Vir Biotechnology Announces Initiation of Phase 2 Clinical Trial Evaluating VIR-2218, Selgantolimod and Nivolumab for the Treatment of Chronic Hepatitis B Virus Infection

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– Trial to evaluate antigen suppression combined with immunomodulation as a functional cure regimen for chronic HBV –

SAN FRANCISCO, Dec. 09, 2021 (GLOBE NEWSWIRE) -- Vir Biotechnology, Inc. (Nasdaq: VIR) today announced that the first patient has been dosed in a Phase 2 clinical trial evaluating novel therapeutic combinations for the treatment of chronic hepatitis B virus (HBV) infection. The multi-arm trial, which is being conducted in collaboration with Gilead Sciences, Inc., is assessing various combinations of VIR-2218, Vir's investigational small interfering ribonucleic acid (siRNA) that mediates RNA interference (RNAi); selgantolimod (GS-9688), Gilead Sciences' investigational TLR-8 agonist; and nivolumab, an approved PD-1 inhibitor, in both nucleos(t)ide (NUC)-suppressed patients and viremic patients. Patients with HBV treatment experience also may receive tenofovir alafenamide fumarate (TAF).

"For the majority of patients with chronic HBV, a functional cure will likely require a sustained reduction in hepatitis B surface antigen and restoration of the immune response," said Carey Hwang, MD, PhD, senior vice president, clinical research, head of chronic infection for Vir Biotechnology. "We believe the combination of VIR-2218 and two immunomodulatory agents has the potential to improve the HBV-specific immune response and possibly achieve a functional cure. With the initiation of this trial, Vir now has four ongoing HBV trials evaluating VIR-2218, the foundation of our combination approaches, with other immunomodulatory agents as part of our ongoing pursuit of a functional cure."

The multi-center, open-label Phase 2 clinical trial is designed to evaluate the safety, tolerability and efficacy of various combinations of VIR-2218, selgantolimod, nivolumab and TAF in adults with chronic HBV. The trial will enroll approximately 120 patients ages 18 to 65 who are either viremic or are virally suppressed on an approved HBV nucleos(t)ide reverse transcriptase inhibitor. Patients who are hepatitis B e antigen (HBeAg)-positive (an indicator of acute viral replication), as well as those who are HBeAg-negative, will be enrolled. The primary efficacy endpoint is the proportion of patients who achieve a functional cure (defined as HBsAg loss and HBV DNA <20 IU/mL at follow-up week 24).

Vir and Gilead retain full rights to their individual product candidates and will discuss the potential path forward for any future combination studies based on the outcome of the Phase 2 trial. The safety and efficacy of VIR-2218 and selgantolimod have not been established. They are investigational compounds, and not approved by the US Food and Drug Administration (FDA) or any other regulatory authority.

About Vir's Broad Clinical Program for the Functional Cure of Chronic HBV Infection
Vir's broad clinical development program for the functional cure of chronic HBV infection aims to develop effective therapies that lead to a functional cure. Ongoing trials include:

- Phase 2 MARCH (Monoclonal Antibody siRNA Combination against Hepatitis B) trial of VIR-2218 in combination with VIR-3434, an investigational HBV-neutralizing monoclonal antibody that has been Fc engineered to include the XX2 "vaccinal mutation," enabling it to potentially function as a T cell vaccine
- Phase 2 trial of VIR-2218 in combination with pegylated interferon-alfa (PEG-IFN-α)
- Phase 2 trial of VIR-2218 in combination with Brii Biosciences' BRII-179 (VBI-2601), an investigational T cell vaccine (led by Brii Biosciences)
- Phase 2 trial of VIR-2218 in combination with selgantolimod, nivolumab and/or TAF
- Phase 1 trial of VIR-3434 monotherapy

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 also to reduce the level of virions and subviral particles in the blood. VIR-3434, which incorporates Xencor's Xtend™ and other Fc technologies, has been engineered to potentially function as a T cell vaccine against HBV in infected patients, as well as to have an extended half-life.

About Vir Biotechnology
Vir Biotechnology is a commercial-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.

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 "aim," "will," "may," "potential," "plan," "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 (as a monotherapy or combination therapies), including in combination with selgantolimod (GS-9688), Gilead Sciences' investigational TLR-8 agonist, and nivolumab, an approved PD-1 inhibitor, to treat and/or prevent chronic HBV infection; the Phase 2 trial of VIR-2218 to evaluate it as a combination therapy; and the timing, design and enrollment plans for Vir's broad clinical development program for the functional cure of chronic HBV infection. Many factors may cause differences between current expectations and actual results, including unexpected safety, tolerability or immunogenicity data or results observed during the Phase 2 trial, challenges in clinical site activation rates or clinical trial enrollment rates that are lower than expected, the failure to achieve the primary outcome of the study, 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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