

## CEPI grants \$17.3 M to Public Health Vaccines(PHV) to accelerate Nipah vaccine trials

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Human trials are underway for a vaccine against Nipah, one of the world's most deadly viruses. These trials are being conducted in Bangladesh, where outbreaks of Nipah disease now cause the deaths of almost 6,000 people annually. The vaccine (PHV02), developed by the U.S.-based biotech company Public Health Vaccines (PHV), will be among the first Nipah vaccine candidates to reach this stage of human testing when it launches in early 2026.

Public Health Vaccines will receive US\$17 million from CEPI to support the trial, building on a previous investment that helped advance Nipah vaccine through early-stage clinical testing (Phase Ia and Phase Ib), demonstrating good safety and immunogenicity in both a one-dose and a two-dose approach.

The additional funds will support the development of this vaccine into Phase II trials to determine its safety, tolerability, manufacturability and ability to generate an immune response.

A total of 500 adult participants and 75 children will be recruited in Bangladesh by the researchers.

"Public Health Vaccine's Nipah virus vaccine candidate has shown promising early results in clinical testing, demonstrating its potential to rapidly induce vaccine immunity after a single injection. This would make it an ideal protective candidate against Nipah, which is a highly lethal virus," said **Dr Kent Kester, CEPI's Executive Director of Research and Development**. "CEPI is delighted to continue its partnership with Public Health Vaccines through this additional

funding, enabling the vaccine to progress into Phase II clinical trials and help bring the promise of protection against Nipah virus closer than ever.â

If the vaccine candidate under trial proves successful and gains regulatory approval, CEPI and PHV will have the option to create a stockpile of the vaccine for use in a Nipah-affected country. This means that should an outbreak emerge in the future, these vaccines could be more readily and rapidly available, helping protect high-risk people such as healthcare workers and ending an outbreak sooner.

Developing countermeasures against disease threats of pandemic potential has never been more important or challenging. PHV is dedicated to developing vaccines to help reduce and control the risk of emerging diseases one threat at a time. Endemic populations at-risk for Nipah virus disease are faced with the increasing risk of outbreaks with no vaccines or treatments; the need is now, said **Dr. Joan Fusco, Principal Investigator and PHV's Chief Operating Officer.**

The PHV02 vaccine is a live, attenuated, recombinant vesicular stomatitis virus (rVSV) vector that expresses the glycoprotein of the Nipah virus (Bangladesh strain) and the Ebola virus glycoprotein, which is required for receptor-mediated viral entry. The immune system recognises the Nipah glycoprotein and produces a response that can neutralise the infectious virus. The rVSV-Nipah vaccine was developed by the Laboratory of Dr. Heinz Feldmann within the Laboratory of Virology, Division of Intramural Research, National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, and has been licensed to PHV by NIAID. PHV02 is based on the same technology as the approved Ebola vaccine, rVSV-ZEBOV, which has been proven to work well and has been used to fight previous Ebola outbreaks.

The VSV-vector-based platform could also be useful for facing a future Disease X—an as-yet-unknown pathogen with pandemic potential—because it allows for rapid plug-and-play vaccine development. As the platform is further validated, scientists could quickly insert genetic material from a new or unknown pathogen into the same VSV backbone, accelerating preclinical work, manufacturing, and regulatory pathways. As such, this project will make a valuable contribution to CEPI's 100 Days Mission—a goal to compress vaccine development timelines in response to a pandemic threat to a little over three months.

CEPI and the PHV are committed to enabling access to any vaccine outputs developed through this partnership, in line with CEPI's Equitable Access Policy. This includes developing a target product profile suitable for low-income and middle-income countries (LMICs), assessing the need for technology transfer to LMICs, and priority supply to LMICs at an affordable price, and a Public Health License. This license grants CEPI the rights to enable the development of the vaccine to move forward quickly in the event of an outbreak and ensures continuity for the vaccine's future development. The clinical trial data generated by this project will be published open access to benefit public health and research communities.