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NEWS RELEASE

# Vir Biotechnology to Present New Data from Its Ongoing Phase 2 Chronic Hepatitis Delta and B Trials Today at AASLD's The Liver Meeting® 2023

11/13/2023

- Initial SOLSTICE data suggests the potential of VIR-3434 + VIR-2218 to address the unmet need for a highly efficacious hepatitis delta therapy -
- New MARCH Part B data demonstrate that VIR-3434 may play an important role in achieving a functional cure for chronic hepatitis B -
- Conference call scheduled for 1:45 p.m. PT / 4:45 p.m. ET, November 13, 2023 -

SAN FRANCISCO--(BUSINESS WIRE)-- Vir Biotechnology, Inc. (Nasdaq: VIR) today announced it will be presenting new data from its ongoing Phase 2 SOLSTICE and MARCH trials evaluating the potential clinical impact that VIR-3434, an investigational monoclonal antibody (mAb), and VIR-2218, an investigational small interfering ribonucleic acid (siRNA), could have for chronic hepatitis delta (CHD) and chronic hepatitis B (CHB) patients at the American Association for the Study of Liver Diseases (AASLD) The Liver Meeting®. These include one late-breaking oral presentation and one late-breaking poster presentation.

## Phase 2 SOLSTICE (CHD)

Initial data to be presented in a late-breaking oral presentation from the ongoing Phase 2 SOLSTICE clinical trial demonstrated that after three subcutaneous doses of either VIR-3434 or VIR-2218 monotherapy, six patients rolled



over into combination therapy with VIR-3434 and VIR-2218. Of the five participants receiving combination therapy who have reached Week 12, 100% had HDV RNA less than the lower limit of quantification<sup>1</sup> with 80% (4 of 5) having undetectable HDV RNA<sup>2</sup>. To date, no participants receiving the combination therapy or VIR-3434 monotherapy have experienced ALT elevations relative to their baseline. ALT elevations >250 IU/ml were observed in two participants who received VIR-2218 monotherapy.

“Chronic hepatitis delta is the most aggressive form of viral hepatitis. There are few treatment options for people living with HDV infection. Undetectable HDV RNA is an important endpoint associated with clinical benefit. These early results from SOLSTICE are unprecedented, with 80% of participants being undetectable at Week 12 of combination therapy,” said Tarik Asselah, M.D., Ph.D., Professor of Hepatology at the Hôpital Beaujon, APHP, Clichy, France, and at the University of Paris, and Head of Viral Hepatitis at INSERM UMR1149, France. “If this result can be reproduced in a much larger group of participants, I believe this potentially once monthly therapy could be transformative for patients.”

“CHD impacts over 12 million people worldwide and approximately 100,000 people here in the United States,” said Phil Pang, M.D., Ph.D., Vir’s Executive Vice President, Chief Medical Officer. “This data highlights Vir’s commitment to developing a game-changing chronic suppressive therapy for this rare disease.”

The company expects to report additional SOLSTICE data for VIR-3434 + VIR-2218 in the second quarter of 2024. The Company is also evaluating VIR-3434 as monotherapy given twice monthly as part of the SOLSTICE trial.

#### Phase 2 MARCH Part B (CHB)

A late-breaking poster presenting new data from the ongoing MARCH Part B trial demonstrates that HBsAg loss rates at the end of treatment (EOT) for the combination of VIR-3434 + VIR-2218 with and without peginterferon alpha (PEG-IFN- $\alpha$ ), when given for 24 weeks, are approximately three times higher than the 5.6% EOT rate previously reported for VIR-2218 + PEG-IFN- $\alpha$ . Specifically, at 24 weeks, 15.0% and 14.3% of participants achieved HBsAg loss at EOT for VIR-3434 + VIR-2218 and VIR-2218 + VIR-3434 + PEG-IFN- $\alpha$ , respectively. In addition, anti-HBs antibody titers > 10 mIU/mL at EOT were detected in 52% (11 of 21) of participants in the triple combination of VIR-3434 + VIR-2218 + PEG-IFN- $\alpha$  cohort versus 11% (2 of 18) with VIR-2218 + PEG-IFN- $\alpha$ .

“The higher proportion of participants achieving anti-HBs titers with the addition of VIR-3434 to VIR-2218 and peginterferon alpha strongly suggests that VIR-3434 not only contributes to HBsAg loss through clearance of HBsAg, but also has the ability to reawaken the immune system and generate HBV-specific immunity,” said Edward Gane, M.D., Professor of Medicine at the University of Auckland, New Zealand, and Chief Hepatologist, Transplant Physician and Deputy Director of the New Zealand Liver Transplant Unit at Auckland City Hospital. “This data implies VIR-3434 can function as an immunostimulant.”

Post treatment data will also be presented, showing that two participants with the highest peak anti-HBs titers who received 24 weeks of VIR-3434 + VIR-2218 + PEG-IFN- $\alpha$  maintained HBsAg loss through post-treatment Week 12. Rebound of HBsAg after EOT was observed in all other participants (19 of 21). The Company will continue to follow all participants through post-treatment Week 24 and beyond.

The new MARCH Part B data builds upon the previously reported VIR-2218 + PEG-IFN- $\alpha$  data in which the Company demonstrated the potential for its siRNA VIR-2218 to enhance EOT and post-treatment HBsAg loss rates: 30% of participants receiving up to 48 weeks of combination therapy achieved EOT HBsAg loss and 16% achieved a sustained HBsAg loss 24 weeks after EOT.

