

FDA-approved Ebola virus vaccine authorized for use against Ebola virus infections, ERVEBO, this vaccine is not effective against SUDV due to the significant variation between Ebola virus and SUDV. ERVEBO is a live recombinant viral vaccine consisting of a vesicular stomatitis virus (VSV) backbone deleted for the VSV envelope glycoprotein and substituted with the envelope glycoprotein of the Ebola virus (Kikwit 1995 strain).

This invention provides a VSV-based vaccine expressing the SUDV-Gulu GP (VSV-SUDV). The VSV backbone of this vaccine appears to be very similar to the VSV backbone used in the ERVEBO vaccine discussed above. This could allow for a quicker and more efficient regulatory approval pathway through the FDA. Efficacy studies in non-human primates demonstrated that a single intramuscular vaccination protected animals from a lethal challenge dose of SUDV even when vaccination occurred only seven days prior to challenge. In addition, pre-exposure to the VSV vector did not inhibit a robust response to the SUDV GP component of the vaccine.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

- Prophylactic usage against SUDV infections in normal or high-risk populations.
- Therapeutic treatment, alone or in combination, in patients with SUDV infection.
- Assay development for surveillance, diagnostic, and prevention measures.

Competitive Advantages:

- Uses a VSV-based system to express antigens thereby increasing safety of the vaccine.
- Efficacious after single low dose vaccination in NHPs.
- VSV-platform induces a strong & rapid immune response.

Development Stage: Pre-clinical.

Inventors: Andrea Marzi, Ph.D., and Heinz Feldmann, MD, Ph.D., both of NIAID.

Publications: Marzi, A, et al., "Species-specific immunogenicity and protective efficacy of a vesicular stomatitis virus-based Sudan virus vaccine: a challenge study in macaques," *Lancet Microbe*, 2023 Mar;4(3): e171-e178. doi: 10.1016/S2666-5247(23)00001-0. Epub 2023 Feb 2.

Intellectual Property: U.S. Provisional Application No. 63/419,637, filed

October 26, 2022, U.S. Provisional Application No. 63/517,246 filed August 02, 2023, and PCT application PCT/US2023/077444 filed on October 20, 2023.

Licensing Contact: To license this technology, please contact Dr. Terrence Joyce at (240) 987-2347, or Terrence.joyce@NIH.gov, and reference E-002-2023.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. For collaboration opportunities, please contact Dr. Terrence Joyce at (240) 987-2347, or Terrence.joyce@NIH.gov.

Dated: January 2, 2024.

Haiqing Li,

Acting Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Eunice Kennedy Shriver National Institute of Child Health and Human Development Initial Review Group; Reproduction, Andrology, and Gynecology Study Section.

Date: February 15, 2024.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710B Rockledge Drive, Room 2125D, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jagpreet Singh Nanda, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2125D, Bethesda, MD 20892, (301) 451-4454, jagpreet.nanda@nih.gov.

Name of Committee: Eunice Kennedy Shriver National Institute of Child Health and Human Development, Initial Review Group; Developmental Biology Study Section.

Date: February 23, 2024.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710B Rockledge Drive, Room 2131B, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jolanta Maria Topczewska, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2131B, Bethesda, MD 20892, (301) 451-0000, jolanta.topczewska@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.865, Research for Mothers and Children, National Institutes of Health, HHS)

Dated: January 3, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-00112 Filed 1-5-24; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2023-0586]

National Commercial Fishing Safety Advisory Committee; September 2023 Meetings

AGENCY: United States Coast Guard, Department of Homeland Security.

ACTION: Notice of availability of recommendations and request for comments.

SUMMARY: The U. S. Coast Guard announces the availability of recommendations from the National Commercial Fishing Safety Advisory Committee (NCFSAC). The Committee met in September 2023 and sent eight recommendations to the Secretary of Homeland Security. The U.S. Coast Guard issues this Notice as the mechanism for receiving public comments and requests public comments on the recommendations.

DATES: Comments must be submitted on or before April 8, 2024.