



## CEPI awards up to US\$43.6 million to Public Health Vaccines, LLC. for development of a single-dose Nipah virus vaccine candidate

- *Public Health Vaccine, LLC. will partner with Crozet Biopharma to develop the Nipah vaccine candidate*
- *Up to \$9 million of this funding will go to Ology Bioservices, Inc., to support manufacturing and stockpiling of the vaccine*

**Oslo, Norway and Cambridge, MA, USA; August 12, 2019**—The Coalition for Epidemic Preparedness Innovations (CEPI) and Public Health Vaccines, LLC. (PHV) have announced a partnering agreement worth up to US\$ 43.6 million to advance the development and manufacture of a vaccine against the Nipah virus—a bat-borne virus that can spread to both humans and livestock. Under the terms of the agreement, CEPI will fund pre-clinical, clinical advancement through Phase 2, and manufacturing and establishment of an investigational stockpile of the vaccine candidate.

The proposed vaccine candidate uses a weakened version of the recombinant vesicular stomatitis virus (rVSV) that expresses a type of Nipah-virus protein (known as glycoprotein G) on its surface (rVSV-Nipah), which can induce protection against the virus. It has a similar vaccine backbone to the rVSV-ZEBOV vaccine that is being used to combat an ongoing Ebola outbreak in the DRC.<sup>1</sup> The rVSV-Nipah vaccine candidate 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. Dr. Feldmann and his research group demonstrated the protective efficacy of the rVSV-Nipah vaccine candidate in preclinical studies.<sup>2,3,4</sup>

The Nipah virus was first identified in 1999 during an outbreak of illness affecting pig farmers and others having close contact with pigs in Malaysia and Singapore. Over 100 human deaths were reported, and over a million pigs were killed in the effort to stop the outbreak.<sup>5</sup> Since then, the virus has travelled thousands of kilometers causing outbreaks in South Asia and Southeast Asia. In June, 2019, a 23-year-old engineering student tested positive for Nipah

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<sup>1</sup> <https://apps.who.int/iris/bitstream/handle/10665/326098/OEW30-2228072019.pdf>

<sup>2</sup> <https://www.ncbi.nlm.nih.gov/pubmed/25865472>

<sup>3</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4829066/>

<sup>4</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5505655/>

<sup>5</sup> [https://academic.oup.com/cid/article/34/Supplement\\_2/S48/459309](https://academic.oup.com/cid/article/34/Supplement_2/S48/459309)



virus in Ernakulam district, Kerala, India.<sup>6</sup> Last year, another outbreak of Nipah virus occurred in the same region, killing 18 of the 19 people who were infected (95% case fatality rate).<sup>7</sup> Nipah virus has been listed as a priority pathogen by the WHO and a category C Bioterrorism agent by the CDC.<sup>8,9</sup>

Richard Hatchett, CEO of CEPI said: “Nipah virus poses a real threat to global health security—it has multiple modes of transmission, causes significant morbidity and mortality, and has shown that it can cause significant societal and economic disruption. The world is in desperate need of a vaccine against this deadly virus. We’re pleased to be working with Public Health Vaccines, Crozet BioPharma, and Ology Bioservices to advance the development of what will be CEPI’s fourth vaccine candidate against the highly pathogenic Nipah virus.”

Mike McGinnis, Chief Business Officer of PHV said: “PHV is enthusiastic about this new collaboration with CEPI to advance our Nipah vaccine candidate and build on the successful efforts of our other rVSV vaccine programs. Our missions are aligned, and we look forward to jointly addressing this important public health threat.”

Tom Monath, Managing Partner and Chief Scientific Officer at Crozet Biopharma said: “Our team includes individuals with several years of experience developing the successful rVSV-ZEBOV Ebola vaccine that will greatly facilitate advancement of the Nipah vaccine, which uses the VSV platform. We are delighted to be supported by CEPI and to be engaged with PHV, Ology Bioservices and other outstanding partners in this endeavor to prevent a life-threatening tropical disease.”

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### **About the Nipah Virus Vaccine**

The vaccine candidate is a live, attenuated recombinant vesicular stomatitis virus (rVSV) vector that expresses the glycoprotein (G) of the Nipah virus (Bangladesh strain). The rVSV construct also contains the ZEBOV glycoprotein GP, which is required for receptor-mediated viral entry. PHV will work closely with a team of industry experts from Crozet Biopharma to develop the vaccine candidate. Ology Bioservices will develop and scale-up the manufacturing process for clinical use of the vaccine and will generate an investigational stockpile of the vaccine candidate for use in the event of a Nipah outbreak as part of a clinical trial.

