NEWS RELEASE

Vir Biotechnology Announces First Patient Dosed in Part 3 of Phase 1 Trial of PSMA-Targeting PRO-XTEN® Dual-Masked T-Cell Engager VIR-5500 in Combination with Androgen Receptor Pathway Inhibitors for the Treatment of Metastatic Prostate Cancer

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– Phase 1 clinical trial designed to assess the safety, pharmacokinetics and preliminary efficacy of VIR-5500 in combination with androgen receptor pathway inhibitors in first-line mCRPC

– Clinical trial builds on encouraging Phase 1 data of monotherapy VIR-5500 in late-line patients presented in January 2025

SAN FRANCISCO--(BUSINESS WIRE)-- Vir Biotechnology, Inc. (Nasdaq: VIR) today announced that the first patient has been dosed in Part 3 of the Company's Phase 1 clinical trial evaluating VIR-5500 in combination with androgen receptor pathway inhibitors (ARPIs). VIR-5500 is an investigational PRO-XTEN® dual-masked T-cell engager (TCE) targeting prostate-specific membrane antigen (PSMA) and will be evaluated in participants in first-line pre-taxane metastatic castration-resistant prostate cancer (mCRPC). VIR-5500 is the only dual-masked PSMA-targeting TCE currently in clinical trials.

"We are excited to advance our VIR-5500 Phase 1 trial with the addition of early line metastatic prostate cancer cohorts exploring combination therapy," said Marianne De Backer, M.Sc., Ph.D., MBA, Chief Executive Officer, Vir Biotechnology. "Opening Part 3 of the Phase 1 trial brings the potential benefits of the universal PRO-XTEN® approach to patients earlier in their cancer journey, when treatment intervention may have the greatest impact on their long-term outcomes."

The Phase 1 clinical trial is an open-label, non-randomized study designed to assess the safety, pharmacokinetics and preliminary anti-tumor activity of VIR-5500 in combination with ARPIs in participants with metastatic prostate

cancer. VIR-5500 is currently being evaluated in the same Phase 1 clinical trial as a monotherapy and has demonstrated promising early anti-tumor activity and a favorable safety profile in heavily pre-treated patients with mCRPC. VIR-5500 incorporates the universal 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.

“VIR-5500 has demonstrated potential as a monotherapy with PSA reductions in heavily pre-treated patients early in dose escalation,” said Mark Eisner, MD, MPH, Chief Medical Officer, Vir Biotechnology. “Building on our understanding of VIR-5500 as a monotherapy, we look forward to evaluating the potential benefit of combining the complementary mechanisms of action of VIR-5500 and ARPIs with the goal to deliver the best possible outcomes for patients.”

Prostate cancer is the most diagnosed cancer in men.[1] Metastatic prostate cancer encompasses disease that has spread beyond the prostate, including both hormone-sensitive and castration-resistant forms. The disease progresses quickly and is a significant burden with limited treatment options. Despite advancements, there is still a significant unmet need for efficacious, well-tolerated treatments that can extend survival and improve quality of life.

References:

[1] Leslie SW, Soon-Sutton TL, Skelton WP. Prostate Cancer, available from: **https://www.ncbi.nlm.nih.gov/books/NBK470550/**, accessed September 2025.

About VIR-5500

T-cell engagers (TCEs) are powerful anti-tumor agents that can direct the immune system, specifically T-cells, to destroy cancer cells. VIR-5500 is an investigational PRO-XTEN® masked TCE currently being evaluated in an open-label, non-randomized Phase 1 clinical trial (**NCT05997615**) designed to assess the safety, pharmacokinetics, and preliminary efficacy of VIR-5500 in participants with metastatic castration-resistant prostate cancer (mCRPC).

VIR-5500 combines a bispecific PSMA and CD3 binding TCE with the PRO-XTEN® masking technology. The universal 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 less frequent dosing regimens.

About Vir Biotechnology

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 universal PRO-XTEN® masking platform for oncology and infectious disease. PRO-XTEN® is a trademark of Amunix Pharmaceuticals, Inc., a Sanofi company.

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-5500, both as a monotherapy and in combination with ARPIs, as a treatment for metastatic prostate cancer, and Vir Biotechnology’s belief that the potential benefits of the universal PRO-XTEN® approach and the complimentary mechanisms of action of VIR-5500 and ARPIs can have the greatest impact on long-term patient outcomes when utilized as an earlier line of therapy; Vir Biotechnology’s preclinical and clinical development plans and expectations for VIR-5500 and its other TCE assets, including protocols for and enrollment into ongoing and planned clinical studies, potential dosing regimens, target endpoints and data readouts; 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 AI 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.