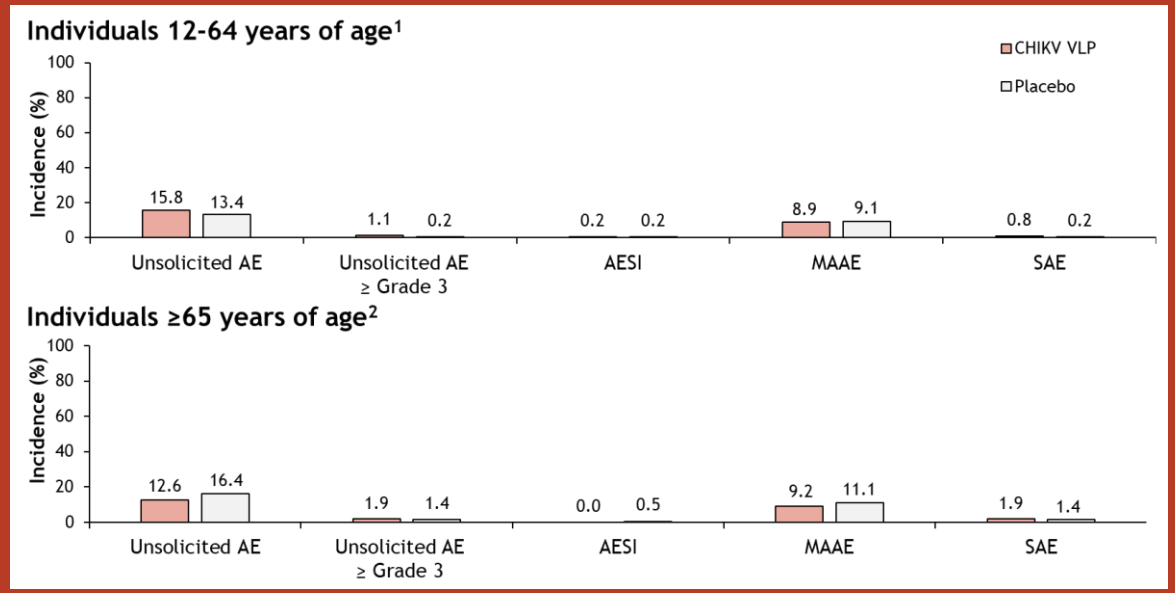
1. Richardson *et al*. doi: https://doi.org/10.1101/2024.10.11.24315179. 2. Tindale et al. doi: https://doi.org/10.1101/2024.10.10.24315205

Mostly mild/moderate Adverse Events



- Incidence of Adverse Events of Special Interest (AESI) and Medically-Attended Adverse Events (MAAEs) did not differ between the vaccine group and the placebo group
- No treatment-related Serious Adverse Events, including medically-attended arthralgia

AESI = adverse event of special interest: defined as new onset or worsening arthralgia that was medically attended; AE = adverse event; MAAE = medically attended adverse event; SAE = serious adverse event

Post-authorisation activities

Pregnancy Registry

Efficacy Study

Paediatric trials

Long-term Follow Up

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Pregnancy Registry

An Observational Prospective Study of the Safety of VIMKUNYA Vaccine Exposure in Pregnant Women and their Offspring

- Exposure to VIMKUNYA (received in a healthcare setting) up to 28 days before conception or during pregnancy
- Enrolment will be determined by passive reporting of pregnancy exposures to VIMKUNYA and consent to the collection of follow-up data
- No limit to participation during the 3-year enrolment period
- European Union and United States

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Efficacy Study

A Phase 3b Randomised, Double-blind, Placebo-controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of an Adjuvanted Chikungunya Virus Virus-like Particle (CHIKV VLP) Vaccine for the Prevention of Chikungunya Disease in Adolescents (12 to <18 Years) and Adults (≥18 Years)

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Objectives

Efficacy: To evaluate the vaccine efficacy of VIMKUNYA compared to placebo in the prevention of laboratory confirmed acute CHIKV disease in adolescents and adults (12 years of age and older)

Safety: To evaluate the safety of VIMKUNYA in adolescents and adults (12 years of age and older)

