Vir Biotechnology Initiates Phase 2 Clinical Trial Evaluating the Combination of VIR-2218 and VIR-3434 as a Functional Cure Regimen for Chronic Hepatitis B Virus Infection

July 15, 2021

SAN FRANCISCO, July 15, 2021 (GLOBE NEWSWIRE) -- Vir Biotechnology, Inc. (Nasdaq: VIR) today announced that the first patient has been dosed in the Phase 2 MARCH (Monoclonal Antibody siRNA Combination against Hepatitis B) trial evaluating VIR-2218 together with VIR-3434 for the treatment of patients with chronic hepatitis B virus (HBV) infection – a combination designed to achieve a functional cure.

VIR-2218 is an investigational small interfering ribonucleic acid (siRNA) designed to inhibit the production of all HBV proteins (X, polymerase, S and core), which may be acting as immune tolerogens. VIR-3434 is an investigational HBV-neutralizing monoclonal antibody designed to block entry of all 10 genotypes of HBV into hepatocytes, as well as reduce the level of virions and subviral particles in the blood. It has also been Fc engineered to include the XX2 “vaccinal mutation,” allowing it to potentially function as a therapeutic T cell vaccine against HBV.

“HBV infection remains an urgent global public health challenge associated with significant morbidity and mortality, and we believe that a combination approach focused on immune restoration will be critical to achieving a functional cure,” said Phil Pang, M.D., Ph.D., Vir’s chief medical officer. “We are excited about the potential of VIR-2218 to serve as the cornerstone of that approach. We believe that combining it with VIR-3434, which has already demonstrated the ability to markedly lower hepatitis B surface antigen at low doses in an ongoing Phase 1 trial, and, most importantly, has the potential to function as a therapeutic T cell vaccine, could be a game changer.”

The multi-center, open-label Phase 2 trial is designed to evaluate the safety, tolerability and efficacy of the combination of VIR-2218 and VIR-3434 in approximately 90 adult patients (ages 18 to 65) with chronic HBV infection receiving nucleot(s)ide reverse transcriptase inhibitor therapy. Both VIR-2218 and VIR-3434 will be administered via subcutaneous injection at varying dose levels over the course of the trial for a treatment period ranging from four to 20 weeks, and a follow-up period of up to 116 weeks, depending on the dosing cohort. The primary endpoints of the trial are the proportion of patients with treatment-emergent adverse events and serious adverse events; grading of post-treatment clinical laboratory parameters; and the proportion of patients achieving a functional cure (defined as undetectable HBsAg and sustained suppression of HBV DNA).

About VIR-2218

VIR-2218 is an investigational 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-3434

VIR-3434 is an investigational subcutaneously administered HBV-neutralizing monoclonal antibody designed to block entry of all 10 genotypes of HBV into hepatocytes and reduce the level of virions and subviral particles in the blood. VIR-3434, which has been Fc engineered to potentially function as a T cell vaccine against HBV in infected patients, also incorporates Xencor’s Xtend™ in order to have an extended half-life.

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 COVID-19, hepatitis B virus, influenza A and human immunodeficiency virus. 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,” “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. Forward-looking statements contained in this press release include, but are not limited to, statements regarding the ability of VIR-2218 and VIR-3434 (as monotherapies or combination therapies) to treat and/or prevent chronic HBV infection, and the timing, design and enrollment plans for the Phase 2 MARCH trial. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during preclinical or clinical studies, challenges in the treatment of hospitalized patients, difficulties in collaborating with other companies or government agencies, challenges in accessing manufacturing capacity, 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. 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.

Contact:

Heather Rowe Armstrong
VP, Investor Relations
harmstrong@vir.bio
+1 415.915.4228

Cara Miller
VP, Corporate Communications
cmiller@vir.bio
+1 415.941.6746

Source: Vir Biotechnology, Inc.