NEWS RELEASE

Vir Biotechnology Announces First Patient Dosed in Phase 1 Clinical Trial of EGFR-Targeting PRO-XTEN™ Dual-Masked T-Cell Engager VIR-5525 for the Treatment of Solid Tumors

2025-07-24

- Phase 1 clinical trial designed to assess the safety, pharmacokinetics and preliminary efficacy of VIR-5525 alone or in combination with pembrolizumab in a variety of EGFR-expressing solid tumors such as NSCLC, CRC, HNSCC and cSCC
- VIR-5525, the Company's third dual-masked T-cell engager leveraging the PRO-XTEN™ technology, is designed to expand the therapeutic index by selectively activating in the tumor microenvironment
- Dose escalation continues for Phase 1 studies of PRO-XTEN™ dual-masked TCEs VIR-5818 (HER2) and VIR-5500 (PSMA), with compelling early clinical response signals and promising safety profiles

SAN FRANCISCO--(BUSINESS WIRE)-- Vir Biotechnology, Inc. (Nasdaq: VIR) today announced that the first patient has been dosed in the Company's Phase 1 clinical trial evaluating VIR-5525, an investigational dual-masked T-cell engager (TCE) targeting EGFR (epidermal growth factor receptor). VIR-5525 will be evaluated for the treatment of a variety of EGFR-expressing solid tumors in areas of high unmet need such as non-small cell lung cancer (NSCLC), colorectal cancer (CRC), head and neck squamous cell carcinoma (HNSCC), and cutaneous squamous cell carcinoma (cSCC).

The Phase 1 clinical trial (**NCT06960395**) is a first-in-human open-label, non-randomized study designed to assess the safety, pharmacokinetics, and preliminary anti-tumor activity of VIR-5525 as a monotherapy and in combination with pembrolizumab. VIR-5525 is Vir Biotechnology's third dual-masked TCE in clinical trials. It incorporates the Company's clinically validated in-licensed PRO-XTEN™ masking technology, which is designed to enable the selective activation of the TCEs in the tumor microenvironment, mitigating damage to healthy cells and reducing toxicity.

EGFR is a clinically validated target known to play a key role in cancer.[1] Although EGFR-targeting therapies are available, they often face limitations due to the development of resistance mechanisms[2] and high toxicities

associated with treatment.[3]

“We are excited to bring our third PRO-XTEN™ dual-masked T-cell engager VIR-5525 to the clinic as we further our mission of transforming the lives of people living with hard-to-treat solid tumors,” said Marianne De Backer, M.Sc., Ph.D., MBA, Chief Executive Officer, Vir Biotechnology. “This achievement is a testament of Vir Biotechnology’s commitment to advancing innovative therapies that address substantial unmet needs in oncology.”

“EGFR has been well characterized as a key oncogenic driver and a marker of poor prognosis in cancer. Traditional therapies have significant limitations, creating a substantial unmet need for highly efficacious and well-tolerated options,” said Mark Eisner, MD, MPH, Chief Medical Officer, Vir Biotechnology. “VIR-5525 harnesses the anti-tumor power of T-cell engagers with a dual-masking approach designed to unlock an expanded therapeutic index. We look forward to evaluating the potential of this clinical candidate in our Phase 1 trial.”

The first patient dosing of VIR-5525 triggers a $75 million milestone payment as part of the Company's 2024 exclusive worldwide license agreement with Sanofi for the PRO-XTEN™ platform and clinical-stage T-cell engagers. This anticipated milestone payment has been held as restricted cash since the transaction closing and was excluded from the Company’s $1.02 billion in cash, cash equivalents and investments reported as of March 31, 2025. The payment will be recognized as a research and development expense in the third quarter of 2025.

Dose escalation continues for Vir Biotechnology’s dual-masked TCEs VIR-5818 (targeting a variety of HER2-expressing solid tumors) and VIR-5500 (targeting PSMA in metastatic castration-resistant prostate cancer). Initial Phase 1 data **presented in January 2025** showed compelling early clinical response signals and promising safety profiles for both clinical candidates in heavily pretreated patients.

