

# Vir Biotechnology Reports Positive Updated Phase 1 Results for PSMA-targeting, PRO-XTEN® Dual-masked T-Cell Engager VIR-5500 in Patients with Metastatic Prostate Cancer

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- Updated Phase 1 dose-escalation data (n=58) show VIR-5500 monotherapy has a favorable safety profile and was well tolerated with no dose-limiting toxicities observed to date
- Dose-dependent anti-tumor activity was observed, with 82% PSA50 and 53% PSA90 declines and RECIST-evaluable objective responses (45% ORR in 5/11 patients) in  $\geq 3,000$   $\mu\text{g}/\text{kg}$  Q3W dosing cohorts
- Vir Biotechnology to host conference call today at 5:30 p.m. ET / 2:30 p.m. PT
- Data will be presented at the 2026 American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium on February 26 (Oral Abstract #17)

SAN FRANCISCO--(BUSINESS WIRE)-- Vir Biotechnology, Inc. (Nasdaq: VIR) today announced new data from the ongoing Phase 1 clinical trial of VIR-5500, a prostate-specific membrane antigen (PSMA)-targeting, PRO-XTEN® dual-masked T-cell engager (TCE) being evaluated in patients with advanced metastatic castration-resistant prostate cancer (mCRPC) who have progressed after multiple lines of therapy (**NCT05997615**). These data suggest that VIR-5500 monotherapy is well tolerated and exhibits promising anti-tumor activity. Data will be presented in an oral presentation at the 2026 American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium on February 26 in San Francisco, CA (Oral Abstract #17).

"We are encouraged by VIR-5500's safety and tolerability profile and the early signals of durable anti-tumor activity in a heavily pre-treated population, which validate our PRO-XTEN® masking strategy aimed at achieving a differentiated therapeutic index," said Marianne De Backer, M.Sc., Ph.D., MBA, Chief Executive Officer, Vir Biotechnology. "Based on these data, we are advancing dose-expansion cohorts and plan to initiate our registrational trial in 2027. We want to thank the patients in our Phase 1 program and their families for participating in the development of VIR-5500."

Data across all patients receiving VIR-5500 monotherapy in the Phase 1 trial (n=58) show that VIR-5500 was generally well tolerated with no dose-limiting toxicities (DLTs) observed to date. Grade  $\geq 3$  treatment-related adverse events occurred in 12% (7/58) of patients and were manageable. Limited cytokine release syndrome (CRS) was observed in 50% (29/58) of patients, with events generally restricted to Grade 1 (fever only). Prophylactic steroids were not required and were only explored in a small cohort of three patients. Enrolled patients were heavily pre-treated (median of four prior lines) and a substantial proportion presented with high tumor burden, including nearly one half with visceral metastases.

Dose-dependent activity was observed across the entire treatment group as measured by both prostate-specific antigen (PSA) declines and radiographic responses. Efficacy data were reported in the highest dose cohorts ( $\geq 3,000$   $\mu\text{g}/\text{kg}$  Q3W; n=22/58) as of the January 9, 2026 data cut-off. In these cohorts, PSA50 declines occurred in 82% (14/17) and PSA90 declines in 53% (9/17) of PSA-evaluable patients. Among RECIST (Response Evaluation Criteria in Solid Tumors)-evaluable patients, objective responses were seen in 45% (5/11). Of the five responders, four achieved confirmed responses with one patient pending confirmation. Reductions on PSMA-PET (positron emission tomography) affirm PSA declines and radiographic responses, with tumor shrinkage observed across multiple lesions, including visceral metastases. These findings support proof-of-concept and further evaluation in expansion cohorts.

“It is remarkable to see these early signs of profound anti-tumor activity in heavily pre-treated mCRPC patients, and the favorable tolerability with minimal CRS to date means VIR-5500 could play a role in treating earlier disease,” said Dr. Johann de Bono, Principal Investigator and Director of the Drug Development Unit and Head of Prostate Cancer Targeted Therapy Group at the Institute of Cancer Research. “For patients with metastatic prostate cancer who have long faced limited treatment choices, VIR-5500 may offer a renewed sense of hope and a potential path to better outcomes.”

