# Vir Biotechnology Announces First Participant Dosed in New Phase 1 Trial Evaluating VIR-1388, an Investigational T Cell Vaccine for the Prevention of HIV

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*– Based on a novel human cytomegalovirus vector platform, VIR-1388 was designed with the goal of creating a novel HIV vaccine –*

*– Phase 1 trial supported by the Bill & Melinda Gates Foundation, the National Institute of Allergy and Infectious Diseases and conducted by the HIV Vaccine Trials Network –*

SAN FRANCISCO, Sept. 20, 2023 (GLOBE NEWSWIRE) -- Vir Biotechnology, Inc. (Nasdaq: VIR) today announced that the first participant has been dosed in a Phase 1 trial evaluating the safety, reactogenicity and immunogenicity of VIR-1388, an investigational novel T cell vaccine for the prevention of human immunodeficiency virus (HIV). The Company expects initial data from the Phase 1 trial in the second half of 2024.

VIR-1388 is based on the human cytomegalovirus (HCMV) vector platform and is designed to stimulate the body to produce immune cells known as T cells that recognize several HIV proteins in a way that differs from prior investigational HIV vaccines. VIR-1388 was developed using applied learnings from VIR-1111, the Company's initial investigational proof-of-concept HIV T cell vaccine based on HCMV.

"HIV continues to be a major global public health challenge with no approved vaccines despite decades of research efforts," said Carey Hwang, M.D., Ph.D., Vir's Senior Vice President, Clinical Research, Head of Chronic Infection. "The initiation of our first clinical trial evaluating VIR-1388 is an important clinical milestone in our pursuit of developing an HIV vaccine and we are grateful to all our partners for their support of this Phase 1 trial. We are hopeful that our unique approach will help close the longstanding public health gap in HIV prevention."

The trial is supported by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, and the Bill & Melinda Gates Foundation. NIAID has provided funding throughout the product development lifecycle of VIR-1388, and the Foundation has also supported the Company's development of therapies for the treatment of HIV, the prevention of tuberculosis and the prevention of malaria. The Phase 1 trial of VIR-1388 will take place in both domestic and international sites within the federally funded HIV Vaccine Trials Network (HVTN) as study HVTN 142.

The HCMV vector is a weakened version of the virus that is designed to deliver the HIV vaccine material to the immune system without causing disease in the trial participants. HCMV has been present in much of the global population for centuries. Most people living with HCMV experience no symptoms and are unaware that they are living with the virus. HCMV remains detectable in the body for life, which suggests it has the potential to deliver and then safely help the body retain HIV vaccine material for a long period of time, potentially overcoming the waning immunity observed with more short-lived vaccine vectors.

According to the Joint United Nations Programme on HIV/AIDS (UNAIDS), approximately 1.5 million people were newly infected with HIV and around 650,000 people worldwide died from AIDS-related deaths in 2021.

**Design of the Phase 1 Trial**
The randomized, double-blind, placebo-controlled Phase 1 trial *(NCT05854381)* is evaluating the safety, reactogenicity and immunogenicity of three different doses of VIR-1388 compared with placebo. The trial is designed to enroll approximately 95 participants ages 18 to 55 who are not living with HIV, with existing antibodies specific to HCMV and in overall good health as determined by medical history, physical exam and laboratory tests.

The overall study design includes two parts. Part A is a lead-in phase enrolling a limited number of HCMV-positive persons of non-childbearing potential with a frequent safety monitoring schedule. Part B will expand enrollment to a broader population of HCMV-positive participants, including persons of childbearing potential. An optional long-term follow-up study will increase study participation for up to three years post first dose.

**About VIR-1388**
VIR-1388 is an investigational subcutaneously administered HIV T cell vaccine based on HCMV that has been designed to elicit abundant T cells that recognize HIV proteins in a way that differs from prior investigational HIV vaccines. VIR-1388 uses applied learnings from VIR-1111, Vir's initial investigational proof-of-concept HIV T cell vaccine, with the goal of creating a safe and effective HIV vaccine.

**About VIR-1111**
VIR-1111 is an investigational subcutaneously administered proof-of-concept HIV T cell vaccine based on HCMV that has been designed to elicit abundant T cells that recognize HIV epitopes in a way that differs from prior HIV vaccines.

**About Vir Biotechnology**
Vir Biotechnology, Inc. is an immunology company focused on combining cutting-edge technologies to treat and prevent infectious diseases and other serious conditions. Vir has assembled two technology platforms that are designed to stimulate and enhance the immune system by exploiting critical observations of natural immune processes. Its current clinical development pipeline consists of product candidates targeting hepatitis B and hepatitis delta viruses, influenza A and B, human immunodeficiency virus and COVID-19. Vir has several preclinical candidates in its pipeline, including RSV/MPV and HPV. Vir routinely posts information that may be important to investors on its website.

**Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "plan," "potential," "aim," "expect," "anticipate," "promising" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on Vir's expectations and assumptions as of the date of this press release. Forward-looking statements contained in this press release include, but are not limited to, statements regarding Vir's strategy and plans; the potential safety and efficacy of VIR-1388; the timing, design and enrollment of the Phase 1 clinical trial; Vir's plans and expectations for its HIV portfolio, including VIR-1388; and risks and uncertainties associated with drug development and commercialization. Many important factors may cause differences between current expectations and actual results, including risks that Vir may not fully enroll the Phase 1 trial; unexpected safety or immune response data or results observed during the trial; the occurrence of adverse safety events; risks of unexpected costs, delays or other unexpected hurdles; difficulties in collaborating with other companies; successful development and/or commercialization of alternative product candidates by Vir's competitors; changes in expected or existing competition; delays in or disruptions to Vir's business or clinical trials due to the COVID-19 pandemic, geopolitical changes or other external factors; and unexpected litigation or other disputes. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical trials may not be indicative of full results or results from later-stage or larger-scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements or the scientific data presented. Other factors that may cause actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Vir's filings with the U.S. Securities and Exchange Commission, including the section titled "Risk Factors" contained therein. Except as required by law, Vir assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

Contacts: Media Carly Scaduto Senior Director, Media Relations cscaduto@vir.bio +1-314-368-5189 Investors Sasha Damouni Ellis Executive Vice President, Chief Corporate Affairs Officer sdamouni@vir.bio