The Company is advancing multiple preclinical dual-masked TCEs against clinically validated targets with potential applications across a variety of solid tumors with high unmet need. These undisclosed candidates integrate the PRO-XTEN™ masking technology with novel TCEs discovered and engineered using Vir Biotechnology’s antibody discovery platform and the Company’s proprietary dAIsY™ (data AI structure and antibody) artificial intelligence engine.

About VIR-5525

T-cell engagers (TCEs) are powerful anti-tumor agents that can direct the immune system, specifically T-cells, to destroy cancer cells. VIR-5525 is an investigational dual-masked TCE currently being evaluated in an open-label, non-randomized Phase 1 clinical trial (**NCT06960395**) designed to assess the safety, pharmacokinetics and preliminary efficacy of VIR-5525 alone or in combination with pembrolizumab.

VIR-5525 combines a bispecific EGFR and CD3 binding TCE with the PRO-XTEN™ masking technology. The PRO-XTEN™ masking technology is designed to keep the TCEs inactive (or masked) until they reach the tumor microenvironment, where tumor-specific proteases cleave off the mask and activate the TCEs, leading to killing of cancer cells by T-cells. By confining the activity exclusively to the tumor microenvironment, we aim to circumvent the traditionally high toxicity associated with unmasked TCEs and increase their efficacy and tolerability. Additionally, the mask is designed to help drug candidates stay in the bloodstream longer in their inactive form, allowing them to better reach the site of action and potentially allowing for less frequent dosing regimens.

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.

Vir Biotechnology has exclusive rights to the PRO-XTEN™ masking platform for oncology and infectious disease. PRO-XTEN™ is a trademark of Amunix Pharmaceuticals, Inc., a Sanofi company.

References:

[1] Sigismund S, Avanzato D, Lanzetti L. Emerging functions of the EGFR in cancer. Mol Oncol. 2017 Nov 27;12(1):3–20.
[2] Hrustanovic G, Lee BJ, Bivona TG. Mechanisms of resistance to EGFR targeted therapies. Cancer Biol Ther. 013 Jan 28;14(4):304–314.
[3] Zhao Y, Cheng B, Chen Z, Li J, Liang H, Chen Y, Zhu F, Li C, Xu K, Xiong S, Lu W, Chen Z, Zhong R, Zhao S, Xie Z, Liu J, Liang W, He J. Toxicity profile of epidermal growth factor receptor tyrosine kinase inhibitors for patients with lung cancer: A systematic review and network meta-analysis. Crit Rev Oncol Hematol. 2021 Apr; 160:103305; Liu T, Jiang S, Teng X, Zhong L, Liu M, Jin Y, Dong M. A comparison of panitumumab and cetuximab in the treatment of KRAS wild-type metastatic colorectal cancer: a systematic review and meta-analysis. Immunopharmacol Immunotoxicol. 2023 Feb; 45(1):1-9.

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 VIR-5525, both as a monotherapy and in combination with pembrolizumab, as a treatment for a variety of EGFR-expressing solid tumors in areas of high unmet need, and Vir Biotechnology's belief that VIR-5525 and the PRO-XTEN™ masking technology can circumvent the traditionally high toxicity associated with unmasked TCEs and unlock an expanded therapeutic index; Vir Biotechnology's preclinical and clinical development plans and expectations for its TCE assets, including protocols for and enrollment into ongoing and planned clinical studies, potential dosing regimens, target endpoints and data readouts; Vir Biotechnology's delivery and recognition of the $75 million milestone payment pursuant to the 2024 exclusive worldwide license agreement with Sanofi; 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; Vir Biotechnology's use of artificial intelligence and machine learning in its efforts to engineer next-generation proteins and in other research and development efforts; 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.