Vir Biotechnology has concluded QW and Q3W monotherapy dose-escalation in late-line mCRPC and has defined a preliminary go-forward dose and regimen recommendation for expansion. In parallel, dose-escalation of VIR-5500 in combination with enzalutamide continues in early-line mCRPC patients. The Company anticipates initiating monotherapy dose-expansion cohorts in late-line mCRPC and combination dose-expansion cohorts in both early-line mCRPC and metastatic hormone-sensitive prostate cancer (mHSPC) in the second quarter of 2026 followed by pivotal Phase 3 trials in 2027.

## Conference Call

Vir Biotechnology will host its fourth quarter and full year 2025 financial results conference call at 5:30 p.m. ET / 2:30 p.m. PT today, when members of the executive team and Dr. de Bono will share the updated VIR-5500 Phase 1

data that is also being presented at the 2026 ASCO Genitourinary Cancers Symposium on February 26. A live webcast will be available at <https://investors.vir.bio> and will be archived for 30 days.

## About Advanced Prostate Cancer

Prostate cancer remains a significant global health burden, representing the most common cancer diagnosis in men and the second leading cause of cancer-related mortality in men behind lung cancer.<sup>1</sup> Despite diagnostic and therapeutic advances, patients with prostate cancer continue to face substantial unmet medical need. While androgen directed therapy can improve outcomes in earlier settings, most patients ultimately relapse and develop metastatic hormone sensitive prostate cancer (mHSPC).<sup>2</sup> mHSPC is characterized by its responsiveness to intensified hormonal interventions designed to reduce androgen levels or block their action. While androgen-directed therapies have improved outcomes in mHSPC settings, the majority of these patients eventually progress to metastatic castration-resistant prostate cancer (mCRPC).<sup>3</sup> This stage is associated with poor clinical outcomes, including limited durability of existing therapies, with a 5-year survival rate of approximately 30%.<sup>4</sup> There is a critical need for safer, more effective, and precisely targeted therapies capable of improving long term disease control and quality of life across the prostate cancer continuum.

## 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<sup>®</sup> dual-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 in participants with metastatic castration-resistant prostate cancer (mCRPC). VIR-5500 is the only dual-masked PSMA-targeting TCE in clinical evaluation.

VIR-5500 combines a bispecific PSMA and CD3 binding TCE with the PRO-XTEN<sup>®</sup> masking technology. The PRO-XTEN<sup>®</sup> 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 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 PRO-XTEN® 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.

#### Footnotes and references:

<sup>1</sup> Kratzer TB, et. al. "Prostate cancer statistics, 2025." CA Cancer J Clin. vol. 75 no. 6 (2025): 485-497. doi:10.3322/caac.70028.

<sup>2</sup> Bernard-Terrier A & Beltran H. "Exploring the biology of metastatic hormone-sensitive prostate cancer: on the road to precision medicine." J Clin Invest. vol. 136 no. 3 (2026):e200920. doi: 10.1172/JCI200920.

<sup>3</sup> Leith A, et. al. "Real-World Treatment Patterns in Metastatic Castration-Resistant Prostate Cancer Across Europe (France, Germany, Italy, Spain, and the United Kingdom) and Japan." Adv Ther. vol. 39 (2022): 2236-2255. doi: 10.1007/s12325-022-02073-w.

<sup>4</sup> Huo, X et al. "Predicting Survival in Metastatic Castration-Resistant Prostate Cancer Patients: Development of a Prognostic Nomogram." Studies in health technology and informatics vol. 323 (2025): 164-168. doi:10.3233/SHTI250070.

## Vir Biotechnology 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 enzalutamide, to treat advanced mCRPC and other forms of prostate cancer (including in earlier disease) and offer patients a path to better outcomes; Vir Biotechnology's clinical development plans and expectations for VIR-5500, including protocols for and enrollment into ongoing and planned clinical trials (including monotherapy dose-expansion cohorts in late-line mCRPC and combination dose-expansion cohorts in both early-line mCRPC and mHSPC in the second quarter of 2026, followed by pivotal Phase 3 trials in 2027), target endpoints and data readouts; Vir Biotechnology's strategy and plans (including its PRO-XTEN® masking strategy aimed at achieving a differentiated therapeutic index); 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; 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.

Vir Biotechnology retains exclusive rights to the PRO-XTEN<sup>®</sup> masking platform for oncology and infectious disease. PRO-XTEN<sup>®</sup> is a trademark of Amunix Pharmaceuticals, Inc., a Sanofi company.

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