

Vir Biotechnology Announces AASLD The Liver Meeting® Presentation & New England Journal of Medicine Publication of Phase 2 Data Demonstrating Tobevibart & Elebsiran Combination Deliver High Rates of Undetectable HDV RNA with Favorable Safety Profile

2025-11-09

- SOLSTICE trial data demonstrate that 66% of chronic hepatitis delta participants receiving a monthly dose of tobevibart and elebsiran achieved undetectable HDV RNA at Week 48
- Combination well-tolerated: No grade 3 or higher treatment-related adverse events and no treatment-related discontinuations
- ECLIPSE registrational program evaluating the combination of tobevibart and elebsiran for chronic hepatitis delta fully underway, with topline data expected in the first quarter of 2027
- Data presented at AASLD The Liver Meeting® and simultaneously published in the New England Journal of Medicine

SAN FRANCISCO--(BUSINESS WIRE)-- Vir Biotechnology, Inc. (Nasdaq: VIR) today announced that Week 48 endpoint analysis from the Company's Phase 2 SOLSTICE trial for chronic hepatitis delta (CHD) demonstrated that participants receiving a monthly dose of the combination of tobevibart and elebsiran achieved robust and sustained rates of hepatitis delta virus (HDV) RNA target not detected (TND), including those participants with cirrhosis and high baseline HDV RNA. The combination also showed alanine aminotransferase (ALT) reductions over time and a favorable safety profile. These data were presented in an oral session at the American Association for the Study of Liver Diseases (AASLD) The Liver Meeting®, in Washington, D.C., and simultaneously **published in the New England Journal of Medicine**.

"Achieving undetectable HDV RNA is a key endpoint in clinical trials, and HDV RNA undetectability is associated with better outcomes for people living with chronic hepatitis delta," said Tarik Asselah, M.D., Ph.D., Professor of

Hepatology at the Hôpital Beaujon, APHP, Clichy, France, and at the University of Paris-Cité, and Head of the unit Viral Hepatitis UMR1149 at INSERM, France. “The combination of tobevibart and elebsiran has consistently demonstrated impressive hepatitis delta virologic suppression in the SOLSTICE Phase 2 trial, and these 48-week data are encouraging as they continue to support its potential to deliver meaningful patient benefit.”

Data demonstrate that 66% (21/32) of participants with CHD receiving a monthly dose of the combination of tobevibart and elebsiran achieved and sustained HDV RNA TND at 48 weeks. Additionally, approximately 90% of participants achieved reduction in hepatitis B surface antigen (HBsAg) to values <10 IU/mL by Week 48. HBsAg reduction indicates suppression of the fundamental biologic mechanisms that HDV requires for viral replication. ALT was normalized in 56% (18/32) of participants by Week 48. The combination was well-tolerated, with no grade 3 or higher treatment-related adverse events and no treatment-related discontinuations. Most treatment-related adverse events were generally mild to moderate and transient.

The combination of tobevibart and elebsiran is currently being evaluated in Vir Biotechnology's ECLIPSE registrational program for the treatment of CHD, which includes three randomized, controlled trials. ECLIPSE 1 has completed enrollment ahead of the Company's expectations. Topline results from ECLIPSE 1, 2, and 3 are expected in the first quarter of 2027.

“The 48-week data from the SOLSTICE Phase 2 trial presented at AASLD's The Liver Meeting® reinforce our confidence that a monthly dose of the combination of tobevibart and elebsiran can deliver meaningful patient benefit with convenient dosing, and I am proud to see the caliber of our data recognized by our publication in the prestigious New England Journal of Medicine,” said Marianne De Backer, M.Sc., Ph.D., MBA, Chief Executive Officer, Vir Biotechnology. “We are committed to advancing our registrational ECLIPSE program efficiently with the goal of addressing the critical unmet needs of the hepatitis delta community.”

CHD is the most severe form of chronic viral hepatitis,¹ recently classified as carcinogenic by the International Agency for Research on Cancer.² People living with the disease rapidly progress to cirrhosis, liver failure³ and liver-related death.¹ There are currently no approved treatments in the U.S., and options are limited in the European Union and globally. The objective is to eliminate the virus, and tobevibart in combination with elebsiran offers the potential to achieve this by tackling the viral lifecycle through multiple mechanisms.

The significant unmet need in CHD and the potential for the combination of tobevibart and elebsiran to provide a much-needed treatment option has been recognized by the U.S. Food and Drug Administration (FDA) with Breakthrough Therapy and Fast Track designations, and by the European Medicines Agency (EMA) with Priority Medicines (PRIME) and orphan drug designations.

