Vir Biotechnology Presents Data on VIR-2218 from Clinical Studies for the Treatment of Hepatitis B at the EASL Digital International Liver Congress™

August 20, 2020

SAN FRANCISCO, Aug. 20, 2020 (GLOBE NEWSWIRE) -- Vir Biotechnology, Inc. (Nasdaq: VIR), a clinical-stage immunology company focused on treating and preventing serious infectious diseases, today announced that data from its VIR-2218 clinical program will be featured at the European Association for the Study of the Liver (EASL) Digital International Liver Congress™ from August 27-29, 2020. VIR-2218 is an investigational small interfering ribonucleic acid (siRNA) that mediates RNA interference (RNAi) for the potential treatment of chronic hepatitis B virus (HBV) infection and is the first investigational medicine from Vir's partnership with Alnylam Pharmaceuticals, Inc. to enter clinical trials.

Among the accepted abstracts is an oral presentation of preliminary antiviral activity and safety results from an ongoing Phase 2 study of VIR-2218 in patients with chronic HBV on nucleotide/nucleoside reverse transcriptase inhibitors (NRTIs), which are standard of care. The data demonstrate that two monthly doses of VIR-2218 resulted in substantial, dose-dependent and durable reductions in hepatitis B surface antigen (HBsAg), a marker of active hepatitis B infection. The data also suggests that the Enhanced Stabilization Chemistry-Plus (ESC+) incorporated into VIR-2218 may result in an improved hepatic safety profile. Additional abstracts include safety and pharmacokinetic data from a Phase 1 study of VIR-2218, as well as preclinical data.

"Chronic HBV infection is a major public health condition impacting almost 300 million people worldwide, and innovative approaches that do not require lifelong treatment are needed to sustainably address the disease," said Phillip Pang, M.D., Ph.D., Chief Medical Officer of Vir. "By suppressing HBV protein expression, VIR-2218 is not only a potent antiviral, but also may serve to remove antigenic inhibition of T and B cell activity directed against HBV, enabling immunologic control. The well-tolerated and substantial dose-dependent reduction in HBsAg demonstrated to date by VIR-2218 supports our belief that it has the potential to serve as the backbone of a finite treatment regimen aimed at providing a functional cure for HBV."

VIR-2218 Scientific Research Presented at EASL

Oral Presentation:

- Preliminary safety and antiviral activity of VIR-2218, an X-targeting HBV RNAi therapeutic, in chronic hepatitis B patients
  Abstract: AS068
  Date: Friday, August 28, 2020
  Time: 11:15-11:30 a.m. CET, includes a live Q&A session
  Lead author: Gane E

The following poster presentations will be available on demand:

- Impact of ESC+ Technology on the Hepatic Safety Profile of GalNAc-Delivered, HBV-Targeted RNAi Therapeutics
  Abstract: SAT424
  Lead author: Gane E

- Pharmacokinetics of VIR-2218, an RNAi Therapeutic for the Treatment of HBV Infection, in Healthy Volunteers
  Abstract: SAT462
  Lead author: Gupta SV

- In Vitro and In Vivo Characterization of VIR-2218, an Investigational RNAi Therapeutic Targeting Hepatitis B Virus
  Abstract: SAT426
  Lead author: Anglero-Rodriguez Y

Advancing Clinical Trials for HBV Therapies

Based on preliminary Phase 2 results, Vir initiated a Phase 2 trial of VIR-2218 administered in combination with pegylated interferon alpha-2a, an approved immunomodulatory agent. Initial clinical data are expected next year.

In May 2020, Vir initiated a Phase 1 clinical trial of VIR-3434, an HBV-neutralizing monoclonal antibody with the potential to also be a therapeutic T cell vaccine. Recently, the first chronic HBV patient was treated in the program, following the study design to progress from healthy volunteers to HBV patients in a staggered, parallel fashion.

A Phase 2 clinical trial of VIR-2218 in combination with VIR-3434 is expected in 2021.

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

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," "potential," "aim," "believe" 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 potential benefits of VIR-2218, pegylated interferon-alpha, ESC+ technology and VIR-3434 (individually or in combination), the expected timing of commencement of clinical trials and availability of clinical data, our goals with respect to the prophylaxis and/or treatment of HBV, the criteria for a functional cure of HBV and the potential ability of our product candidates to demonstrate such criteria, the potential of ESC+ technology to enhance the safety and therapeutic index of VIR-2218 and other siRNAs, and the potential benefits of Vir's collaboration with Alnylam Pharmaceuticals, Inc. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data or results observed during clinical trials, difficulties in obtaining regulatory approval, 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 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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