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NEWS RELEASE

# Vir Biotechnology Announces Clinical Advances Across Hepatitis Delta and Hepatitis B Programs at AASLD's The Liver Meeting® 2024

2024-10-15

– Phase 2 SOLSTICE Safety and Efficacy Data in Hepatitis Delta Trial at Week 24 to Be Presented –

– Oral and Five Poster Presentations Highlight Important Progress in Hepatitis Delta and Hepatitis B Clinical Programs, and Deliver Key Insights on the Burden of Disease Among Patient Segments in Hepatitis Delta –

SAN FRANCISCO--(BUSINESS WIRE)-- Vir Biotechnology, Inc. (NASDAQ:VIR) today announced it will present new data from the Phase 2 SOLSTICE clinical trial evaluating the efficacy and safety profile of tobevibart, an investigational monoclonal antibody (mAb), and elebsiran, an investigational small interfering ribonucleic acid (siRNA) for the potential treatment of chronic hepatitis delta.

These data will be presented in an oral presentation at the upcoming American Association for the Study of Liver Diseases (AASLD) The Liver Meeting<sup>®</sup>, in San Diego, CA, November 15-19, 2024. Vir will also present five poster presentations that further characterize these investigational therapies as well as recent efforts to improve the assessment and evaluation of hepatitis delta infection, and insights into the economic burden of hepatitis delta for patients and society. Vir will also share advances from across the chronic hepatitis B development program.

“There is an urgent need for effective therapies for people living with hepatitis delta who can face rapid progression to liver cirrhosis and liver cancer. We are excited by the latest data from our hepatitis delta development program, and we look forward to sharing our latest findings at AASLD as we work to help patients living with this debilitating



condition,” said Mark Eisner, M.D., M.P.H., Executive Vice President and Chief Medical Officer, Vir Biotechnology. “Further, patients living with chronic hepatitis B face lifelong treatment and an increased risk of cirrhosis and liver cancer, so developing a functional cure could transform their lives. We are pleased to share data further characterizing our investigational therapies as we continue on our mission to advance a functional cure.”

Vir will be presenting the following abstracts:

- Efficacy and safety of tobevibart (VIR-3434) alone or in combination with elebsiran (VIR-2218) in participants with chronic hepatitis delta virus infection: Week 24 primary endpoint analysis from the Phase 2 SOLSTICE trial  
Session: Hepatitis D: Natural History and Treatment  
Date: Monday, November 18  
Time: 6:15 – 6.30 p.m. PT  
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
- Pharmacokinetics and safety of a single dose of elebsiran (VIR-2218, siRNA) subcutaneously administered in adult participants with moderate renal impairment (Poster #1340)  
Session: Hepatitis B  
Date: November 15  
Time: 1:00 – 2:00 p.m. PT  
Presenter: Li Wang, Associate Director, Clinical Pharmacology, Vir Biotechnology, Inc.
- Dose-Dependent Effects of Neutralizing Anti-HBs Monoclonal Antibody VIR-3434 on Hepatitis B Surface Antigen Composition (Poster #1409)  
Session: Hepatitis B  
Date: November 15  
Time: 1:00 – 2:00 p.m. PT  
Presenter: Florian van Bömmel, M.D., Professor of Medicine, Division of Hepatology, Department of Medicine II, Leipzig University Medical Center.
- Safety Profile of tobevibart (VIR-3434) and elebsiran (VIR-2218) for the treatment of chronic hepatitis B and delta (CHB and CHD) (Poster #1375)  
Session: Hepatitis B  
Date: November 15  
Time: 1:00 – 2:00 p.m. PT  
Presenter: Alina Jucov, M.D., Ph.D., Arensia Exploratory Medicine GmbH, Düsseldorf, Germany, and Nicolae Testemitanu, State University of Medicine and Pharmacy, Chişinău, Moldova.

- Review of evidence to support the use of surrogate endpoints and fibroscan in hepatitis D infection (Poster #1174)

Session: Hepatitis – Other Infections

Date: November 15

Time: 1:00 – 2:00 p.m. PT

Presenter: Prajakta Bhounsule, Director, Health Economy and Marketing, Vir Biotechnology, Inc.

