# Initial Data from Ongoing Phase 1 Trial of VIR-3434 for Chronic Hepatitis B Virus Infection Demonstrates Significant and Rapid Reduction in Hepatitis B Surface Antigen

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– Novel HBV-neutralizing monoclonal antibody with therapeutic vaccine potential demonstrated a mean HBsAg reduction from baseline of 1.3 log10 IU/mL by day eight –

SAN FRANCISCO, Jan. 26, 2021 (GLOBE NEWSWIRE) -- Vir Biotechnology, Inc. (Nasdaq: VIR) today announced initial topline data from its ongoing trial of VIR-3434 in patients with chronic hepatitis B virus (HBV) infection. Data from the first blinded cohort of eight patients, two of whom received placebo and six of whom received a single dose of 6 mg of VIR-3434, showed that six of eight patients achieved a mean reduction of 1.3 log10 IU/mL in serum hepatitis B virus surface antigen (HBsAg) by day eight, the day when nadir was achieved in most patients.

VIR-3434 is an 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. It has also been Fc engineered to include the XX2 “vaccinal mutation,” allowing it to potentially function as a T cell vaccine, in this case, against HBV. The XX2 vaccinal mutation, which has the potential to transform standard antibodies into T cell vaccines, has also been incorporated into one of Vir’s investigational COVID-19 monoclonal antibodies, VIR-7832, which is currently planned to enter a Phase 1b/2a trial this quarter. Vir has licensed exclusive rights to the XX2 mutation for use in infectious diseases.

“The need for a functional cure for the nearly 300 million people living with chronic HBV is paramount. Lowering HBsAg may help unlock a patient’s immune system, allowing it to provide the immune control necessary to achieve a functional cure,” said Kosh Agarwal, M.D., lead study investigator and consultant hepatologist and transplant physician at the Institute of Liver Studies, King’s College Hospital NHS Foundation Trust in London. “These early, first-in-patient results are exciting because they demonstrate that even at a very low dose, VIR-3434 is able to markedly lower HBsAg.”

“Extrapolating from our preclinical data, we expected it might require much higher doses of VIR-3434 to achieve this level of HBsAg knockdown. To have achieved it with a dose of 6 mg is unexpected,” said Phillip Pang, M.D., Ph.D., Chief Medical Officer of Vir. “Coupled with initial data that shows VIR-3434 was well tolerated at up to 3,000 mg in healthy volunteers, I am hopeful that we are seeing just the beginning of VIR-3434’s capabilities.”

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 with HBsAg levels less than 1,000 IU/ml. 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. Additional data will be submitted for presentation at an upcoming medical conference. A Phase 2 trial combining VIR-3434 with Vir’s HBV-targeting siRNA, VIR-2218, is expected to commence in the second half of this year.

**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-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 potentially function as a T cell vaccine against HBV in infected patients, as well as to have an extended half-life.

**About VIR-7832**
VIR-7832 is a dual-action monoclonal antibody. Preclinical data suggest it has the potential to both block viral entry into healthy cells and an enhanced ability to clear infected cells. The antibody binds to an epitope on SARS-CoV-2 that is shared with SARS-CoV-1 (the virus which causes SARS), indicating that the epitope is highly conserved, which may make it more difficult for resistance to develop. VIR-7832 also has been designed to achieve high concentration in the lungs to ensure optimal penetration into airway tissues affected by SARS-CoV-2 and to have an extended half-life. Importantly, VIR-7832 has been engineered to potentially enhance virus-specific T cell function, which could help treat and/or prevent COVID-19 infection.

**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. Forward-looking statements contained in this press release include, but are not limited to, statements regarding initial data from ongoing trial of VIR-3434 in the treatment of patients with HBV, the therapeutical vaccine potential of both VIR-3434 and VIR-7832, which have both been engineered to include the XX2 vaccinal mutation, expected timing of clinical study results and clinical trial design

around VIR-3434, VIR-7832, and the combination of VIR-3434 with VIR-2218.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 our competitors, changes in expected or existing competition, delays in or disruptions to our business or clinical trials due to the COVID-19 pandemic, geopolitical changes or other external factors, and unexpected litigation or other disputes.

Contact:

Investors
Neera Ravindran, M.D.
VP, Head of Investor Relations & Strategic Communications
nravindran@vir.bio
+1-415-506-5256

Media
Cara Miller
VP, Corporate Communications
cmiller@vir.bio
+1-415-941-6746

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