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NEWS RELEASE

Vir Biotechnology Announces Encouraging Safety and Efficacy Data in Ongoing Dose Escalation Trials for Dual Masked T-Cell Engagers VIR-5818 in Solid Tumors and VIR-5500 in mCRPC

2025-01-08

– Compelling early clinical response signals for VIR-5818 and VIR-5500 in heavily pretreated patients with various solid tumors

- ○ VIR-5818: In patients receiving doses ≥400 µg/kg, tumor shrinkage observed in 50% (10/20) of participants with various HER2-expressing cancers; confirmed partial responses in 33% (2/6) of participants with HER2-positive CRC
- ○ VIR-5500: PSA declines in 100% (12/12) and PSA $_{50}$ response confirmed in 58% (7/12) of mCRPC patients with first step dose ≥120 µg/kg

– Promising safety profile with MTD not yet reached for VIR-5818 or VIR-5500 and no dose-limiting cytokine release syndrome (CRS) observed; no CRS greater than grade 2 reported

– Initial clinical data demonstrate PRO-XTEN™ masking technology may lead to minimal systemic unmasking and unlocks expanded therapeutic index

– Investor conference call January 8, 2025, at 5:00 a.m. PT / 8:00 a.m. ET, available on **https://investors.vir.bio**

SAN FRANCISCO--(BUSINESS WIRE)-- Vir Biotechnology, Inc. (Nasdaq: VIR) today is presenting initial Phase 1 data from two of its dual-masked T-cell engagers (TCEs): VIR-5818, targeting a variety of HER2-expressing solid tumors; and VIR-5500, targeting PSMA in metastatic castration-resistant prostate cancer (mCRPC). Data show encouraging preliminary safety and efficacy profiles with no dose-limiting cytokine release syndrome (CRS), maximum tolerated dose (MTD) not yet reached as dose escalation continues, and early clinical response signals observed in heavily pretreated participants. These initial results provide clinical support for Vir Biotechnology's in-licensed PRO-XTEN™ masking technology, which is designed to enable the selective activation of TCEs in the tumor microenvironment, mitigating damage to healthy cells and reducing toxicity.

"Overcoming the toxicity-driven limitations of traditional T-cell engagers could address an important unmet medical need in cancer care," said Marianne De Backer, M.Sc., Ph.D., MBA, Chief Executive Officer, Vir Biotechnology. "Preliminary safety and efficacy data for our dual-masked T-cell engagers VIR-5818 and VIR-5500 are compelling, and we will continue dose escalation with an opportunity to expand the therapeutic window. We are encouraged that our candidates may enable efficacious and well-tolerated treatment regimens, potentially improving outcomes for people living with a range of solid tumors."

VIR-5818: PRO-XTEN™ Initial Proof-of-Concept and Potential First-in-Class HER2 Immunotherapy

Despite availability of HER2-targeting therapies, there remains a significant unmet need for treatments with novel mechanisms of action to improve tolerability and extend survival. Currently, no HER2-directed immunotherapies are approved for solid tumors. The preliminary safety and efficacy data of VIR-5818 support the tumor-specific activation of PRO-XTEN™ dual-masked TCEs and the potential of this technology to broaden the therapeutic index of TCEs.

VIR-5818 is being evaluated in a Phase 1 clinical trial (NCT05356741) designed to study its safety and pharmacokinetics alone, and in combination with pembrolizumab, in participants with a variety of HER2-expressing cancers, including breast and colorectal cancer (CRC). The study has enrolled 79 heterogeneous and heavily pretreated participants in monotherapy cohorts.

Early efficacy data indicate that 50% (10/20) of participants receiving VIR-5818 doses ≥400 µg/kg experienced dose-dependent tumor shrinkage across multiple HER2-positive tumor types. This includes participants who had received up to 9 prior lines of therapy. Strong anti-tumor activity was observed in a subset of participants with HER2-positive CRC who have exhausted standard of care. In this subset, confirmed partial responses (cPRs) were seen in 33% (2/6) of participants at early doses, and one patient continued in cPR for more than 18 months as of the data cut-off.

