



For Immediate Release  
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### **Polyvalent DNA/Protein HIV Vaccine Showed Excellent Immunogenicity in a Multi-Center Human Study**

[MAY 6, 2021] – The human immunogenicity of WHV’s investigational HIV vaccine candidate, PDPHV (Polyvalent DNA/Protein HIV Vaccine), is promising based on the recent phase 1 data reported at the Full Group Meeting of HIV Vaccine Trial Network (HVTN) in early May 2021.

PDPHV is composed of five DNA vaccine plasmids and four gp120 recombinant proteins. The DNA vaccines were used to prime the immune system (T cells and B cells) to receive a boost of HIV proteins, which signals the body to produce protective antibodies against HIV. PDPHV is the first and only vaccine formulation that includes viral Env antigens from all four major circulating HIV subtypes to advance to safety and immunogenicity studies in humans.

PDPHV completed its safety and immunogenicity testing in a Phase I clinical trial ([HVTN 124](#)) for healthy adult human volunteers managed by the HIV Vaccine Trials Network (HVTN), which is funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). The mission of the HVTN is to fully characterize the safety, immunogenicity, and efficacy of HIV vaccine candidates with the goal of developing a safe, effective vaccine as rapidly as possible for prevention of HIV globally.

The HVTN 124 study team reported that PDPHV was safe and well tolerated in its full course of 18 months of study. No serious adverse event was observed. More significantly, the majority of HVTN 124 study participants who received the experimental PDPHV developed high level HIV specific CD4+ T cells and antibody responses across very diverse HIV subtypes. Such antibodies showed high levels of antibody dependent cellular cytotoxicity activity (a function of killing virus infected cells) and the ability to neutralize a wide range of Tier 1b HIV viral isolates in a laboratory-based assay.

“The immunogenicity data of HVTN 124 is remarkable” said Jim Kublin, MD., Executive Director of HVTN. “How to elicit strong immune responses and how to ensure such immune responses can be directed against diverse viral strains circulating in the world are two major challenges in the HIV vaccine field. PDPHV data showed great progress to address both questions.”

PDPHV was originally developed from Dr. Shan Lu’s laboratory at the University of Massachusetts Medical School (UMMS). He received more than \$50 million from NIAID/NIH to oversee the development and manufacturing of PDPHV. WHV licensed PDPHV from UMMS in early 2018 for its further clinical development. WHV is also establishing broad collaborations with academic and industry partners including the Infectious Disease Research Institute (IDRI) in Seattle, Washington, which developed and manufactured the adjuvant used to stimulate responses to the protein component of the PDPHV vaccine. WHV is also investing in producing additional supplies of PDPHV for more advanced human studies.

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