iavi Translating science into global health impact

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

# IAVI VSV-MARV Vaccine Program Update

**Swati Gupta, DrPH, MPH, VP Emerging Infectious Diseases and Epidemiology, IAVI on behalf of Marburg project team**

WHO Filovirus CORC Meeting | 21 Jan 2025

1

IAVI gratefully acknowledges the generous support provided by the following major funders

Biomedical Advanced Research and Development Authority (BARDA) | Foundation for the National Institutes of Health | National Institute of Allergy and Infectious Diseases | amfAR, The Foundation for AIDS Research | Broadway Cares/Equity Fights AIDS | The City of New York, Economic Development Corporation | Congressionally Directed Medical Research Program (DoD) | GSK | The Hearst Foundations | Keith Haring Foundation | Merck & Co., Inc., Kenilworth, NJ, USA (known as MSD outside the USA and Canada)

And many other generous individuals and partners around the world

As of July 2024

2

## IAVI and an extensive network of partners are advancing multiple VSVΔG-GPx vaccines across the development continuum, including VSV-MARV

**Marburg***
Funded by *Biomedical Advanced Research and Development Authority (BARDA)*
- Pre-clinical studies complete
- Preparing for Phase 1

**Lassa Fever***
Funded by *Coalition for Epidemic Preparedness Innovation (CEPI)* and *European & Developing Countries Clinical Trials Partnership (EDCTP)*
- Phase 1 in U.S. and W. Africa complete
- Phase 2 enrolling in Liberia, Nigeria, and Ghana

Design → Preclinical Research → Early Development → Manufacturing Development → Clinical Development

Manufacturing Development: GMP Manufacturing; Regulatory; Nonclinical safety

**Crimean Congo Hemorrhagic Fever (CCHF)**

**Ebola Sudanvirus***
Funded by *Biomedical Advanced Research and Development Authority (BARDA)*
- Phase 1 study (US) (IAVI C108) complete
- Late-stage development underway

* Licensed through the Public Health Agency of Canada

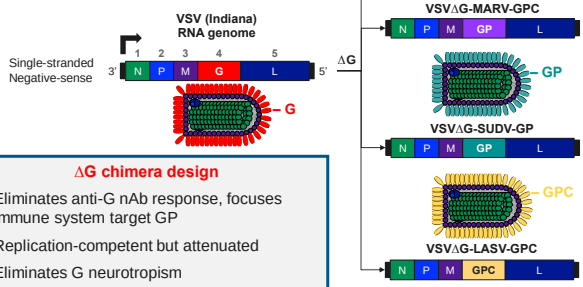




## Key Attributes of VSV

### IAVI's portfolio is based on the replication-competent VSVΔG chimeric virus technology used for Merck's Ebola Zaire vaccine (ERVEBO®)

**VSV**
- Does not cause serious human illness
- **Does not cause immune dysfunction that interferes with development of adaptive immunity**



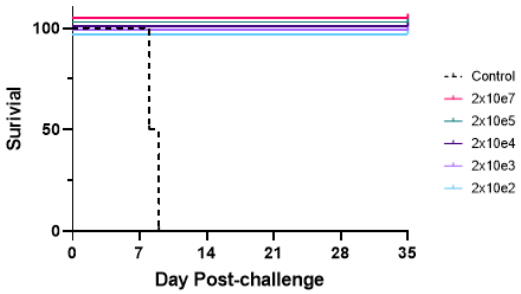

**ΔG chimera design**
- Eliminates anti-G nAb response, focuses immune system target GP
- Replication-competent but attenuated
- Eliminates G neurotropism
- **Presents authentic GP targets in context of a mild but immunostimulatory infection**

**Vaccination of people with VSVΔG-ZEBOV-GP**
- Safe and highly efficacious in people:
  - Administered to over 300,000 people
  - **High level efficacy demonstrated** in ring vaccination trial
  - Effective in outbreak
- **Single dose induces protective immunity**
- **Protective immunity develops rapidly (≤10 days)**
- Vaccination induces serum nAbs
- nAbs detectable at 2 years after vaccination

**VSVΔG-HFV-GPs nonclinical efficacy**
- **Single dose protects 100% of macaques from high-dose IM challenge**
- **Very low doses are protective**
- Protective immunity develops rapidly
- Vaccination shortly after challenge also protects
- Vaccination induces nAbs
- **Protection is durable for 1 year**

## Status of IAVI's VSV-MARV vaccine program

**VSVΔG-MARV-mediated protection against MARV-Angola challenge**




**Non-clinical:**

- **Single dose** VSVΔG-MARV is 100% efficacious in NHP challenge model with MARV-Angola strain
- No viremia and clinical signs/symptoms of MARV disease detected
- Vaccine induced potent systemic immunity (anti-GP binding titers and viral neutralization responses)

**Clinical:**

- Phase 1 trial (double-blind placebo-controlled) to be performed in US with 120 participants starting 3Q25
- Primary endpoint is safety and immunogenicity of vaccine delivered as a single IM injection at dose levels ranging from $2x10^4$ to $2x10^7$ pfu

**Manufacturing:**

- IAVI has DP which is currently undergoing release testing
- Availability end of 1Q25

5