“It is important to remember that while these are small participant numbers, this immunologic data is the first evidence that, when part of a combination regimen, our vaccinal antibody VIR-3434 has the potential to play an important role in facilitating a functional cure for patients living with chronic hepatitis B. I am therefore very much looking forward to seeing what will happen when VIR-3434 and VIR-2218 are given, with and without peginterferon alpha, for 48 weeks,” said Pang. “What has been repeatedly observed with peginterferon immunotherapy is that the majority of the benefit occurs after the first 24 weeks of treatment. Thus, we may be seeing just the beginnings of the potential of our regimens.”

The Company is on track for sharing the MARCH Part B 48-week EOT data in the fourth quarter of 2024.

#### Late-Breaker Oral Presentation – Phase 2 SOLSTICE

The Monoclonal Antibody VIR-3434 And siRNA VIR-2218 for the Treatment of Chronic Hepatitis D Virus: Preliminary Results from the Phase 2 SOLSTICE Trial (Abstract #5004)

Date: Monday, November 13 at 3:00 p.m. ET

Presenter: Tarik Asselah, M.D., Ph.D., Professor of Hepatology at the Hôpital Beaujon, APHP, Clichy, France, and at the University of Paris, and Head of Viral Hepatitis at INSERM UMR1149, France

#### Late-Breaker Poster Presentation – Phase 2 MARCH Part B

VIR-2218 and VIR-3434 With or Without Pegylated Interferon Alfa-2A for the Treatment of Chronic HBV Infection: End of Treatment (EOT) Results After 24 Weeks of Therapy (March Study Part B) (Abstract #48500)

Date: Monday, November 13 at 1:00 p.m. ET

Presenter: Edward Gane, M.D., Professor of Medicine at the University of Auckland, New Zealand, and Chief Hepatologist, Transplant Physician and Deputy Director of the New Zealand Liver Transplant Unit at Auckland City Hospital

The abstracts for these and the other six AASLD presentations are available under Events & Presentations in the Investors section of the Vir website [here](#). The final presentations will be posted after 3:30 pm ET today.

Vir will host an investor conference call to discuss the Phase 2 CHD & CHB AASLD data at 1:45 p.m. Pacific Time / 4:45 p.m. Eastern Time on November 13th. A live webcast will be available on <https://investors.vir.bio> and will be archived on [www.vir.bio](http://www.vir.bio) for 30 days.

#### About Chronic Hepatitis B

Chronic hepatitis B (CHB) infection remains an urgent global public health challenge associated with significant morbidity and mortality. Approximately 300 million people around the world are living with CHB, 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/or poor tolerability. Vir is working to achieve a functional cure for the millions of people with CHB around the world through its broad and differentiated portfolio.

#### About Chronic Hepatitis Delta

Chronic hepatitis delta (CHD) infection occurs as a simultaneous co-infection or super-infection with chronic hepatitis B. An estimated 12 million people globally are infected with CHD, representing approximately 5% of those infected with CHB. CHB-CHD co-infection is considered the most severe form of chronic viral hepatitis due to more rapid progression toward hepatocellular carcinoma and liver-related death.

#### About VIR-3434

VIR-3434 is an investigational subcutaneously administered antibody designed to block entry of hepatitis B and hepatitis delta viruses into hepatocytes and 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 hepatitis B virus and hepatitis delta virus, as well as to have an extended half-life. VIR-3434 was identified using Vir's proprietary monoclonal antibody discovery platform.

#### About VIR-2218

VIR-2218 is an investigational subcutaneously administered hepatitis B virus-targeting small interfering ribonucleic acid (siRNA) that Vir believes has the potential to stimulate an immune response and have direct antiviral activity against hepatitis B virus and hepatitis delta virus. 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 could 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 Biotechnology, Inc.

Vir Biotechnology, Inc. is an immunology company focused on combining cutting-edge technologies to treat and prevent infectious diseases and other serious conditions. Vir has assembled two technology platforms that are designed to stimulate and enhance the immune system by exploiting critical observations of natural immune processes. Its current clinical development pipeline consists of product candidates targeting hepatitis delta and hepatitis B viruses and human immunodeficiency virus. Vir has several preclinical candidates in its pipeline, including those targeting influenza A and B, COVID-19, RSV/MPV and HPV. 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,” “plan,” “potential,” “aim,” “expect,” “anticipate,” “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 Vir’s strategy and plans, the potential clinical effects of VIR-3434 and VIR-2218, the potential benefits, safety and efficacy of VIR-3434 and VIR-2218 (as monotherapies and as combination therapies with and without PEG-IFN- $\alpha$ ), data from Vir’s multiple ongoing trials evaluating VIR-3434 and VIR-2218, Vir’s plans and expectations for its HBV and HDV portfolios, and risks and uncertainties associated with drug development and commercialization. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data or results observed during clinical trials or in data readouts; the occurrence of adverse safety events; risks of unexpected costs, delays or other unexpected hurdles; difficulties in collaborating with other companies; 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. 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.

1 The lower limit of quantitation (LLOQ) of HDV RNA is <63 IU/mL and the limit of detection (LOD) is 14 IU/mL.

2 Undetectable HDV RNA is defined as < limit of detection, 14 IU/mL.

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Source: Vir Biotechnology, Inc.