NEWS RELEASE

Vir Biotechnology Enrolls First Patient in Phase 3 ECLIPSE Registrational Program for Chronic Hepatitis Delta

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- First patient enrolled in ECLIPSE 1 Phase 3 clinical trial evaluating combination of tobevibart and elebsiran for chronic suppressive treatment

- ECLIPSE program designed to enable regulatory submissions and support reimbursement and access

- Rapid study start indicative of significant unmet need for chronic hepatitis delta treatment

SAN FRANCISCO--(BUSINESS WIRE)-- Vir Biotechnology, Inc. (Nasdaq: VIR) today announced the enrollment of the first patient in its Phase 3 ECLIPSE registrational program. The ECLIPSE registrational program is designed to evaluate the efficacy and safety of tobevibart in combination with elebsiran in people living with chronic hepatitis delta (CHD). ECLIPSE 1, the first trial of the program to be initiated, and ECLIPSE 2 are Phase 3 trials designed to provide the registrational data needed for submission to multiple regulatory agencies. ECLIPSE 3, a Phase 2b trial, is designed to provide important supportive data to help enable access and reimbursement strategies in key European markets.

“The start of the ECLIPSE program marks a pivotal moment for patients living with hepatitis delta and for Vir Biotechnology. With a proven track record of developing treatments powering the immune system to transform lives this achievement is a testament to our ability to rapidly advance impactful treatments from discovery to patient care,” said Marianne De Backer, M.Sc., Ph.D., MBA, Chief Executive Officer, Vir Biotechnology.

“The data from our SOLSTICE Phase 2 trial suggest that tobevibart and elebsiran can rapidly reduce hepatitis delta virus to undetectable levels, potentially driving important benefit for patients,” said Mark Eisner, M.D., M.P.H., Chief Medical Officer, Vir Biotechnology. “We are excited to further evaluate the potential of this combination in our

Phase 3 program."

CHD is a debilitating inflammatory liver disease caused by the hepatitis delta virus (HDV).[1] It is the most severe form of chronic viral hepatitis[2] and on average, people living with CHD will progress to cirrhosis and liver failure within 5 years.[3] There is a high unmet medical need for effective treatments, as there are no approved therapies in the U.S., and options are limited in the European Union and globally. The objective of therapy is to eliminate the virus. Tobevibart in combination with elebsiran offers the potential to achieve this by tackling the viral lifecycle through multiple mechanisms.

"Chronic hepatitis delta can be a devastating diagnosis, leaving all those impacted in the U.S. facing an uncertain future without approved treatment options," said Chari A. Cohen, DrPH, M.P.H., President, Hepatitis B Foundation. "It is exciting to see potential new therapies for hepatitis delta, such as the combination of tobevibart and elebsiran, which could offer new hope to a community that has been waiting for efficacious treatment options for far too long."

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

About the ECLIPSE Registrational Program

ECLIPSE is a Phase 3 registrational program to evaluate the safety and efficacy of tobevibart in combination with elebsiran in patients with chronic hepatitis delta. ECLIPSE includes three randomized, controlled trials designed to evaluate the combination therapy in comparison to deferred treatment or bulevirtide. ECLIPSE 1, the first trial of the program to be initiated, is a Phase 3 trial that will assess the efficacy and safety of tobevibart and elebsiran compared to deferred treatment in regions such as the U.S. where bulevirtide is not available or other regions where its access is limited. ECLIPSE 2 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 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.

ECLIPSE 1 plans to enroll 120 participants in the U.S. or other regions where bulevirtide use is limited. Participants will be randomized 2:1 to receive either tobevibart in combination with elebsiran or deferred treatment. During the deferred treatment period, participants will receive only nucleoside reverse transcriptase inhibitors (NRTIs). After

the initial delay period, participants will be switched to the combination therapy of tobevibart and elebsiran. The composite primary endpoint measures HDV RNA at the lower limit of quantification target not detected or HDV RNA TND (defined as HDV RNA < 0 IU/mL) and ALT normalization at Week 48, compared to the deferred treatment group at the end of their deferred treatment period.

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 and patients with chronic hepatitis B.

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 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 the treatment of patients with chronic hepatitis delta and patients with chronic hepatitis B.

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 infectious disease programs for chronic hepatitis delta and chronic hepatitis B infections 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 February 2025

[2] WHO Hepatitis Delta Factsheet – **Hepatitis D (who.int)**, accessed February 2025

[3] CDC **What is Hepatitis D - FAQ | CDC**, accessed February 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 it can offer transformative benefits for these patients; 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 studies, target endpoints and data readouts; 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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