Vir Biotechnology to Provide Pipeline Update at 38th Annual J.P. Morgan Healthcare Conference

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SAN FRANCISCO, Jan. 13, 2020 (GLOBE NEWSWIRE) -- Vir Biotechnology, Inc. (Nasdaq: VIR), a clinical-stage immunology company focused on combining immunologic insights with cutting-edge technologies to treat and prevent serious infectious diseases, will present tomorrow, January 14th, at the 38th Annual J.P. Morgan Healthcare Conference in San Francisco.

“In 2020, we plan to double the number of clinical programs in our pipeline and announce key data from our ongoing hepatitis B and influenza A programs,” said George Scangos, Ph.D., Chief Executive Officer of Vir. “The data that we are generating across our portfolio continue to affirm our immunologic approach to infectious disease drug development and we look forward to sharing our results more broadly within the scientific and medical communities over the coming year.”

Dr. Scangos will present new data from the company’s clinical programs and provide an update on anticipated milestones across Vir’s development pipeline, which includes two candidates for the functional cure of hepatitis B virus (HBV), a universal prophylaxis for influenza A, and a T cell vaccine for human immunodeficiency virus (HIV).

HBV

New data from the ongoing Phase 2 trial of VIR-2218, an HBV-targeting small interfering ribonucleic acid (siRNA) being developed for the functional cure of HBV, continue to show substantial reductions in HBV surface antigen (HBsAg) and that VIR-2218 continues to be generally well-tolerated.

- All HBeAg negative and positive patients who received two doses of 200 mg of VIR-2218 (n=6) achieved at least a 1.0 $\log_{10}$ decline in HBsAg. At Day 85, a mean decline of 1.5 $\log_{10}$ was observed in both HBeAg negative and positive patients.
- No alanine aminotransaminase (ALT) abnormalities greater than or equal to three times the upper limit of normal have been observed in any person treated with VIR-2218, including the 37 healthy volunteers given up to 900 mg of VIR-2218 and the 24 patients who received up to two doses of 200 mg of VIR-2218.
- Data through at least week 16 on all VIR-2218 dose cohorts are expected to be available in the first half of 2020.

The company anticipates that two new trials with VIR-2218 will start later this year, including a Phase 2 trial of VIR-2218 in China, in collaboration with Brii Biosciences, and a Phase 2 combination trial of VIR-2218 and pegylated interferon-alpha (PEG-IFN-α). In addition, VIR-3434, an HBV-neutralizing monoclonal antibody (mAb) designed to block entry of all 10 genotypes of HBV into hepatocytes, reduce the level of virions and subviral particles in the blood, and potentially function as a T cell vaccine, is on track for clinical trial application (CTA) approval in the first half of 2020.

Influenza A

VIR-2482, a mAb antibody being developed as universal prophylaxis for influenza A, continues to progress in the clinic, with all four dose cohorts (60mg, 300 mg, 1200 mg, and 1800 mg) in healthy volunteers completed and regulatory approvals on track to commence Phase 2 dosing in the southern hemisphere in the second quarter of 2020.

The company continues to anticipate data from the first flu season of the trial to be available in the second half of 2020 and from the second flu season of the trial to be available in the first half of 2021.

HIV

VIR-1111, an HIV T cell vaccine based on human cytomegalovirus (HCMV), continues to be on track for an investigational new drug (IND) submission in the first half of 2020.

Presentation at 38th Annual J.P. Morgan Healthcare Conference

Vir will webcast its presentation from the conference tomorrow, January 14th, at 2:00 p.m. PST (5:00 p.m. EST). A live webcast of the presentation can be accessed under Events & Presentations in the Investors section of the Vir website at www.vir.bio and will be archived there following the presentation for 30 days.

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. Currently in a Phase 1/2 clinical trial, VIR-2218 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. Initial data suggest that VIR-2218 is generally well-tolerated in healthy volunteers given as a single dose up to 900 mg and in patients with chronic HBV on nucleotide/nucleoside reverse transcriptase inhibitors (NRTIs) given VIR-2218 as two doses of 20 mg, 50 mg, 100 mg or 200 mg each dose. Initial data also demonstrate substantial reductions in HBsAg in patients at doses ranging from 20 mg to 200 mg. VIR-2218 is the first asset in the company’s collaboration with Alnylam Pharmaceuticals, Inc. to enter clinical trials. Additional clinical data for this trial is anticipated in the first half of 2020.

About VIR-3434
VIR-3434 is a subcutaneously administered HBV-neutralizing mAb designed to block entry of all 10 genotypes of HBV into hepatocytes, to reduce the level of virions and subviral particles in the blood, and potentially function as a T cell vaccine against HBV in infected patients. It has also been engineered to have an extended half-life. Vir anticipates CTA approval for VIR-3434 in the first half of 2020 and anticipates clinical data from this trial to be available in the first half of 2021.

About VIR-2482
VIR-2482 is an intramuscularly administered influenza A-neutralizing mAb currently in a Phase 1/2 clinical trial. VIR-2482 is designed to act as a universal prophylaxis for influenza A. *In vitro*, VIR-2482 has been shown to cover all major strains of influenza A that have arisen since the 1918 Spanish flu pandemic. It has the potential to overcome the limitations of current flu vaccines and lead to meaningfully higher levels of protection due to its broad strain coverage and because it does not rely on an individual to create their own protective antibody response. VIR-2482 has been half-life engineered so that a single dose has the potential to last the entire flu season, which is typically five to six months long. Vir anticipates clinical data from the first flu season of the Phase 1/2 clinical trial to be available in the second half of 2020 and from the second flu season of this trial to be available in the first half of 2021.

About VIR-1111
VIR-1111 is a subcutaneously administered HIV T cell vaccine based on HCMV that has been designed to elicit T cells that recognize HIV epitopes that are different from those recognized by prior HIV vaccines and to stimulate a different and specific type of T cell immune response to HIV, known as an HLA-E restricted immune response. VIR-1111 is designed to establish proof of concept in a Phase 1 clinical trial to determine whether the unique immune response observed in preclinical studies can be replicated in humans. Vir plans to submit an IND for VIR-1111 in the first half of 2020.

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 five product candidates targeting hepatitis B virus, influenza A, 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" 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 timing of program updates and data disclosures for Vir's clinical trials and the anticipated timing of IND and CTA submissions and/or approvals for its product candidates, among others. Many factors may cause differences between current expectations and actual results including unexpected safety or efficacy data observed during preclinical or clinical studies, clinical site activation rates or clinical trial enrollment rates that are lower than expected, changes in expected or existing competition, 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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