PHASE 1

Sudan virus vaccine development program

Translating **science** into **global** health impact

IAVI is developing a vaccine candidate for protection against Sudan virus (SUDV) and contributed to outbreak responses in sub-Saharan Africa.

The candidate uses recombinant vesicular stomatitis virus (rVSV), the same technology behind Merck's Ebola Zaire vaccine, ERVEBO®, which is licensed in more than a dozen countries.

About SUDV

- In the *Filoviridae* family of highly pathogenic viruses, which are considered potential agents of bioterror.[1]
- Endemic to sub-Saharan Africa (sSA).
- One of four orthoebolavirus species known to causes illness in humans.
- Causes a severe and often fatal viral hemorrhagic fever called Sudan virus disease or SVD (or sometimes Ebola disease).
- Zoonotic; transmission by wildlife to humans can result in onward transmission between humans.
- No vaccine or specific treatment is available; existing Ebolavirus (EBOV) vaccines don't protect against SUDV.
- Included in the World Health Organization (WHO) Pathogen Prioritization framework as a priority pathogen for which a vaccine is urgently needed.
- Highest risk of infection among health workers, family members of infected people, and people who hunt and consume wildlife in affected regions.

Results

- Currently in Phase 1 clinical development; trial planned in the U.S.
- Conducted first-in-human Phase 1, placebo-controlled clinical trial in the U.S (NCT05724472).
- Phase 1 results show one dose is safe, well-tolerated, and elicits an immune response that can be detected for at least six months after vaccination.
- Preclinical challenge studies show that 100% of vaccinated animals were protected from infection.

SUDV by the numbers

0
Approved vaccines or therapeutics

9
Reported outbreaks caused by SUDV in sSA

12-13%
Secondary attack rate in past outbreaks[2]

41-100%
Case fatality rates in past SUDV outbreaks in sSA[3]

99%
Risk of neonatal loss[3]

$1 billion
Cost of Ebola disease outbreak response to date[4]

Impact

In 2025, WHO prioritized evaluation of IAVI's SUDV candidate vaccine*, which was already prepositioned in Uganda, as part of a global collaborative effort supporting the country's SVD outbreak response.[5] The resulting ring vaccination trial (TOKEMEZA SVD) evaluating rVSVΔG-SEBOV-GP was initiated by Makerere University Lung Institute in Kampala just four days after the outbreak was declared. Tokemeza is Swahili for "to eradicate" or "to eliminate." The outbreak was declared over on April 26, 2025. A total of 14 cases and four deaths were recorded.

Ring vaccination is a targeted vaccination strategy that aims to identify contacts of an index case. This group of individuals forms a "ring" of the index case's social contact network; this ring of people is subsequently invited to consent for vaccination. Ring vaccination has proven useful during past outbreaks caused by EBOV.

At least 17 rings were formed and randomized for vaccination as part of TOKEMEZA SVD. The resulting data from this study will be used to inform next steps for IAVI's SUDV vaccine R&D program.

> **"An effective, accessible vaccine could transform the outlook for communities facing the risk of future SUDV outbreaks."**

– Swati Gupta, vice president and head of emerging infectious diseases and epidemiology, IAVI

Partnerships

- IAVI's SUDV R&D program is funded by the U.S. Biomedical Advanced Research Authority, the Dutch Government, and the Japanese Ministry of Finance.
- We are pursuing fast, flexible manufacturing solutions. In 2024, IAVI and Institut Pasteur de Dakar (IPD) in Senegal established a collaboration to research, develop, manufacture, and commercialize a range of novel vaccine candidates for both endemic and emerging infectious disease (EID) threats – all manufactured using a common vaccine production platform.
- We collaborate closely with the Viral Hemorrhagic Fever Consortium, a group of experts in affected countries.
- The Public Health Agency of Canada (PHAC) provided IAVI with a nonexclusive license to the rVSV vaccine candidates. The vector was developed by scientists at PHAC's National Microbiology Laboratory.

Visit IAVI's emerging infectious diseases page for more information.

**In 2022, Merck, known as MSD outside the United States and Canada, produced and donated to IAVI vials of rVSVΔG-SEBOV-GP candidate vaccine from existing investigational drug substance to supplement IAVI's ongoing SUDV vaccine development program. IAVI now acts as developer and regulatory sponsor and is responsible for all aspects of future development of rVSVΔG-SEBOV-GP.*

[1] https://pmc.ncbi.nlm.nih.gov/articles/PMC3394174/
[2] https://www.researchgate.net/publication/391119006_Transmission_characteristics_of_Sudan_virus_disease_outbreak_in_Uganda_in_early_2025
[3] https://www.afro.who.int/health-topics/ebola-disease/sudan-virus-disease
[4] https://pmc.ncbi.nlm.nih.gov/articles/PMC10583089/#s3
[5] https://cdn.who.int/media/docs/default-source/blue-print/who-vaccine-prioritization-report-uganda-ebola-trial-nov-16-2022.pdf

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