- Assessing economic burden among unique patient segments in an HDV-infected population (Poster #3294)

Session: Health Services and Public Health Research

Date: November 17

Time: 1:00 – 2:00 p.m. PT

Presenter: Prajakta Bhounsule, Director, Health Economy and Marketing, Vir Biotechnology, Inc.

## About Tobeivart (VIR-3434)

Tobeivart is an investigational broadly neutralizing monoclonal antibody targeting the hepatitis B surface antigen. It is designed to inhibit the entry of hepatitis B and hepatitis delta viruses into hepatocytes, and to reduce the level of circulating viral and subviral particles in the blood. Tobeivart was identified using Vir's proprietary antibody discovery platform and has been engineered to have an extended half-life and optimized binding to immune cells. Tobeivart is administered subcutaneously, and it is currently in clinical development for treatment of patients with chronic hepatitis B and patients with chronic hepatitis delta.

## About Elebsiran (VIR-2218)

Elebsiran is an investigational hepatitis B virus-targeting small interfering ribonucleic acid (siRNA) designed to degrade hepatitis B virus RNA transcripts and limit the production of hepatitis B surface antigen. Current data indicates that it has the potential to have direct antiviral activity against hepatitis B virus and hepatitis delta virus. Elebsiran is administered subcutaneously, and it is currently in clinical development for treatment of patients with chronic hepatitis B and patients with chronic hepatitis delta. It is the first asset in Vir's collaboration with Alnylam Pharmaceuticals, Inc. to enter clinical studies.

## About Chronic Hepatitis Delta

Chronic hepatitis delta (CHD) is a long-lasting, inflammatory liver disease caused by the hepatitis D virus (HDV), which requires the presence of hepatitis B virus (HBV) for its replication<sup>1</sup>. CHD affects nearly 5% of people who have a chronic infection with HBV, and it is considered by the World Health Organization to be the most severe form of chronic viral hepatitis<sup>2</sup>. Co-infection with HDV accelerates progression towards liver cancer and liver-

related death by almost a decade in comparison to HBV mono-infected persons, independently of their age<sup>3</sup>. There is no cure, and treatment options are limited.

#### References:

<sup>1</sup> NIH National Institute of Diabetes and Digestive and Kidney Diseases **Hepatitis D - NIDDK (nih.gov)**, accessed September 2024.

<sup>2</sup> WHO Hepatitis Delta Factsheet - **Hepatitis D (who.int)**, accessed September 2024

<sup>3</sup> CDC <https://www.cdc.gov/hepatitis/hdv/hdvfaq.htm>

## About Chronic Hepatitis B

Chronic hepatitis B (CHB) is a long-lasting, inflammatory liver disease caused by the hepatitis B virus (HBV)<sup>1</sup>. The World Health Organization estimates that 254 million people were living with CHB infection in 2022, with 1.2 million new infections each year, and an estimated 1.1 million yearly deaths associated to the disease<sup>2</sup>. Complications from CHB may include liver cirrhosis, liver failure and liver cancer<sup>3</sup>. Although CHB can be treated, there's no cure available today<sup>1</sup>.

#### References:

<sup>1</sup> CDC **Hepatitis B Basics | Hepatitis B | CDC**

<sup>2</sup> WHO Hepatitis B Factsheet - **Hepatitis B (who.int)**, accessed September 2024

<sup>3</sup> NIH National Institute of Diabetes and Digestive and Kidney Diseases **Hepatitis B - NIDDK (nih.gov)**, accessed September 2024.

## About Vir Biotechnology, Inc.

Vir Biotechnology, Inc. is a clinical-stage biopharmaceutical company focused on powering the immune system to transform lives by discovering and developing medicines for serious infectious diseases and cancer. Vir's clinical-stage portfolio includes infectious disease programs for chronic hepatitis delta and chronic hepatitis B infections, in addition to multiple oncology programs. Vir also has a preclinical portfolio of programs across a range of other infectious diseases and oncologic malignancies. 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 tobevibart and elebsiran, the potential benefits, safety and efficacy of tobevibart and elebsiran, the timing, nature and significance of data from Vir’s multiple ongoing trials evaluating tobevibart and elebsiran, Vir’s plans and expectations for its CHD and CHB programs, 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 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.

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Source: Vir Biotechnology, Inc.