Vir Biotechnology Presents New Clinical Data from Ongoing Trials of VIR-2218 and VIR-3434 in Patients with Chronic Hepatitis B Virus Infection at the International Liver Congress 2021

June 25, 2021

– Results demonstrate positive safety profiles and a reduction in HBsAg for two novel HBV therapies administrated as monotherapy or in combination with other agents –

– Management to host conference call today, Friday, June 25, 2021, at 11:00 a.m. ET –

SAN FRANCISCO, June 25, 2021 (GLOBE NEWSWIRE) -- Vir Biotechnology, Inc. (Nasdaq: VIR) today announced new data from its ongoing Phase 2 clinical trials of VIR-2218 and ongoing Phase 1 studies of VIR-3434 in patients with chronic hepatitis B virus (HBV) infection. The results, which demonstrate positive safety findings plus a reduction in hepatitis B surface antigen (HBsAg) for both compounds, were presented in two oral and two poster presentations at the European Association for the Study of the Liver (EASL) International Liver Congress 2021, which is taking place virtually. Vir will hold a conference call and webcast today, Friday, June 25, 2021, at 11:00 a.m. ET, to discuss the new data presented at the meeting.

In summary, data presented this week demonstrate the promising safety profile and potential durable response of VIR-2218, an investigational small interfering ribonucleic acid (siRNA) that mediates RNA interference (RNAi), through 48 weeks. In a separate analysis evaluating VIR-2218 in combination with pegylated interferon alfa (PEG-IFN-α) for 12 weeks, a more rapid and substantial HBsAg decline was observed in the co-administration cohort compared to VIR-2218 alone. The treatment regimen resulted in no new safety signals.

Additionally, two new analyses from an ongoing Phase 1 trial of VIR-3434 showed no safety signals in healthy volunteers dosed with up to 3,000 mg, and a rapid reduction in HBsAg levels one week after subcutaneous administration of this investigational HBV-neutralizing monoclonal antibody, which has been Fc engineered to include the XX2 “vaccinal mutation,” allowing it to potentially function as a T cell vaccine.

“For years, the field has been hoping that viral antigen knockdown will help unlock the ability of immunomodulatory agents to control chronic hepatitis B – a devastating viral disease resulting from a loss of immune control,” said Phil Pang, M.D., Ph.D., Vir’s chief medical officer. “These new data are exciting because they suggest this may indeed be the case. Knockdown of all HBV proteins by VIR-2218, coupled with the immunomodulatory agent pegylated interferon alfa, resulted in potentially more than additive declines in hepatitis B surface antigen. Findings also strongly support our overall strategic approach of combining VIR-2218 with various immune modulators. Meanwhile, the monotherapy results for VIR-3434, which speak for themselves, support my belief that the combination of VIR-3434 and VIR-2218 has significant potential. That combination trial is expected to start in the second half of this year.”

VIR-2218: Key Data
Results from a Phase 2 multiple-ascending dose trial of VIR-2218 in 32 patients with chronic HBV infection evaluating the safety and antiviral activity of two doses of VIR-2218 (20 to 200 mg) administered subcutaneously four weeks apart demonstrate:

- Dose-dependent reductions in HBsAg through 48 weeks in both trial participants with hepatitis B e antigen (HBeAg), a marker of actively replicating HBV, and those without.
- Of the 12 participants who received the 100 mg or 200 mg dose, four participants experienced sustained HBsAg reductions of >1 $\log_{10}$ IU/mL and absolute HBsAg levels below 100 IU/mL through Week 48.
- Treatment with VIR-2218 achieved dose-related reductions in other viral biomarkers; one patient receiving 200 mg experienced HBeAg loss at Week 24 and anti-HBe seroconversion at Week 16 that was sustained through Week 48.
- Adverse events were mild, and no dose-dependent changes in post-treatment ALT levels (a signal of liver damage) occurred. No trial participants discontinued treatment.

Oral Presentation: Prof. Edward Gane, M.D., professor of medicine at the University of Auckland and chief hepatologist, transplant physician and deputy director of the New Zealand Liver Transplant Unit (Abstract #44).

