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NEWS RELEASE

Vir Biotechnology Receives Positive Opinion on Orphan Drug Designation for Tobevibart and Elebsiran in Chronic Hepatitis Delta from European Medicines Agency

2024-11-18

– Orphan designation in E.U. supports development of treatments for life-threatening or chronically debilitating conditions with significant unmet medical need –

– Phase 2 SOLSTICE 24-week primary endpoint data for tobevibart and elebsiran in chronic hepatitis delta to be presented today at AASLD The Liver Meeting –

– Positive opinion on E.U. orphan drug designation follows U.S. FDA fast track designation, highlighting growing recognition of the potential of tobevibart and elebsiran in chronic hepatitis delta –

SAN FRANCISCO--(BUSINESS WIRE)-- Vir Biotechnology, Inc. (Nasdaq: VIR) today announced that the European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP), has issued a positive opinion on the application for orphan drug designation of tobevibart and elebsiran for the treatment of chronic hepatitis delta (CHD). This opinion is based on encouraging preliminary data from the Phase 2 SOLSTICE trial. Vir Biotechnology will present 24-week data from the Phase 2 SOLSTICE trial at AASLD The Liver Meeting® in San Diego, CA, on November 18 at 6.15 p.m. PT. An investor conference call is scheduled for November 19, 2024, at 5.15 a.m. PT / 8.15 a.m. ET.

CHD is a severe, progressive liver disease caused by the hepatitis delta virus (HDV) [1] . It is considered the most

aggressive form of chronic viral hepatitis [2] , with patients often progressing to cirrhosis and liver failure within 5 years of infection [3] . Currently, there is no approved treatment in the United States, and treatment options are limited in the European Union and globally.

“Chronic hepatitis delta dramatically raises the risk of severe liver disease, including cancer, and eventually death, so new therapeutic options are urgently needed,” said Mark Eisner, M.D., M.P.H., Executive Vice President and Chief Medical Officer, Vir Biotechnology. “The COMP’s positive opinion on tobevibart and elebsiran reflects the potential of this combination to address a critical gap in hepatitis delta care. Our clinical data to date has been encouraging, suggesting that this approach could meaningfully improve outcomes for patients living with this devastating disease.”

The European Commission will evaluate the COMP’s positive opinion and consider tobevibart and elebsiran for orphan drug designation. This designation is for medicines intended to treat rare, life-threatening or chronically debilitating conditions where no other satisfactory treatment option is available, or where the medicine can be of significant benefit to those affected by a specific condition. The designation provides special incentives in the E.U., including access to specific scientific advice, fee reductions, and 10 years of market exclusivity once the medicine is approved.

In June 2024, the U.S. Food and Drug Administration (FDA) granted **fast track designation** for the combination of tobevibart and elebsiran for the treatment of CHD. This designation is intended to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need.

Investor Conference Call

Vir Biotechnology will host an investor conference call on November 19, 2024 at 5.15 a.m. PT / 8.15 a.m. ET. A live webcast will be available on **https://investors.vir.bio/** and will be archived on **www.vir.bio** for 30 days.

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

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

About Elebsiran

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 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. It's clinical-stage portfolio includes infectious disease programs for chronic hepatitis delta and chronic hepatitis B infections and programs across several clinically validated targets in solid tumor indications. Vir Biotechnology also has a preclinical portfolio of programs across a range of other 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.

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