For Immediate Release
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FDA Clears Worcester HIV Vaccine Investigational New Drug Application for Vaccine to Prevent HIV Infections

[JANUARY 27, 2021] –Worcester HIV Vaccine (WHV) has received clearance from the U.S. Food and Drug Administration for its Investigational New Drug (IND) application for a novel polyvalent DNA/prime-protein boost vaccine to prevent HIV, called PDPHV. The IND calls for the Worcester-based start-up to explore different vaccination designs in a phase 1b clinical trial to be launched in February 2021. A phase II clinical trial is expected to follow.

Based on discoveries by Shan Lu, MD, PhD, professor of medicine, and licensed from UMass Medical School, WHV's vaccine employs a polyvalent DNA-prime/protein-boost technology to target multiple subtypes of HIV-1. PDPHV is a novel vaccine composed of five DNA plasmids and four gp120 recombinant proteins. The DNA component is used to prime the immune system to receive a boost of HIV proteins, which stimulate the body to produce potent antibodies against HIV.

"In a little over two years since the founding of WHV, we have filed our first IND. This is a major achievement and a true milestone for WHV," said Yegor Voronin, PhD, chief operating officer of WHV. "The excellent safety results of PDPHV and positive preliminary immunogenicity data we have from earlier clinical trials give us confidence to rapidly develop our own clinical program."

An earlier version of this vaccine was tested in a single-site clinical trial conducted at UMass Medical School, and the second generation of the vaccine has been recently tested at six US sites by the HIV Vaccine Trials Network (HVTN) under protocol HVTN 124. HVTN is funded by the National Institute of Allergy and Infectious Diseases (NIAID). Dr. James Kublin, Executive Director of HVTN, commented on the news: "I am very encouraged by the safety data and preliminary immunogenicity results of the HVTN124 trial and excited to see WHV's further progress in advancing this promising vaccine candidate."

PDPHV is the first and only vaccine formulation that includes natural viral antigens from all four major circulating HIV subtypes to advance to safety and efficacy trials in humans. Full immunogenicity results from HVTN 124 will be released in 2021.

Over the last two decades, Dr. Lu's lab has received more than $50 million in NIAID funding to oversee the development and manufacturing of PDPHV. WHV licensed PDPHV from UMass Medical School in early 2018 for development.

WHV has worked with Waisman Biomanufacturing, a contracted manufacturing organization, to use their proprietary technology to manufacture DNA plasmids with purer quality and higher yields than previously. Recently, Target Health, LLC, a New York-based CRO with many years of regulatory experience, joined the WHV team to help prepare and file the IND.

WHV is also collaborating with the Infectious Disease Research Institute (IDRI) in Seattle, which developed and manufactured the adjuvant used to stimulate responses to the protein component of the PDPHV vaccine. Adjuvants can be broadly leveraged to develop vaccines against many viruses, and are

components of several COVID-19 vaccine candidates to broaden and lengthen the duration of protection against the SARS-CoV-2 virus.

“HIV remains a leading infectious cause of death worldwide, and is one of the most challenging viruses to protect against with a vaccine,” said Corey Casper, M.D., chief executive officer of IDRI. “IDRI is excited to contribute its immune-enhancing adjuvant, GLA-SE — with a proven safety and immunogenicity profile in thousands of humans to date — to this critical vaccine effort.”

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