Efficacy Study

Event-driven study enrolment

6-month to 3-year follow up

Initiation planned from Q3 2025 dependent on the declaration of a CHIKV outbreak

Final study report tentatively planned for submission by August 2030

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Efficacy Study

Event-driven study enrolment

6-month to 3-year follow up

Initiation planned from Q3 2025 dependent on the declaration of a CHIKV outbreak

Final study report tentatively planned for submission by August 2030

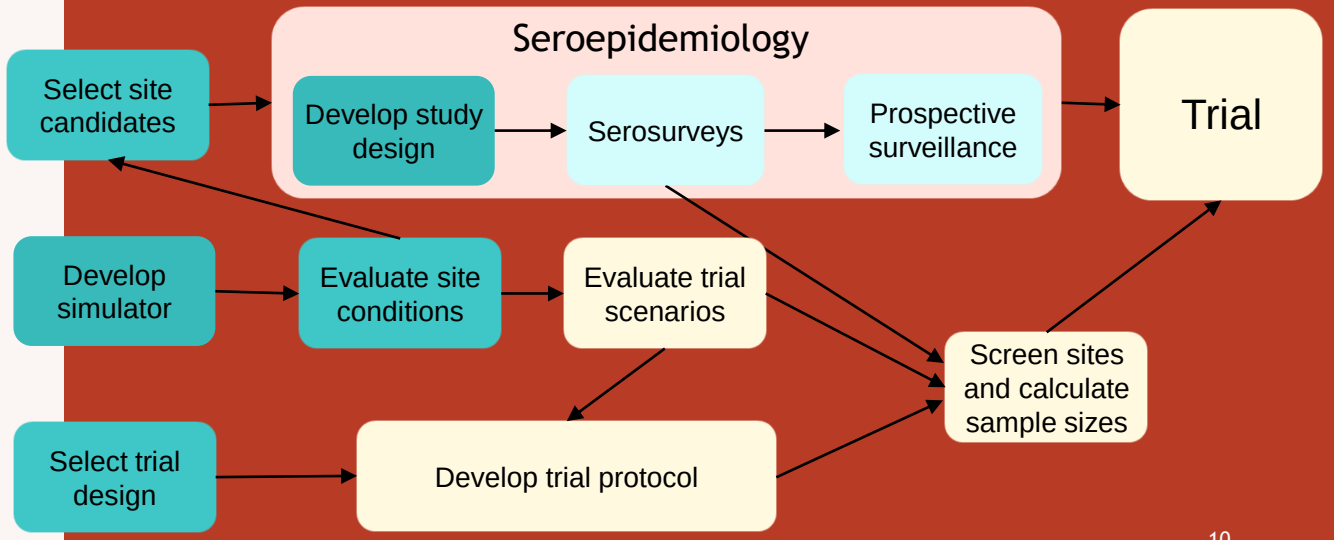
Multiple sites engagement across several countries

Sero-epidemiological studies, sites assessment and simulation modelling

Adoption of a design responsive to CHIKV surveillance and focus on communities with the highest transmission potential

Elucidate epidemiology
- Transmission criteria:
  - Identify ideal/likely scenarios
  - Assess historical data
  - Develop simulation model

Assess feasibility
- Feasibility criteria
  - Identify constraints
  - Profile eligible sites
  - Rank sites



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Paediatric studies

Study	Design
Phase 4 safety and immunogenicity Paediatric Study: 2 to less than 12 years of age Due to start 2025	Randomised, controlled, double-blind
Phase 4 safety and immunogenicity Paediatric Study: 0 to less than 2 years of age Due to start 2029	Randomised, controlled, double-blind

Long-term Follow Up

Study	Design
Phase 3 long-term follow up to evaluate immunogenicity through 5 years, with and without a booster dose 3 to 5 years postvaccination Started 2023	Rollover from BN's phase 3 studies, randomised, double-blind

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Potential for outbreak response…

- Rapid onset of protective immunity and broad indication can make Vimkunya a suitable tool for outbreak response
- **BN is actively in dialogue with French Regional and National Authorities to support the management of the ongoing outbreak in La Réunion, and for other areas at potential risk like Mayotte and Martinique**
- Current vaccine recommendations by French Authorities are limited to Valneva's Ixchiq, as the vaccine was licensed earlier. New recommendations are anticipated

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Haute Authorité de Santé. Utilisation du vaccin Ixchiq dans le context épidémique de chikungunya dans les territoires de La Réunion et de Mayotte. Feb 2025. Link. Accessed April 2025

… and strategic partnerships

- Agreement with Biological E. Limited (BE), India, to expand access to BN's CHIKV vaccine in LMICs
- Contract manufacturing agreement to enable future supply to endemic LMICs
- Technology transfer of the manufacturing process. Option to transfer the drug substance process at a later stage.
- **BN continues to explore opportunities to provide global access to its CHIKV vaccine through license- and distribution partners**

Thank you!

Manufacturing: Thörishaus, Switzerland

R&D: **Martinsried, Germany**

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