Vir Biotechnology Initiates Phase 1 Clinical Trial of VIR-3434 for Chronic Hepatitis B Virus Infection

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Novel investigational HBV-neutralizing monoclonal antibody with therapeutic vaccine-like properties

SAN FRANCISCO, May 27, 2020 (GLOBE NEWSWIRE) -- Vir Biotechnology, Inc. (Nasdaq: VIR) today announced the initiation of a Phase 1 clinical trial of VIR-3434, an investigational monoclonal antibody that neutralizes hepatitis B virus (HBV) and has been engineered to potentially also act as a therapeutic vaccine. The commencement of first-in-human dosing marks the start of Vir's second clinical program aimed at a functional cure for HBV.

"We firmly believe that a functional cure will require a cocktail of drugs that has both antiviral and immune stimulatory activity. We have selected our drug candidates with this in mind," said Phillip Pang, M.D., Ph.D., Chief Medical Officer of Vir. "In the case of VIR-3434, it is remarkable to have a drug candidate that by itself has the potential to be both an antiviral and a therapeutic vaccine. When combined with our siRNA candidate, VIR-2218, we believe that this cocktail could achieve very high rates of functional cure."

VIR-3434 is an HBV-neutralizing monoclonal antibody designed to block entry of all 10 genotypes of HBV into hepatocytes, and also to reduce the level of virions and subviral particles in the blood. It has also been Fc engineered to include the XX2 "vaccinal mutation," for which Vir has licensed exclusive rights for all infectious diseases. VIR-2218, an investigational small interfering ribonucleic acid (siRNA) that mediates RNA interference, is currently being investigated in a Phase 2 trial for the treatment of chronic HBV infection.

"The vaccinal mutations incorporated into the Fc domain of VIR-3434 act in concert to potentially trigger the correct FcGamma receptors on dendritic cells, resulting in their maturation," said Jeffrey V. Ravetch, M.D., Ph.D., Theresa and Eugene M. Lang Professor and Head of the Leonard Wagner Laboratory of Molecular Genetics and Immunology at The Rockefeller University, who discovered these mutations and their role. "If they work in humans the way they do in mice, after this antibody has captured an HBV virion or subviral particle, we believe the antibody will deliver this payload to immature dendritic cells, stimulating them to mature and subsequently result in HBV specific T cells."

The Phase 1 clinical trial of VIR-3434 is a randomized, placebo-controlled trial designed to assess the safety, tolerability, pharmacokinetics, antiviral and immunomodulatory activity of VIR-3434 in healthy volunteers and patients with chronic HBV infection. The company plans to enroll patients at multiple trial sites in several countries in the Asia Pacific and European regions. The trial is designed to progress from healthy volunteers to chronic HBV patients in a staggered, parallel fashion with the goal of rapidly generating early proof-of-concept data in patients. Data are expected to be available in 2021.

"The initiation of this clinical trial is welcome news as we pursue new agents that can, either individually or in combination, stop viral replication and reignite the body's immune response to restore control," said Edward J. Gane, M.D., Professor of Medicine at the University of Auckland, New Zealand and Chief Hepatologist, Transplant Physician and Deputy Director of the New Zealand Liver Transplant Unit at Auckland City Hospital and a lead investigator of the trial.

About Hepatitis B

Approximately 290 million people globally are chronically infected with HBV and approximately 900,000 of them die from HBV-associated complications each year. There is a significant unmet medical need for more effective therapies that lead to life-long control of the virus after a finite duration of therapy, which is the definition of a functional cure. For a registrational trial to demonstrate a functional cure, the formal endpoint accepted by the U.S. Food and Drug Administration (FDA) is undetectable hepatitis B virus surface antigen (HBsAg), defined as less than 0.05 international units per milliliter, as well as HBV DNA less than the lower limit of quantification, in the blood six months after the end of therapy. Currently, a year-long course of pegylated interferon-alpha (PEG-IFN-α) is the best available curative therapy. It has a low functional cure rate of approximately three to seven percent. Alternatively, suppressive therapy with nucleotide/nucleoside reverse transcriptase inhibitors (NRTIs) is commonly used, but patients often require a lifetime of therapy.

About VIR-3434

VIR-3434 is a subcutaneously administered HBV-neutralizing monoclonal antibody designed to block entry of all 10 genotypes of HBV into hepatocytes and also to reduce the level of virions and subviral particles in the blood. VIR-3434 has been engineered to have an extended half-life as well as to potentially function as a T cell vaccine against HBV in infected patients.

About VIR-2218

VIR-2218 is a subcutaneously administered HBV-targeting siRNA that has the potential to stimulate an effective immune response and have direct antiviral activity against HBV. It is the first siRNA in the clinic to include Enhanced Stabilization Chemistry Plus (ESC+) technology to enhance stability and minimize off-target activity, which potentially can result in an increased therapeutic index. VIR-2218 is the first asset in the company's collaboration with Alnylam Pharmaceuticals, Inc. to enter clinical trials.

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 hepatitis B virus, influenza A, SARS-CoV-2, human immunodeficiency virus and tuberculosis. For more information, please visit www.vir.bio.

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," "expect," "plan," "anticipate," "estimate," "intend," "potential," "to be" 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 the requirements for a functional cure for HBV, the potential benefits of VIR-3434 and VIR-2218 (individually or in combination), and the timing, design and planned program updates and data disclosures for the Phase 1 clinical trial of VIR-3434, including trial enrollment rates and site activation plans. Many factors may cause differences between current expectations and actual results including unexpected safety or efficacy data observed during preclinical or clinical studies, difficulty in collaborating with other companies or government agencies, challenges in accessing manufacturing capacity, clinical site activation rates or clinical trial enrollment rates that are lower than expected, changes in expected or existing competition, delays or disruptions on our business or clinical trials due to the COVID-19 pandemic, 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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