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Public Health Vaccines announces initiation of first clinical trial evaluating its Marburg virus vaccine

CAMBRIDGE, MA – March 21, 2024 – Public Health Vaccines, LLC (PHV), a biotechnology company out of Cambridge, MA developing novel products against emerging infectious diseases, has started its Phase 1 clinical trial (NCT06265012) to evaluate the safety and immunogenicity of the company's single-dose vaccine (PHV01) against Marburg virus—a hemorrhagic fever virus of the Filoviridae family that causes Marburg Virus Disease, a rare but severe hemorrhagic fever that affects people and non-human primates and has a case fatality rate of up to 88%. In addition to being a naturally occurring public health threat on the World Health Organization's list of priority pathogens with potential to cause future outbreaks and pandemics, Marburg virus has been identified as a Category A Select Agent.

The Phase 1 clinical trial is randomized, single-blind, placebo-controlled, ascending dose study to evaluate the safety and immunogenicity of PHV01 (rVSV Δ G-MARV-GP [Angola]) in healthy adults in the U.S. The PHV01 vaccine is leveraging the proven recombinant vesicular stomatitis virus (rVSV) vector platform originally developed by the Public Health Agency of Canada (PHAC) to develop a single-dose vaccine against Marburg Virus. PHV01 is a live, attenuated rVSV vector expressing the glycoprotein of MARV (Angola) that utilizes the same vector system as the approved rVSV-EBOV vaccine against Ebola Zaire and is known for inducing a rapid onset of protection after a single dose.

PHV01 has been funded by the Biomedical Advanced Research and Development Authority (BARDA), part of the HHS Administration for Strategic Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services under contract number HHSO100201900022C. If PHV development efforts continue successfully, BARDA has the option to provide up to \$72 million in funding, enabling the completion of a Phase 2 clinical trial and additional activities on the regulatory path to approval.

Joan Fusco, PHV's Chief Operating Officer, commented, "In light of the Marburg outbreaks in Africa last year and in certain countries for the first time, it's critically important to have a complement of vaccine countermeasures with clinical data ready to address this rising infectious disease threat. PHV is dedicated to developing its PHV01 vaccine for endemic use and global preparedness. Our Phase 1 clinical trial is not only the first step towards that goal, but also the first clinical trial of a recombinant VSV-based Marburg vaccine. Like the rVSV-EBOV vaccine, we hope to achieve similar success with PHV01. PHV is grateful for BARDA's continued support in making this first step a reality. This pivotal milestone was reached due to the unwavering commitment and dedication of PHV, its core team and wide network of collaborators – thank you all."

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About Public Health Vaccines, LLC

Public Health Vaccines, LLC. (PHV), headquartered in Cambridge, Massachusetts, is a privately held biotechnology company developing products for the prevention and control of emerging infectious diseases; including vaccines against Marburg virus, Sudan ebolavirus, and Nipah virus.

For more information, please visit www.phvaccines.com or email info@phvaccines.com.