Preliminary safety data demonstrate that VIR-5818 is generally well-tolerated, with minimal grade 1 or 2 CRS (20%

and 10%, respectively) and no grade 3 or greater CRS observed in any of the 79 participants across doses up to 1000 µg/kg. Most treatment-emergent adverse events (TEAEs) were low grade, reversible and manageable. The MTD has not yet been reached. Preliminary pharmacokinetics and safety data indicate low systemic unmasking of the TCE, suggesting tumor-specific activation. Dual masking results in a half-life of approximately 6 days, which may enable a less frequent dosing regimen. As a result, Vir Biotechnology is currently evaluating a Q3W dosing regimen.

VIR-5500: First Dual-Masked PSMA-Targeting TCE

Prostate cancer is the second most diagnosed cancer in men[1] . Despite advancements, there is still a significant unmet need for efficacious, well-tolerated treatments that can extend survival and improve quality of life.

VIR-5500 is being evaluated in a Phase 1 clinical trial (NCT05997615) designed to assess its safety, pharmacokinetics, and preliminary efficacy in participants with mCRPC. The study has enrolled 18 participants with significant disease burden who have received 3 to 6 prior lines of therapy.

Early efficacy data show encouraging signs of prostate-specific antigen (PSA) responses, and PSA reductions were observed in 100% (12/12) of participants after an initial dose ≥120 µg/kg. PSA $_{50}$ response was confirmed in 58% (7/12) of participants receiving a first dose ≥120 µg/kg.

Preliminary data show a promising safety profile, with no dose-limiting toxicities observed up to 1000 µg/kg without prophylactic corticosteroids. Safety findings showed minimal grade 1 or 2 CRS (17% and 11%, respectively) and no grade 3 or greater CRS at any dose. Most TEAEs were low grade. No hearing loss has been reported, suggesting safety benefits of dual masking in preventing on-target, off-tumor toxicities. Dose escalation is ongoing, and the MTD for VIR-5500 has not yet been reached. Preliminary pharmacokinetics and safety data indicate tumor-specific activation with minimal unmasking outside the tumor. The dual-masked TCE shows a desirable half-life of 8-10 days, which is enabling Vir Biotechnology to evaluate a Q3W dosing regimen. The safety and tolerability profile observed for VIR-5500 in ongoing dose escalation, together with the observed signs of early anti-tumor activity at low doses, may enable a wide therapeutic index.

About VIR-5818, VIR-5500, VIR-5525

VIR-5818, VIR-5500, VIR-5525 are investigational, clinical candidates currently being evaluated for the treatment of solid tumors. These assets leverage the PRO-XTEN™ masking technology with three different T-cell engagers (TCEs) targeting HER2, PSMA, and EGFR, respectively.

TCEs are powerful anti-tumor agents that can direct the immune system, specifically T-cells, to destroy cancer cells. 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 driving the activity exclusively to the tumor microenvironment, we aim to circumvent the traditionally high toxicity associated with 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 for patients and clinicians.

References:

[1] Ferlay J, Ervik M, Lam F, Laversanne M, Colombet M, Mery L, Piñeros M, Znaor A, Soerjomataram I, Bray F (2024). Global Cancer Observatory: Cancer Today. Lyon, France: International Agency for Research on Cancer. Accessed December 31, 2024.

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 infectious disease programs for chronic hepatitis delta and chronic hepatitis B infections 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.

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 Biotechnology’s oncology solid tumor portfolio, preclinical pipeline and PRO-XTEN™ masked TCE platform, including the capability to overcome toxicity-driven limitations of traditional TCEs and expand therapeutic index with efficacious and well-tolerated TCE treatment regimens, which could improve outcomes for people living with a range of solid tumors; Vir Biotechnology’s clinical development plans and expectations for its TCE assets, including with respect to potential dosing regimens; 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; the timing and amount of Vir Biotechnology's actual operating expenses, as determined in accordance with U.S. Generally Accepted Accounting Principles; difficulties in collaborating with other companies, some of whom may be competitors of Vir Biotechnology or otherwise have divergent interests, and uncertainty as to whether the benefits of Vir Biotechnology's various collaborations can ultimately be achieved; 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 the 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.

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