Vir Biotechnology Announces New Data From the MARCH Hepatitis B Trial, Unveils New Hepatitis D Clinical Program and Highlights Broad Hepatitis Portfolio at Virtual Hepatitis Portfolio R&D Day

April 27, 2022

– Strategic clinical program for hepatitis B and D with potential for multiple value drivers in 2022 –

– Virtual R&D Day webcast scheduled for today, Wednesday, April 27, at 12:00 pm ET / 9:00 am PT –

SAN FRANCISCO, April 27, 2022 (GLOBE NEWSWIRE) -- Vir Biotechnology, Inc. (Nasdaq: VIR) today announced that the Company will review its robust hepatitis portfolio, including initial data from the first cohort of the MARCH (Monoclonal Antibody siRNA Combination against Hepatitis B) trial evaluating VIR-2218 in combination with VIR-3434, as well as a new program aimed at chronic hepatitis D. Details will be discussed today at 12:00 pm ET / 9:00 am PT during Vir's virtual Hepatitis Portfolio R&D Day.

"We are pleased to share encouraging data from the MARCH trial, which suggest that VIR-2218 and VIR-3434 are additive in reducing hepatitis B surface antigen, with no drug-related safety signals reported to date – supporting our strategy of combining antivirals with immunomodulators," said George Scangos, Ph.D., Vir's chief executive officer. "We are also excited to announce a new synergistic program that will leverage our differentiated assets to treat hepatitis D, the most aggressive form of viral hepatitis for which there are limited treatment options. Together with the other ongoing combination trials in our pipeline, we believe we have multiple opportunities to achieve meaningful outcomes for both hepatitis B and D."

Hepatitis Portfolio R&D Day Webcast Details
Vir's Hepatitis Portfolio R&D Day will feature presentations from Vir's senior leadership team, as well as an overview of the epidemiology and impact of hepatitis B and D by Jordan Feld, M.D., M.P.H., a leading physician-scientist specializing in viral hepatitis and liver disease. The agenda is as follows:

- ***Introduction*** – George Scangos, Ph.D., Vir's Chief Executive Officer
- ***Overview and challenges of treating hepatitis B and D*** – Dr. Feld, R. Phelan Chair in Translational Liver Disease Research, Professor of Medicine, University of Toronto, Research Director, Toronto Centre for Liver Disease, Senior Scientist, Sandra Rotman Centre for Global Health, TGRI, Toronto General Hospital
- ***Vir's hepatitis portfolio: rationale and strategy*** – Phil Pang, M.D., Ph.D., Vir's Chief Medical Officer
- ***Review Vir's hepatitis B development pipeline and announce new program directives*** - Carey Hwang, M.D., Ph.D., Vir's Senior Vice President, Clinical Research, Head of Chronic Infection
- ***Q&A and closing remarks***

Participants can register for the Hepatitis Portfolio R&D Day here. A live webcast of the event will be accessible under Events & Presentations in the Investors section of the Vir website at www.vir.bio and will be archived there for 30 days.

Anticipated Hepatitis Milestones

In 2022, the Company expects to report data from multiple trials for the treatment of chronic hepatitis B virus (HBV) infection including:

- Additional data from the Phase 1 monotherapy trial of VIR-3434 and the Phase 2 monotherapy trial of VIR-2218 (first half of 2022).
- Additional data from the Phase 2 trial of VIR-2218 in combination with PEG-IFN-α (second half of 2022).
- Additional data from the first cohort (Part A) of the Phase 2 MARCH trial evaluating safety, pharmacokinetics and hepatitis B surface antigen (HBsAg) suppression (second half of 2022).
- Initial data from the Phase 2 trial evaluating VIR-2218 in combination with BRII-179, an investigational T cell vaccine, for the potential treatment of chronic HBV infection, led by Brii Biosciences (second half of 2022).

Beyond 2022, the Company expects to report:

- Initial data from the Phase 2 trial evaluating various combinations of VIR-2218, selgantolimod, Gilead's investigational TLR-8 agonist, and nivolumab, an approved PD-1 inhibitor for HBV (first half of 2023).
- Initial data from the second cohort (Part B) of the Phase 2 MARCH trial for HBV to determine dose, length of treatment and evaluate triple cocktails, when VIR-3434 is given every four weeks (second half of 2023).

- Initial data from a Phase 2 viremic trial (STRIVE/THRIVE) of VIR-2218 in combination with VIR-3434 in the second half of 2023, following trial initiation in the second half of 2022.

- Initial data from a Phase 2 trial of VIR-2218 in combination with VIR-3434 for the treatment of HDV in 2023, following trial initiation in the second half of 2022.

Recent Publications
The Company recently sponsored a *Nature Outlook Supplement* titled "The Push to Eliminate a Viral Liver Disease." This special edition, focused on chronic HBV, features independent news features and commentary pieces from leading academics focused on the latest advances in treatment, efforts to improve diagnosis and screening, and why equitable access to treatments and prevention methods will be central to eradicating HBV by 2030.

About Chronic Hepatitis B and D
Chronic hepatitis B virus (HBV) infection remains an urgent global public health challenge associated with significant morbidity and mortality. Approximately 300 million people around the world are living with HBV and approximately 900,000 of them die from associated complications each year. These patients are significantly underserved by existing therapies with low functional cure rates, lifelong daily therapy and poor tolerability.

Hepatitis D virus (HDV) infection occurs as a simultaneous co-infection or super-infection with HBV. An estimated 12 million patients globally are infected with HDV, representing approximately 5% of those infected with HBV. HDV-HBV co-infection is considered the most severe form of chronic viral hepatitis due to more rapid progression towards hepatocellular carcinoma and liver-related death.

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. Vir routinely posts information that may be important to investors on its website.

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," "expect," "promise," "goal," "anticipate," "could" 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, but are not limited to, statements regarding the data from its VIR-2218 and VIR-3434 clinical trials, the ability of VIR-2218 and VIR-3434 (as monotherapies or combination therapies) to treat and/or prevent chronic HBV infection, initial data from the combination of VIR-2218 with TLR-8 agonist and nivolumab, Brii Biosciences Phase 2 trial evaluating VIR-2218 in a combination trial with BRII-179, the timing, design and enrollment plans for the Phase 2 MARCH trial and Vir's plans for its HDV program. 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, difficulties in collaborating with other companies, challenges in accessing manufacturing capacity, clinical site activation rates or clinical trial enrollment rates that are lower than expected, 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 (including the ongoing conflict between Russia and the Ukraine) or other external factors and unexpected litigation or other disputes. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements, or the scientific data presented. 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.

This press release contains hyperlinks to third-party information. Such information is not deemed to be incorporated by reference in this press release. Vir disclaims responsibility for such third-party information.

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