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NEWS RELEASE

Vir Biotechnology Receives FDA Breakthrough Therapy Designation and EMA PRIME Designation for Tobevibart and Elebsiran in Chronic Hepatitis Delta

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– Designations aim to expedite the development and review of promising therapies for serious conditions with unmet medical needs –

– Phase 3 ECLIPSE registrational program in chronic hepatitis delta to begin in the first half of 2025 –

SAN FRANCISCO--(BUSINESS WIRE)-- Vir Biotechnology, Inc. (Nasdaq: VIR) today announced that tobevibart and elebsiran have received U.S. Food and Drug Administration (FDA) Breakthrough Therapy designation and European Medicines Agency (EMA) Priority Medicines (PRIME) designation for the treatment of chronic hepatitis delta (CHD). The designations are supported by compelling positive safety and efficacy data from the Phase 2 SOLSTICE trial, from which the Company recently presented new **data** at AASLD The Liver Meeting® in San Diego, U.S. Vir Biotechnology's Phase 3 ECLIPSE registrational program evaluating tobevibart and elebsiran in CHD will commence in the first half of 2025.

CHD is a chronic, progressive liver disease caused by the hepatitis delta virus[1] and is the most severe form of chronic viral hepatitis[2] . CHD increases the risk of liver cancer and accelerates progression to cirrhosis and liver failure, which often occurs within 5 years of infection[3] . There is no approved treatment in the U.S., and options are limited in the European Union and globally.

"Chronic hepatitis delta has devastating effects on liver and overall health, yet people living with this condition are

still waiting for highly effective therapeutic options," said Mark Eisner, M.D., M.P.H., Executive Vice President and Chief Medical Officer, Vir Biotechnology. "The Phase 2 SOLSTICE trial data suggests that tobevibart and elebsiran can rapidly and deeply suppress the hepatitis delta virus, driving it to undetectable levels. Receiving FDA Breakthrough Therapy and European PRIME designations recognizes this combination's potential to transform the lives of people living with CHD. We look forward to advancing the Phase 3 ECLIPSE program as quickly as possible."

FDA Breakthrough Therapy designation aims to expedite the development and regulatory reviews of investigational therapies for serious conditions that demonstrate promising preliminary clinical evidence and potential improvement over existing therapies. EMA PRIME designation is granted to investigational medicines that target conditions with unmet medical needs for which no treatment option exists, or where they can offer a major therapeutic advantage over existing treatments. It fosters early exchange with the EMA to facilitate robust data collection, high-quality marketing authorization applications and expedited evaluations so that medicines can reach patients earlier. These designations follow FDA **Fast Track designation** and EMA Committee for Orphan Medicinal Products (COMP) **positive opinion** on orphan drug designation received earlier this year.

About the Phase 2 SOLSTICE Trial

SOLSTICE is a Phase 2 study to evaluate the safety, tolerability, and efficacy of tobevibart, alone or in combination with elebsiran, in patients with chronic hepatitis delta. This Phase 2 study is a multi-center, open-label, randomized study. Primary endpoints include proportion of participants with undetectable hepatitis delta virus (HDV) RNA (defined as HDV RNA equal or greater than 2 $\log_{10}$ decrease from baseline or below limit of detection) up to week 24, alanine aminotransferase (ALT) normalization (defined as ALT below upper limit of normal) up to week 24, and treatment-emergent adverse events (TEAEs) and serious adverse events (SAEs) up to 118 weeks. Secondary endpoints include proportion of participants with undetectable HDV RNA and different timepoints and up to 192 weeks. More information about this trial can be found at **clinicaltrials.gov** (NCT05461170).

About Tobevibart and Elebsiran

Tobevibart 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. Tobevibart, which incorporates Xencor's Xtend™ and other Fc technologies, has been engineered to have an extended half-life and was identified using Vir Biotechnology's proprietary monoclonal antibody discovery platform. Tobevibart is administered subcutaneously, and it is currently in clinical development for the treatment of patients with chronic hepatitis B and patients with chronic hepatitis delta.

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 the treatment of patients with chronic hepatitis B and patients with chronic hepatitis delta. It is the first asset in Vir Biotechnology's collaboration with Alnylam Pharmaceuticals, Inc. to enter clinical studies.

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 double-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 2024.
[2] WHO Hepatitis Delta Factsheet - **Hepatitis D (who.int)**, accessed September 2024.
[3] CDC **What is Hepatitis D - FAQ | CDC**.

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 Biotechnology'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 Biotechnology'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 Biotechnology's multiple ongoing trials evaluating tobevibart and elebsiran, Vir Biotechnology'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 Biotechnology's competitors;

changes in expected or existing competition; delays in or disruptions to Vir Biotechnology'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 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 contained herein to reflect any change in expectations, even as new information becomes available.

Media

Arran Attridge
Senior Vice President, Corporate Communications
aattridge@vir.bio

Investors

Richard Lepke
Senior Director, Investor Relations
rlepke@vir.bio

Source: Vir Biotechnology, Inc.