

# Vir Biotechnology Grants Norgine Exclusive Commercial License to Chronic Hepatitis Delta Treatment Candidate in Europe, Australia & New Zealand, Including Global Cost Sharing Agreement for Ongoing ECLIPSE Clinical Development Program

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- Vir Biotechnology to receive EUR 55 million initial reimbursement payment upon closing, and up to EUR 495 million in clinical, regulatory and sales milestones, along with tiered, mid-teen to high-twenties percent royalties on net sales
- Companies to share clinical development costs for ongoing ECLIPSE registrational program with Norgine contributing approximately 25% of go-forward external costs
- ECLIPSE 3, designed to support access and reimbursement in Europe and other key geographies, has completed enrollment

SAN FRANCISCO--(BUSINESS WIRE)-- Vir Biotechnology, Inc. (Nasdaq: VIR) today announced that the Company has granted Norgine Pharma UK Limited, an affiliate of Norgine, a leading European specialty pharmaceutical company, an exclusive license for the commercial rights to the combination of tobevibart and elebsiran for the treatment of chronic hepatitis delta (CHD) in Europe, Australia and New Zealand.

Per the terms of the agreement, Vir Biotechnology will receive an initial reimbursement payment of EUR 55 million and is eligible to receive up to EUR 495 million in clinical, regulatory and sales milestones, and tiered, mid-teen to high-twenties percent royalties on net sales in Norgine's licensed territory. Vir Biotechnology retains all commercialization rights for tobevibart and elebsiran in the United States and other markets outside of the Greater China Territory.<sup>1</sup> In addition, clinical development costs for the ongoing trials in Vir Biotechnology's ECLIPSE registrational program (ECLIPSE 1, 2 and 3) will be shared, with Norgine contributing approximately 25% of go-

forward external costs. As a result of this agreement, Vir Biotechnology expects that current cash, cash equivalents and investments will be extended into the fourth quarter of 2027, based on the current operating plan.

“We believe Norgine has the ideal expertise and reach in key international markets to maximize the impact of our investigational treatment for CHD,” said Marianne De Backer, M.Sc., Ph.D., MBA, Chief Executive Officer, Vir Biotechnology. “People living with this devastating disease deserve efficacious, safe and convenient treatment options. This agreement advances our commitment to sustainably develop and commercialize the tobevibart and elebsiran combination treatment globally while advancing our innovative clinical pipeline.”

The combination of tobevibart and elebsiran is a potentially first-of-its-kind therapy for the treatment of CHD, bringing together an investigational human monoclonal antibody and a small interfering RNA (siRNA) with the goal of disrupting the viral lifecycle through multiple mechanisms. The combination is currently under evaluation for the treatment of CHD in Vir Biotechnology’s ECLIPSE registrational program.

Vir Biotechnology also confirmed completion of enrollment for ECLIPSE 3, a Phase 2b head-to-head trial to evaluate tobevibart and elebsiran compared with bulevirtide in bulevirtide-naïve patients. ECLIPSE 3 is designed to provide important supportive data to help establish access and reimbursement in Europe and other key geographies.

Forty-eight week data from the Phase 2 SOLSTICE trial presented last month at the American Association for the Study of Liver Diseases (AASLD) The Liver Meeting® and simultaneously published in the New England Journal of Medicine demonstrated that two thirds (66%, 21/32) of participants receiving a monthly dose of the combination of tobevibart and elebsiran achieved hepatitis delta virus (HDV) RNA target not detected (TND). Importantly, the combination regimen achieved a high proportion of TND in participants with cirrhosis and high baseline HDV RNA. The combination was well-tolerated, with no grade 3 or higher treatment-related adverse events and no treatment-related discontinuations.

“We are excited to collaborate with Vir Biotechnology to advance care in CHD and improve patient access to this innovative therapy,” said Janneke van der Kamp, Chief Executive Officer, Norgine. “By combining our expertise in hepatology and specialty care with cutting-edge science from Vir Biotechnology, we are reinforcing our commitment to improving healthcare outcomes. Collaborations like this affirm Norgine’s position as a partner-of-choice for companies seeking a trusted collaborator in Europe, Australia and New Zealand.”

The closing of this transaction with respect to certain jurisdictions outside the United States is subject to Norgine receiving regulatory approval from applicable authorities as may be required.

## 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 (CHD).

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 HBsAg. 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 CHD.

The combination of tobevibart and elebsiran has been granted Breakthrough Therapy and Fast Track designations by the U.S. Food and Drug Administration (FDA), and Priority Medicines (PRIME) and orphan drug designations by the European Medicines Agency (EMA).

## About Chronic Hepatitis Delta (CHD)

CHD is the most severe form of chronic viral hepatitis<sup>2</sup> and was recently classified as carcinogenic by the International Agency for Research on Cancer.<sup>3</sup> People living with the disease rapidly progress to cirrhosis, liver failure<sup>4</sup> and liver-related death.<sup>2</sup> There are currently no approved treatments in the U.S., and options are limited in the European Union and globally.

## 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 portfolio of preclinical programs across a range of infectious diseases and oncologic malignancies. Vir Biotechnology routinely posts information that may be important to investors on its website.

<sup>2</sup>People's Republic of China, Hong Kong, Taiwan and Macau

<sup>3</sup>NIH National Institute of Diabetes and Digestive and Kidney Diseases **Hepatitis D - NIDDK (nih.gov)**, accessed September 2025

Karagas, Margaret R et al., Carcinogenicity of hepatitis D virus, human cytomegalovirus, and Merkel cell polyomavirus, The Lancet Oncology, Volume 426, Issue 8, 994 – 995.

CDC **What is Hepatitis D - FAQ | CDC**, accessed September 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 first-of-its-kind therapy and address the unmet needs of 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 (including the expectation of topline data for all three trials in the first quarter of 2027); Vir Biotechnology’s immediate and potential future financial and other obligations under the agreement with Norgine; Vir Biotechnology’s belief that the agreement and grant of the license to Norgine, with its reach in key international markets, can help maximize the impact of the combination of tobevibart and elebsiran as a treatment for CHD; the timing of the anticipated closing of the transaction with Norgine, including receipt of any necessary regulatory approvals; 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; difficulties in collaborating with other companies, some of whom may be competitors of Vir Biotechnology or otherwise have divergent interests, and uncertainty as to whether the benefits of Vir Biotechnology’s various collaborations can ultimately be achieved; 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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Source: Vir Biotechnology, Inc.