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<sup>6</sup> <https://qz.com/india/1635545/nipah-virus-returns-to-haunt-indias-kerala-state/>

<sup>7</sup> <https://www.who.int/csr/don/07-august-2018-nipah-virus-india/en/>

<sup>8</sup> <https://www.who.int/blueprint/priority-diseases/en/>

<sup>9</sup> [https://fas.org/biosecurity/resource/documents/CDC\\_Bioterrorism\\_Agents.pdf](https://fas.org/biosecurity/resource/documents/CDC_Bioterrorism_Agents.pdf)



### **About CEPI**

CEPI is an innovative partnership between public, private, philanthropic, and civil organisations launched in Davos in 2017 to develop vaccines to stop future epidemics. CEPI has received multi-year funding from Norway, Germany, Japan, Canada, Australia, and the Bill & Melinda Gates Foundation, and Wellcome. CEPI has also received single-year investments from the Governments of Belgium and the United Kingdom. The European Union provides financial support for relevant projects through their Horizon 2020 programme as well as through the European and Developing Countries Clinical Trials Partnership. CEPI has reached over US\$750 million of its \$1 billion funding target. Since its launch in January 2017, CEPI has announced three calls for proposals. The first call was for candidate vaccines against Lassa virus, Middle East Respiratory Syndrome coronavirus (MERS-CoV), and Nipah virus. The second call was for the development of platforms that can be used for rapid vaccine development against unknown pathogens. The third call was for candidate vaccines against Chikungunya and Rift Valley fever viruses. To date, CEPI has committed to investing over \$456 million in vaccine development. This includes 19 vaccine candidates against its priority pathogens (six against Lassa virus, five against MERS-CoV, four against Nipah virus, two against Chikungunya, two against Rift Valley fever) and three vaccine platforms to develop vaccines against Disease X. To assess the effectiveness of these platforms 7 additional vaccine candidates are being developed (two against influenza, one against Marburg virus, two against Rabies virus, one against Respiratory Syncytial Virus, and one against yellow fever).

Learn more at [CEPI.net](http://CEPI.net). Follow us at [@CEPIvaccines](https://twitter.com/CEPIvaccines).

### **About PHV**

Public Health Vaccines, LLC. (PHV), headquartered in Cambridge, Massachusetts, is a privately-held biotechnology company developing vaccines for the prevention and control of emerging infectious diseases. The company's initial focus has been to develop vaccines against Marburg virus and Sudan ebolavirus (MARV and SUDV) utilizing the rVSV platform with support from the US Government's Biomedical Advanced Research and Development Authority (BARDA). PHV entered into a license agreement with the Public Health Agency of Canada (PHAC) to leverage the advanced recombinant vesicular stomatitis virus (rVSV) vector platform that PHAC discovered in 2005, to develop vaccines against Marburg virus and Sudan ebolavirus.

### **About Ology Bioservices**

Ology Bioservices is a privately-held, full-service Contract Development Manufacturing Organization (CDMO) serving both government and commercial clients, specializing in biologic drug substance manufacturing, from early stage through commercial product. The company has 183,000 square feet of manufacturing, process development and QA/QC space in its state-of-the-art, Department of Defense Advanced Development and Manufacturing Facility in Florida. The company's infrastructure provides unique services to its clients, including full regulatory support from preclinical through licensure, clinical trial operational support and



bioanalytical testing, as well as cGMP manufacturing up to Biosafety Level 3 (BSL3). Ology Bioservices has 20 years of experience developing and manufacturing drugs and biologics for the U.S. Government, with over \$500M in government contracts awarded over that time. The team at Ology Bioservices has decades of experience manufacturing, developing and licensing vaccines and protein/antibody therapeutics. For more information, visit the company's website at [www.ologybio.com](http://www.ologybio.com).

**About Crozet BioPharma**

Crozet BioPharma, LLC, headquartered in Devens, Massachusetts, is a biotechnology company developing medical countermeasures for infectious disease and cancer. Crozet's team includes individuals with deep experience and a track record of developing 10 licensed vaccines. Most recently the team, while at NewLink Genetics, enabled the transfer to Merck and registration efforts for the rVSV-EBOV Ebola vaccine and is partnered with PHV to deliver a rVSV-Marburg vaccine. Crozet has entered into a partnership agreement with Public Health Vaccines to manage the technical development of the candidate VSV-Nipah vaccine. For more information, visit the company's website at [www.crozetbiopharma.com](http://www.crozetbiopharma.com)

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