

Vir Biotechnology Announces PSMA-targeted PRO-XTEN® Dual-masked T-cell Engager VIR-5500 Received FDA Fast Track Designation for the Treatment of Prostate Cancer

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SAN FRANCISCO--(BUSINESS WIRE)-- Vir Biotechnology, Inc. (Nasdaq: VIR) today announced that the U.S. Food and Drug Administration (FDA) granted Fast Track designation to VIR-5500, a PSMA-targeted PRO-XTEN® dual-masked T-cell engager (TCE), for the treatment of late-line metastatic castration-resistant prostate cancer (mCRPC). VIR-5500 is being co-developed by Astellas Pharma Inc. and Vir Biotechnology through a global strategic collaboration.

"Receiving Fast Track designation reflects the potential of VIR-5500 to address an area of serious unmet need in late-line mCRPC and the strong momentum we have achieved with Astellas as we prepare to enter pivotal Phase 3 development in 2027," said Marianne De Backer, President and Chief Executive Officer of Vir Biotechnology. "We look forward to working with the FDA to rapidly advance the development of VIR-5500 for people living with mCRPC."

"People living with advanced prostate cancer need new treatment options that can offer meaningful and durable benefit," said Moitreyee Chatterjee-Kishore, Executive Vice President and Head of Oncology Development, Astellas. "This Fast Track designation reinforces the importance of advancing VIR-5500 with urgency, and we are committed to exploring its potential to make a meaningful difference for patients and their families."

FDA Fast Track designation is intended to facilitate and expedite the development and review of drugs to treat serious conditions and fill an unmet need.

VIR-5500 is being evaluated in a Phase 1 study across six dose-expansion cohorts. The monotherapy dose-expansion cohorts include patients with taxane naïve mCRPC, radioligand therapy naïve mCRPC and radioligand therapy exposed mCRPC. The combination regimen dose-expansion cohorts include VIR-5500 in combination with enzalutamide in early-line mCRPC, VIR-5500 in combination with docetaxel in early-line mCRPC and VIR-5500 in

combination with darolutamide in metastatic hormone sensitive prostate cancer (mHSPC). Phase 1 data reported earlier this year showed VIR-5500 was generally well tolerated and exhibited promising anti-tumor activity in patients with mCRPC. Phase 3 trials are anticipated to begin in 2027.

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 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, enabling 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 PRO-XTEN[®] Dual-masked T-cell Engagers (TCEs)

T-cell engagers (TCEs) are powerful anti-tumor agents designed to direct the immune system, specifically T-cells, to destroy cancer cells. TCEs have become an important treatment option for blood cancers, but their usage in solid tumors has been limited due to toxicity. The universal PRO-XTEN[®] masking technology is designed to extend the half-life of the molecule and to keep 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 extending the half-life and confining activity to the tumor microenvironment, the PRO-XTEN[®] technology could limit toxicity, widen the therapeutic index of TCEs, and potentially enable less frequent dosing regimens.

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.

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

²Bernard-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.

³Leith 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.

⁴Huo, 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/SHIT250070.

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 oncologic malignancies. Vir Biotechnology routinely posts information that may be important to investors on its website.

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 FDA Fast Track designation and potential expedited development for VIR-5500 to address an area of serious unmet need in late-line mCRPC; the therapeutic potential of VIR-5500, both as a monotherapy and as part of combination regimens, to be a treatment for advanced mCRPC (including in early-line) and mHSPC; Vir Biotechnology's clinical development plans and expectations for VIR-5500, including protocols for and enrollment into ongoing and planned clinical trials (including pivotal Phase 3 trials in 2027), 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; 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 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.

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