Vir Biotechnology Announces Initiation of Phase 1 Clinical Trial to Evaluate a Novel Vaccine Platform

January 6, 2021

– Culmination of a decade-long collaboration with Oregon Health & Science University and the Bill & Melinda Gates Foundation –

SAN FRANCISCO, Jan. 06, 2021 (GLOBE NEWSWIRE) -- Vir Biotechnology, Inc. (Nasdaq: VIR), a clinical-stage immunology company focused on treating and preventing serious infectious diseases, announced that the first patient was dosed in late December 2020 in a Phase 1 clinical trial of VIR-1111, an investigational human immunodeficiency virus (HIV) T cell vaccine. VIR-1111 is a proof-of-concept vaccine designed to test the hypothesis that this new approach can elicit potentially protective immune responses that differ from other HIV vaccines. VIR-1111 is uniquely designed to elicit abundant and durable CD4 and CD8 T cells that are programmed to attack virus-infected cells. This trial is being conducted in collaboration with Oregon Health & Science University's (OHSU) Vaccine and Gene Therapy Institute with support from the Bill & Melinda Gates Foundation.

"We are pleased to have initiated the first Phase 1 trial to evaluate our T cell platform, which explores the potential for immune-programmed vaccines to treat and prevent serious infectious diseases like HIV," said Herbert "Skip" Virgin, M.D., Ph.D., chief scientific officer of Vir. "If observed, a programmed immune response could be a significant step forward in the fight against HIV and in the field of vaccines, with ramifications that could extend to other challenging areas like cancer immunotherapy."

The randomized, placebo-controlled, Phase 1 clinical trial is evaluating the safety and immunogenicity (ability to induce an immune response) of VIR-1111. The trial is enrolling healthy adults (ages 18 to 50) who are considered to be at low risk of HIV infection and who were previously infected with human cytomegalovirus (HCMV). They will receive two doses of VIR-1111 or placebo given by subcutaneous injection and be assessed for safety, reactogenicity (common, expected adverse reactions following vaccination, such as pain and redness), tolerability and immunogenicity.

The viral vector technology that will be used in this trial was developed in a collaboration between Vir scientists and a team of OHSU scientists led by Louis Picker, M.D., and Klaus Frueh, Ph.D.

"Along with the many OHSU investigators who worked on this project over the years, we are very excited that this new vaccine platform is being evaluated in a clinical trial," Drs. Picker and Frueh said. "This marks the first time that this new type of vaccine is being tested in humans. If successful, this approach could provide an entirely new set of tools for vaccine development."

Key publications highlighting the potential impact of this approach include:

- A live-attenuated RhCMV/SIV vaccine shows long-term efficacy against heterologous SIV challenge (Science Translational Medicine, 2019);
- Enhancing safety of cytomegalovirus-based vaccine vectors by engaging host intrinsic immunity (Science Translational Medicine, 2019);
- CD8+ T cell programming by cytomegalovirus vectors: applications in prophylactic and therapeutic vaccination (Current Opinion in Immunology, 2017);
- Broadly targeted CD8+ T cell responses restricted by major histocompatibility complex E (Science, 2016); and
- Cytomegalovirus vectors violate CD8+ T cell epitope recognition paradigms (Science, 2013).

About VIR-1111

VIR-1111 is a subcutaneously administered 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 is a clinical-stage immunology company focused on combining immunologic insights with cutting-edge technologies to treat and prevent serious infectious diseases. Vir has assembled four technology platforms that are designed to stimulate and enhance the immune system by exploiting critical observations of natural immune processes. Its current development pipeline consists of product candidates targeting SARS-CoV-2, hepatitis B virus, influenza A, human immunodeficiency virus and tuberculosis. For more information, please visit www.vir.bio.

Vir 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," "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. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this press release include statements regarding Vir's

collaboration with Oregon Health & Science University and the Bill & Melinda Gates Foundation, the timing of the first patient dosed in the Phase 1 clinical trial for VIR-111, the design and potential ability of VIR-1111 to program specific T cell responses, the potential benefits that immune-programmed vaccines could have in the treatment and prevention of serious infectious diseases like HIV, the design for the Phase 1 clinical trial for VIR-111, including information on the immune response already observed in preclinical studies, details regarding patient enrollment and dosing, as well as statements around the use and potential impact of viral vector technology in prophylactic and therapeutic T cell vaccination and CD8+ T cell responses. Many factors may cause differences between current expectations and actual results, including unexpected safety, tolerability, or immunogenicity data or results observed during the Phase 1 clinical trial, the failure to replicate in humans the specific immune response observed in non-human primates in the preclinical trial, challenges in clinical site activation rates or clinical trial enrollment rates that are lower than expected, 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. 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.

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Source: Vir Biotechnology, Inc.