NEWS RELEASE

Vir Biotechnology Receives FDA IND Clearance and Fast Track Designation for Tobevibart and Elebsiran for the Treatment of Chronic Hepatitis Delta Infection

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Fast Track designation follows positive preliminary Phase 2 trial data presented at the European Association for the Study of the Liver Congress 2024 and underscores the unmet need for people living with chronic hepatitis delta

SAN FRANCISCO--(BUSINESS WIRE)-- Vir Biotechnology, Inc. (Nasdaq: VIR) today announced that the U.S. Food and Drug Administration (FDA) has cleared its investigational new drug (IND) application and granted Fast Track designation for the combination of tobevibart and elebsiran for the treatment of chronic hepatitis delta infection. Tobevibart, an investigational monoclonal antibody, and elebsiran, an investigational small interfering ribonucleic acid, are currently being evaluated in the Company's Phase 2 SOLSTICE hepatitis delta clinical trial, with complete 24-week treatment data on track to be reported in the fourth quarter.

"The IND clearance and Fast Track designation from the FDA, along with the encouraging preliminary data from our Phase 2 hepatitis delta trial, underscore the potential of tobevibart and elebsiran to transform the treatment landscape for people living with this severe and life-threatening disease," said Marianne De Backer, M.Sc., Ph.D., MBA, Vir's Chief Executive Officer. "We are committed to working closely with health authorities to bring this potential groundbreaking treatment to patients as quickly as possible, addressing a critical unmet medical need."

The FDA's Fast Track designation is intended to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The World Health Organization considers hepatitis delta to be the most severe form of chronic viral hepatitis due to more rapid progression towards liver cancer and liver-related death. It is estimated that at least 12 million people are living with chronic hepatitis delta globally.

In June, the Company **announced preliminary Phase 2 SOLSTICE trial data** which suggests treatment with tobevibart alone or in combination with elebsiran was generally well tolerated and participants achieved high rates of virologic response at weeks 12 and 24, durable virologic response through 48 weeks, and high rates of ALT normalization. The complete 24-week treatment data is expected in the fourth quarter. The Company is working to expedite the initiation of its next study, the ECLIPSE trial. The open-label, randomized, controlled ECLIPSE trial is designed to support potential registration and will evaluate the safety and efficacy of a monthly-administered subcutaneous injection of tobevibart and elebsiran using the current standard of care therapy as a comparator.

About the Phase 2 SOLSTICE Trial

The SOLSTICE trial (NCT05461170) is evaluating the safety, tolerability and efficacy of tobevibart and elebsiran for the treatment of people living with chronic hepatitis delta. One cohort is evaluating the combination of tobevibart and elebsiran dosed every 4 weeks with a second cohort evaluating tobevibart monotherapy every 2 weeks. Approximately 50% of participants have compensated cirrhosis.

About Tobevibart (VIR-3434)

Tobevibart is an investigational subcutaneously administered antibody designed to inhibit entry of hepatitis B and hepatitis delta viruses into hepatocytes, neutralize both hepatitis B virus and hepatitis delta virus virions, and to reduce the level of virions 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's proprietary monoclonal antibody discovery platform.

About Elebsiran (VIR-2218)

Elebsiran is an investigational subcutaneously administered 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. Vir believes it has the potential to have direct antiviral activity against hepatitis B virus and hepatitis delta virus. It is the first siRNA in the clinic to include Enhanced Stabilization Chemistry Plus (ESC+) technology to enhance stability and minimize off-target activity, which potentially could result in an increased therapeutic index. Elebsiran is the first asset in the Company's collaboration with Alnylam Pharmaceuticals, Inc. to enter clinical trials.

About Vir Biotechnology, Inc.

Vir Biotechnology, Inc. is an immunology company focused on powering the immune system to transform lives by treating and preventing infectious diseases and other serious conditions, including viral-associated diseases. Vir has assembled two technology platforms that are designed to modulate the immune system by exploiting critical

observations of natural immune processes. Its current clinical development pipeline consists of product candidates targeting hepatitis delta and hepatitis B viruses, and human immunodeficiency virus. Vir has several preclinical candidates in its pipeline, including those targeting influenza A and B, COVID-19, RSV/MPV and HPV. Vir routinely posts information that may be important to investors on its website.

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’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’s strategy and plans, the potential clinical effects of tobevibart and elebsiran, the potential benefits, safety and efficacy of tobevibart and elebsiran, data from Vir’s multiple ongoing trials evaluating tobevibart and elebsiran, the ability of tobevibart and elebsiran (as monotherapies or combination therapies) to treat and/or prevent chronic hepatitis Delta (CHD) or chronic hepatitis B virus (CHB), Vir’s plans and expectations for its CHD and CHB programs, the timing and outcome of Vir’s planned interactions with the FDA, Vir’s ability to realize the benefits from receiving the Fast Track designation from the FDA, whether Vir maintains Fast Track designation and/or receives any additional accelerated development paths from the FDA for tobevibart and elebsiran (as monotherapies or combination therapies) to treat and/or prevent CHD or CHB, timing and enrollment for Vir’s ECLIPSE trial, and risks and uncertainties associated with drug development and commercialization. Many factors may cause differences between current expectations and actual results, including that receiving Fast Track designation might not result in a more expedited development or regulatory review process, and such a designation does not increase the likelihood that the combination of tobevibart and elebsiran for the treatment of chronic hepatitis delta infection will receive marketing approval in the United States; the Fast Track designation does not change the standards for regulatory approval; the FDA may later decide that the combination of tobevibart and elebsiran for the treatment of chronic hepatitis delta infection no longer meets the conditions for qualification or that the time period for FDA review or approval will not be shortened; 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’s competitors; changes in expected or existing competition; delays in or disruptions to Vir’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's filings with the U.S. Securities and Exchange Commission, including the section titled "Risk Factors" contained therein. Except as required by law, Vir 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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