NEWS RELEASE

Vir Biotechnology Initiates Second Pivotal Trial in Its Global ECLIPSE Registrational Program for Chronic Hepatitis Delta

2025-07-31

- First patient enrolled in ECLIPSE 2 Phase 3 clinical trial evaluating the switch to the combination of tobevibart and elebsiran in patients not achieving undetectable hepatitis delta virus RNA despite bulevirtide treatment
- ECLIPSE 2 is a pivotal trial designed to support global marketing applications, including in the U.S. and Europe

SAN FRANCISCO--(BUSINESS WIRE)-- Vir Biotechnology, Inc. (Nasdaq: VIR) today announced the enrollment of the first participant in the ECLIPSE 2 Phase 3 clinical trial, which is designed to compare the combination of tobevibart and elebsiran to continued bulevirtide monotherapy in participants with chronic hepatitis delta (CHD) who have not achieved undetectable hepatitis delta virus (HDV) RNA despite bulevirtide treatment. ECLIPSE 2 is one of three trials in Vir Biotechnology's registrational ECLIPSE program for CHD, which was **initiated in March 2025**. ECLIPSE 2 is designed to provide the registrational efficacy and safety data needed for potential submission to global regulatory agencies, including agencies in the U.S. and Europe.

"Patients living with chronic hepatitis delta, a known cause of liver cancer, are waiting for effective options to change the course of their disease," said Marianne De Backer, M.Sc., Ph.D., MBA, Chief Executive Officer, Vir Biotechnology. "We are excited about the rapid progress of our ECLIPSE program, which demonstrates our unwavering commitment to deliver a highly effective treatment for people living with chronic hepatitis delta."

"We are encouraged by the transformational potential of tobevibart and elebsiran to rapidly drive the hepatitis delta virus to undetectable levels, as demonstrated by compelling data from our Phase 2 SOLSTICE clinical trial. We remain focused on advancing this investigational combination for chronic hepatitis delta with utmost urgency," said Mark Eisner, M.D., M.P.H., Executive Vice President and Chief Medical Officer, Vir Biotechnology.

CHD is the most severe form of chronic viral hepatitis,[1] with people living with the disease rapidly progressing to cirrhosis, liver failure[2] 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 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.

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 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**), 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, is currently recruiting. 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 2 plans to enroll participants in regions where bulevirtide is approved for the treatment of CHD. Participants who fail to achieve virologic suppression (defined as failure to achieve HDV RNA TND) after a minimum 24 weeks of bulevirtide treatment will be randomized 2:1 to switch to the combination of tobevibart and elebsiran or continue receiving bulevirtide. The primary endpoint in ECLIPSE 2 measures HDV RNA at the lower limit of quantification target not detected, HDV RNA TND (defined as HDV RNA = 0 IU/mL), at Week 24.

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] WHO Hepatitis Delta Factsheet – **Hepatitis D (who.int)**, accessed June 2025
[2] CDC **What is Hepatitis D - FAQ | CDC**, accessed June 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 be a highly effective and transformative treatment option 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.

Media

Corporate Communications, Vir Biotechnology

corporatecomms@vir.bio

Investors

Richard Lepke

Senior Director, Investor Relations

rlepke@vir.bio

Source: Vir Biotechnology, Inc.