



For Immediate Release

Thursday, December 1, 2022

## WHV Joins the World in Commemorating World AIDS Day 2022

United with people around the world in the fight against HIV, we at WHV reaffirm our commitment to help end the HIV pandemic with our continued efforts in developing a safe and effective HIV vaccine to significantly reduce new infections around the world. Today, the WHV team celebrates the achievements of the HIV vaccine research community in 2022 by reflecting on our accomplishments during the past 12 months:

WHV's greatest pride this year is the progress of the phase 1b WHV138 trial, a single-site randomized controlled trial testing the safety and immunogenicity of the polyvalent DNA/Protein HIV Vaccine candidate (PDPHV) in two different treatment groups using a co-administration regimen in repeated doses. As the IND-holder of PDPHV, WHV successfully filed their first IND annual report with the FDA and passed the Safety Monitoring Board review without any safety concerns. After successfully concluding enrollment of 42 healthy volunteers in the midst of the COVID-19 pandemic, WHV138 is now approaching the finishing line in volunteer vaccinations which is followed by a 12-month safety follow-up period.

PDPHV is currently the only vaccine tested in humans with a formulation consisting of DNA-encoded gp120 antigens of four different clades (A, B, C, and AE) and matched recombinant gp120 proteins. This heterologous HIV vaccine candidate has shown promising results using a DNA prime – Protein boost regimen in the preceding phase 1a HVTN124 trial, a multi-center randomized controlled trial sponsored by the HIV Vaccine Trials Network (HVTN) and funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). Secondary analyses of HVTN124 indicate that PDPHV has the potential to elicit cross-protective, high magnitude, and large breadth immune responses. Therefore, WHV strives to quickly advance the product development program of PDPHV and has begun planning a phase 2 trial to further investigate the immunogenicity of this promising vaccine candidate. With such a low-risk safety profile and very positive preliminary immunogenicity results, PDPHV could play a major role in the worldwide HIV prevention efforts since a safe and effective preventative HIV vaccine is one of the necessary tools to control the HIV pandemic.

In addition to the clinical trial's progress, WHV was able to help advance the HIV vaccine field by contributing to the growing body of knowledge with complex research studies resulting from WHV's vaccine development program. With the support of renowned research partners, three different posters featuring the first- and second-generation PDPHV were presented at two major conferences this year. Two poster presentations were held at the [2022 Keystone Symposium on HIV Vaccines](#) in March and two posters were presented at the [2022 ISV Annual Congress](#) in September. Moreover, at the recent HVTN Full Group Meeting held in Seattle, WA in October,



HVTN124 immunogenicity data were presented in a comparison analysis across multiple HVTN studies, focusing on possible correlates of protection against HIV infection. This exploratory analysis suggests that PDPHV has the strongest potential at achieving higher levels of antibody responses than any other vaccine candidate tested so far.

These preliminary data are an encouraging note that with PDPHV, the HIV vaccine field has a vaccine candidate in the pipeline with great promise to potentially be protective against HIV infection. However, additional extensive research is required to further explore these observations – a challenge that WHV and their partners are excited to dive into.

Another big milestone reached earlier this year is WHV's move to a new research facility to accommodate their quickly progressing vaccine development program. Previously using M2D2 incubator space at the University of Massachusetts Chan Medical School (UMCMS) in Worcester, MA, where PDPHV originated from Dr. Shan Lu's lab, WHV is now operating at a new location with much larger space and independent from UMCMS to further develop their research work.

Most recently, the WHV team was graciously welcomed into the International AIDS Society (IAS) Corporate Partnership Program as a Bronze member for the coming year. It is an honor for WHV to be working alongside world-leading HIV vaccine experts who have also joined this multi-stakeholder group that is aiming to support industry's contribution to HIV vaccine R&D. Together, we hope to address the ongoing critical need to accelerate the development of a safe and effective HIV vaccine that can eventually be used for our ultimate goal: The prevention of new HIV infections worldwide.

###