

Vir Biotechnology Announces First Patient Dosed in Phase 1 Dose-expansion Cohorts Evaluating PSMA-targeted, PRO-XTEN® Dual-masked T-cell Engager VIR-5500 in Patients with Metastatic Prostate Cancer

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- Phase 1 trial designed to assess the safety, pharmacokinetics and preliminary efficacy of VIR-5500 in both early and late-line metastatic castration-resistant prostate cancer (mCRPC) and metastatic hormone-sensitive prostate cancer (mHSPC)
- Dose-expansion builds on promising Phase 1 monotherapy dose-escalation data in mCRPC presented in February 2026

SAN FRANCISCO--(BUSINESS WIRE)-- Vir Biotechnology, Inc. (Nasdaq: VIR) today announced that the first patient has been dosed in one of three expansion cohorts in the Phase 1 trial evaluating VIR-5500, a prostate-specific membrane antigen (PSMA)-targeted, PRO-XTEN® dual-masked T-cell engager (TCE) for metastatic prostate cancer (NCT05997615). The Phase 1 trial is measuring the safety and efficacy of VIR-5500 monotherapy in late-line mCRPC, and of VIR-5500 in combination with an androgen receptor pathway inhibitor (ARPI) in early-line mCRPC and mHSPC.

“The initiation of the VIR-5500 expansion cohorts underscores the significant momentum behind this program and the enthusiasm we are seeing across the clinical community,” said Marianne De Backer, M.Sc., Ph.D., MBA, Chief Executive Officer, Vir Biotechnology. “We are encouraged by the promising anti-tumor activity shown in the Phase 1 data announced earlier this year and look forward to collaborating with Astellas after closing of the transaction to explore VIR-5500’s potential to make a meaningful difference across the spectrum of metastatic prostate cancer.”

The monotherapy expansion cohort in late-line mCRPC is the first to begin enrollment based on the monotherapy dose-escalation data that **showed VIR-5500 has a favorable safety profile and promising anti-tumor activity in mCRPC**. These safety and efficacy data were presented at the 2026 American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium in February. Based on these data, the selected dose regimen to be evaluated in

this monotherapy expansion cohort is Q3W 800/2000/3500 µg/kg step-up dosing. This expansion cohort will measure safety and efficacy, including Prostate-Specific Antigen (PSA) response rate and Objective Response Rate (ORR) in patients with mCRPC who are refractory following treatment with multiple prior lines of therapy including at least one second-generation ARPI and one taxane regimen in addition to standard-of-care radioligand-based therapy.

“Building on the encouraging Phase 1 dose-escalation monotherapy data, this milestone represents an important step in further evaluating VIR-5500’s best-in-class potential,” said Anthony Jarkowski, Primary Focus Lead, Immunoncology, Astellas. “We look forward to starting our collaboration with Vir Biotechnology to potentially benefit more people living with prostate cancer, where there remains a significant unmet medical need.”

Dose-escalation of VIR-5500 in combination with enzalutamide continues in early-line mCRPC patients. The Company anticipates dosing of first patients in the combination dose-expansion cohorts in both early-line mCRPC and mHSPC over the coming months, followed by pivotal Phase 3 trials in 2027.

About Advanced Prostate Cancer

Prostate cancer remains a significant global health burden, representing the second leading cause of cancer-related mortality in men behind lung cancer.¹ While diagnostic and therapeutic advances like androgen-directed therapy can improve outcomes in earlier settings, most patients ultimately relapse and develop metastatic hormone sensitive prostate cancer (mHSPC).² mHSPC is characterized by its responsiveness to intensified hormonal interventions designed to reduce androgen levels or block their action. The majority of these patients eventually progress to metastatic castration-resistant prostate cancer (mCRPC).³ This stage is associated with poor clinical outcomes, including limited durability of existing therapies, with a 5-year survival rate of approximately 30%.⁴ 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[®] 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[®] 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 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:

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

² 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.

³ 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.

⁴ 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 be a best-in-class treatment for advanced mCRPC (including in early-line) and other indications across the spectrum of prostate cancer and make a meaningful difference for these patients, where there remains a significant unmet medical need; Vir

Biotechnology's clinical development plans and expectations for VIR-5500, including protocols for and enrollment into ongoing and planned clinical trials (including combination dose-expansion cohorts in both early-line mCRPC and mHSPC over the coming months, followed by pivotal Phase 3 trials in 2027), target endpoints and data readouts; the timing of the anticipated closing of the transaction with Astellas, including receipt of any necessary regulatory clearances; 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; 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[®] masking platform for oncology and infectious disease. PRO-XTEN[®] is a trademark of Amunix Pharmaceuticals, Inc., a Sanofi company.

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