"Bundibugyo virus Outbreak Response Vaccines" (BundiVx) Program

The "Bundibugyo virus Outbreak Response Vaccines" (BundiVx) Program aims to advance the development of Bundibugyo ebolavirus (BDBV) vaccine candidates leveraging a proven filovirus platform with demonstrated single dose protective efficacy in outbreaks.

Filoviruses, including ebolaviruses and marburgviruses, continue to pose a significant threat to U.S. national health security due to their potential to cause severe hemorrhagic disease, high mortality rates, and rapidly escalating outbreaks. The only FDA-licensed filovirus vaccine is ERVEBO (Merck), a vesicular stomatitis virus (VSV)-based vaccine indicated for the prevention of disease caused by Zaire ebolavirus (EBOV). A single dose of ERVEBO demonstrated protection during the 2014–2016 West Africa outbreak and the 2018 DRC outbreak.

On May 15, 2026, an outbreak of Ebola virus disease in Ituri Province was confirmed and subsequently determined to be caused by BDBV. There are currently no BDBV-specific vaccines that are licensed or in clinical development that could be leveraged in outbreak response trials.

The end goal of the BundiVx program is to (1) produce current Good Manufacturing Practice (cGMP) Phase 1 clinical trial material (CTM) and meet regulatory requirements to enable use of investigational candidate(s) in a clinical trial for the ongoing 2026 BDBV outbreak and (2) identify successful BDBV vaccine candidates for potential further development.

Work is anticipated to include the following:

- Task 1. Manufacturing development through production of current Good Manufacturing Practice (cGMP) clinical trial material (CTM)
    - Task 1a. Process development to engineering run
    - Task 1b. Production of cGMP Phase 1 CTM (up to 10,000 doses)
- Task 2. IND-enabling nonclinical studies
    - All critical path IND-enabling studies to enable successful Phase 1 IND
- Task 3. Phase 1 clinical trial
- Task 4. Manufacturing up to 100,000 doses of cGMP CTM
- Task 5. Outbreak clinical trial logistical support (e.g., dose labeling, shipping, storage; clinical trial sample shipping; immune assay testing in development progress immune assays and analysis)

Release of the future Request for Project Proposal (RPP) is notional but anticipated to be imminent.

The RPP is expected to have the following mandatory eligibility criteria:

- Proposed approach must use a VSV-based platform technology

- Developer must have development and manufacturing experience with the platform in the context of a filovirus vaccine
- At the time of proposal submission, the developer and proposed Contract Development and Manufacturing Organization (CDMO) partner must already have a demonstrated ongoing manufacturing relationship involving the platform technology and the manufacturing system/process proposed for this effort
- Developer must commit to providing material produced to BARDA, or to a BARDA-selected partner, for testing in nonclinical models, nonclinical assays, and/or clinical assays