About the ECLIPSE Registrational Program

ECLIPSE is a registrational program to evaluate the safety and efficacy of tobevibart in combination with elebsiran in patients with chronic hepatitis delta (CHD). ECLIPSE includes three randomized, controlled trials designed to evaluate the combination therapy in comparison to deferred treatment or bulevirtide. ECLIPSE 1 (**NCT06903338**) is a Phase 3 trial evaluating the safety and efficacy of tobevibart in combination with elebsiran compared to deferred treatment in the U.S. or other regions where bulevirtide use is limited. ECLIPSE 2 (**NCT07128550**) is a Phase 3 trial that will evaluate the efficacy and safety of switching to tobevibart and elebsiran in people with CHD who have not achieved viral suppression with bulevirtide therapy. ECLIPSE 1 and 2 are designed to provide the registrational efficacy and safety data needed for potential submission to global regulatory agencies. ECLIPSE 3 (**NCT07142811**) is a Phase 2b head-to-head trial to evaluate tobevibart and elebsiran compared with bulevirtide in bulevirtide-naïve patients, and it is designed to provide important supportive data to help establish access and reimbursement in key markets.

About Tobevibart and Elebsiran

Tobevibart is an investigational broadly neutralizing monoclonal antibody targeting the hepatitis B surface antigen (HBsAg). 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. Tobevibart was identified using Vir Biotechnology's proprietary monoclonal antibody discovery platform. The Fc domain has been engineered to increase immune engagement and clearance of HBsAg immune complexes and incorporates Xencor's Xtend™ technology to extend half-life. Tobevibart is administered subcutaneously, and it is currently in clinical development for the treatment of patients with chronic hepatitis delta.

Elebsiran is an investigational hepatitis B virus-targeting small interfering ribonucleic acid (siRNA) discovered by Alnylam Pharmaceuticals, Inc. It is designed to degrade hepatitis B virus RNA transcripts and limit the production of hepatitis B surface antigen. Current data indicate 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 the treatment of patients with chronic hepatitis delta.

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. Its clinical-stage portfolio includes programs for chronic hepatitis delta and multiple dual-masked T-cell engagers across validated targets in solid tumor indications. Vir Biotechnology also has a preclinical portfolio of programs across a range of infectious diseases and oncologic malignancies. Vir Biotechnology routinely posts information that may be important to investors on its website.

References:

¹ NIH National Institute of Diabetes and Digestive and Kidney Diseases **Hepatitis D - NIDDK (nih.gov)**, accessed September 2025

² Karagas, Margaret R et al., Carcinogenicity of hepatitis D virus, human cytomegalovirus, and Merkel cell polyomavirus, *The Lancet Oncology*, Volume 26, Issue 8, 994 – 995.

³ CDC **What is Hepatitis D - FAQ | CDC**, accessed September 2025

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 “should,” “could,” “may,” “might,” “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. Forward-looking statements contained in this press release include, but are not limited to, statements regarding: the therapeutic potential of the combination of tobevibart and elebsiran to treat CHD and Vir Biotechnology’s belief that monthly dosing of the combination can deliver meaningful patient benefit and address the critical unmet needs of the hepatitis delta community; Vir Biotechnology’s clinical development plans and expectations for the ECLIPSE Phase 3 registrational program, including protocols for and enrollment into ongoing and planned clinical trials, target endpoints and data readouts (including the expectation of topline data for all three trials in the first quarter of 2027); Vir Biotechnology’s strategy and plans; and any assumptions underlying any of the foregoing. Many factors may cause differences between current expectations and actual results, including, without limitation: unexpected safety or efficacy data or results observed during clinical studies or in data readouts, including the occurrence of adverse safety events; risks of unexpected costs, delays or other unexpected hurdles; challenges in accessing manufacturing capacity; clinical site activation rates or clinical enrollment rates that are lower than expected; the timing and outcome of Vir Biotechnology’s planned interactions with regulatory authorities, as well as general difficulties in obtaining any necessary regulatory approvals; successful development and/or commercialization of alternative product candidates by Vir Biotechnology’s competitors, as well as changes in expected or existing competition; geopolitical changes or other external factors; and unexpected litigation or other disputes. In light of these risks and uncertainties, the events or circumstances referred to in the forward-looking statements may not occur. 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 studies may not be indicative of full results or results from later stage or larger scale clinical studies and do not ensure regulatory approval. The actual results may vary from the anticipated results, and the variations may be material. You are cautioned not to place undue reliance on any scientific data presented or these forward-looking statements, which

are based on Vir Biotechnology's available information, expectations and assumptions as of the date of this press release. Other factors that may cause Vir Biotechnology's actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Vir Biotechnology's filings with the U.S. Securities and Exchange Commission, including the section titled "Risk Factors" contained therein. Except as required by law, Vir Biotechnology assumes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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