In a separate ongoing Phase 2 trial, 47 adult patients with chronic HBV infection were assigned to receive subcutaneously injected VIR-2218 alone or in combination with PEG-IFN-α. Preliminary results through Week 12 of the treatment period demonstrate:

- VIR-2218 alone and in combination with PEG-IFN-α were associated with HBsAg reductions of >1 $\log_{10}$ IU/mL by Week 12.
- Co-administration of VIR-2218 with PEG-IFN-α (Cohort 3) resulted in a more rapid and substantial HBsAg decline compared to VIR-2218 alone.
- In Cohort 3, the mean HBsAg decline from baseline was 2.0 $\log_{10}$ IU/mL at Week 12 and 0.6 $\log_{10}$ IU/mL greater than in the two cohorts evaluating VIR-2218 alone.
- In published studies, PEG-IFN-α alone in virally suppressed patients was associated with ≤ 0.25 $\log_{10}$ IU/mL HBsAg decline, on average, over the first 12 weeks.
- No treatment-related grade ≥3 treatment-emergent adverse events or serious adverse events were reported with VIR-2218

alone or in combination with PEG-IFN-α, and the combination did not appear to increase the known side effects of PEG-IFN-α.

Poster Presentation: Prof. Man-Fung Yuen, D.Sc., M.D., Ph.D., chair professor and chief of the division of gastroenterology and hepatology, deputy head of the department of medicine and Li Shu Fan Medical Foundation professor in medicine at The University of Hong Kong (Abstract #824).

VIR-3434: Key Data

Results from a Phase 1 trial evaluating VIR-3434 in 40 virally suppressed patients with chronic HBV infection who were randomized to receive a single low dose of either 6 mg or 18 mg for four weeks demonstrate:

- Treatment with VIR-3434 resulted in rapid >1 $\log_{10}$ IU/mL reductions in HBsAg, with the largest reductions (>1.5 $\log_{10}$ IU/mL) observed in the 18 mg cohort; maximum reductions were generally observed within one week.
- No new safety signals were identified with single doses of VIR-3434; all adverse events were grade 1 or 2.
- No significant changes in liver-related laboratory parameters or clinically significant changes in ALT or other liver-related laboratory parameters were reported.

Oral Presentation: Kosh Agarwal, M.D., consultant hepatologist and transplant physician at the Institute of Liver Studies, King's College Hospital NHS Foundation Trust in London (Abstract #211).

In a separate Phase 1 trial in 40 healthy adult volunteers evaluating single doses of up to 3,000 mg of VIR-3434 administered subcutaneously or intravenously, results demonstrate:

- Subcutaneous administration of VIR-3434 showed favorable pharmacokinetic properties, with VIR-3434 remaining in the serum for 24 weeks.
- No new safety signals were identified; specifically, no grade 3/4 adverse events, serious adverse events or adverse events leading to trial discontinuation were reported.

Poster Presentation: Sneha Gupta, Ph.D., associate director of clinical pharmacology at Vir Biotechnology (Abstract #43).

Conference Call and Webcast Details

Management will host a conference call and webcast featuring Professor Yuen at 11:00 a.m. ET today, June 25, 2021, to discuss the new data presented at the International Liver Congress 2021.

To access the call via telephone, please dial (833) 727-9519 (*North America*) or (830) 213-7696 (*International*), conference ID: 5476112.

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.

The Company has used, and intends to continue to use, the Investors page of its website as a means of disclosing material non-public information and for complying with its disclosure obligations under Regulation FD. Accordingly, investors should monitor the Company's Investors website, in addition to following the Company's press releases, Securities and Exchange Commission filings, public conference calls, presentations and webcasts.

About Vir's Clinical Program for Chronic HBV

In addition to the ongoing Phase 2 trials of VIR-2218 alone and in combination with pegylated interferon-alfa (PEG-IFN-α), Vir entered into a clinical collaboration with Gilead Sciences, Inc. to evaluate VIR-2218 in a Phase 2 combination therapy trial with selgantolimod (GS-9688), Gilead's investigational TLR-8 agonist, and nivolumab, an approved PD-1 inhibitor, in both treatment-experienced and treatment-naïve patients with HBV. The trial, aimed at developing a functional cure for chronic HBV, is expected to start in the second half of 2021. Additionally, Vir's collaborator Brii Biosciences initiated a Phase 2 trial evaluating VIR-2218 in combination with BRII-179 (VBI-2601), an investigational T cell vaccine, for the treatment of chronic HBV infection.

In addition to the ongoing Phase 1 trial evaluating VIR-3434 for the treatment of patients with chronic HBV, Vir plans to initiate a Phase 2 trial of VIR-3434 in combination with VIR-2218 in the second half of 2021.

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 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 clinical data from Vir's ongoing trials of VIR-2218 and VIR-3434, timing of the Phase 2 trial of VIR-3434 in combination with VIR-2218, the ability of VIR-2218, VIR-3434, and a combination of both in treating patients with chronic hepatitis B virus infection and Vir's collaboration with Gilead Sciences, Inc. to evaluate VIR-2218 in a combination therapy trial with GS-9688. 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.

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