



POWERING THE IMMUNE SYSTEM
TO TRANSFORM LIVES

NEWS RELEASE

Vir Biotechnology Acts on Expanded Strategy of Powering the Immune System Through Exclusive Worldwide License Agreement with Sanofi for Multiple Potential Best-in-Class Clinical-Stage T-cell Engagers

8/1/2024

– Bolsters clinical pipeline and adds near-term value creation opportunities –

– Licenses proprietary masking platform with goal of minimizing off-tumor toxicity and offering expanded therapeutic index in patients –

– Strategic deal highly synergistic with Vir's mAb engineering platform and T-cell biology expertise –

SAN FRANCISCO--(BUSINESS WIRE)-- Vir Biotechnology, Inc. (Nasdaq: VIR) today announced that it has entered into an exclusive worldwide license agreement with Sanofi for three clinical-stage masked T-cell engagers (TCEs) and exclusive use of the protease-cleavable masking platform for oncology and infectious diseases, acquired by Sanofi from Amunix Pharmaceuticals. The clinical-stage assets include SAR446309 (AMX-818), a dual-masked HER2-targeted TCE; SAR446329 (AMX-500), a dual-masked PSMA-targeted TCE; and SAR446368 (AMX-525), a dual-masked EGFR-targeted TCE. Sanofi's proprietary masking platform can be applied to TCEs, cytokines, and other molecules by exploiting the intrinsically high protease activity of the tumor microenvironment to specifically activate drugs in tumor tissues. The selective activation of the molecules in the tumor microenvironment potentially increases the therapeutic index (TI) and mitigates toxicities associated with the systemic immune activation seen with traditional



TCEs.

"At Vir, the cornerstone of our commitment is and always will be patient-centered, with the aim to advance transformative medicines for patients facing severe diseases with unmet medical needs. Despite recent innovation in cancer therapeutics, the prognosis for many patients remains poor and treatment-associated toxicity is a major problem," said Marianne De Backer, M.Sc., Ph.D., MBA, Vir's Chief Executive Officer. "These potential best-in-class T-cell engagers aim to help address these problems and further us in our mission of powering the immune system to transform lives."

This deal announcement coincides with the Company's **statement** today on its strategic restructuring initiatives to prioritize its clinical-stage pipeline opportunities.

Sanofi's masking platform has yielded three promising clinical-stage TCE programs:

- SAR446309 is a dual-masked HER2xCD3 TCE in Phase 1 clinical study including participants with metastatic treatment resistant HER2+ tumors such as breast and colorectal cancers. Increasing the TI through this proprietary dual masking may allow for both monotherapy and combinations with checkpoint inhibitors.
- SAR446329 is a dual-masked PSMAxCD3 TCE in Phase 1 clinical study including participants with metastatic castration-resistant prostate cancer. Increasing the TI through this proprietary dual masking may allow for both monotherapy and combinations.
- SAR446368 is a dual-masked EGFRxCD3 TCE with a cleared IND. Phase 1 clinical study, which is expected to begin enrollment in the first quarter of 2025 or sooner, will include participants with EGFR-expressing tumors of various types such as colorectal, squamous cell carcinoma of the head and neck, non-small cell lung cancer, and renal cell carcinoma.

As part of the strategic agreement with Sanofi, key employees with extensive scientific and development expertise in TCEs, and in-depth experience using the masking platform technology, will join Vir upon receipt of Hart-Scott-Rodino (HSR) Act clearance.

"A central focus of our discovery team has been conditionally activated biologics, so adding this platform and key talents is highly strategic for us," said Jennifer Towne, Ph.D., Vir's Executive Vice President and Chief Scientific Officer. "Our demonstrated deep understanding of T-cell immunology, robust infrastructure, and leading machine learning and antibody engineering capabilities will create opportunities for real synergies and patient-centric innovation."

Pursuant to this agreement, Sanofi will receive an upfront payment and is eligible to receive future development, regulatory and commercial net sales-based milestone payments and tiered royalties on worldwide net sales. This

agreement is subject to regulatory approval.

This strategic licensing transaction marks a significant milestone in Vir's commitment to develop transformative therapeutics for some of the most severe diseases. Across its portfolio of clinical assets, below are anticipated upcoming catalysts:

- Tobevibart +/- Elebsiran : Phase 2 SOLSTICE 24-week treatment data for chronic hepatitis delta virus infection expected in the fourth quarter of 2024.
- Tobevibart + Elebsiran +/- PEG-IFN- α : Phase 2 MARCH Part B 48-week end of treatment data for hepatitis B virus infection expected in the fourth quarter of 2024.
- SAR446309 : Phase 1 monotherapy and combination study data expected in the second half of 2025.
- SAR446329 : Phase 1 monotherapy study data expected in the second half of 2025.
- SAR446368 : Phase 1 study to begin enrollment in the first quarter of 2025 or sooner.

Evercore Group L.L.C. acted as Vir's exclusive financial advisor and Ropes & Gray LLP acted as Vir's legal advisor for this transaction.

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. Vir's clinical-stage portfolio includes infectious disease programs for chronic hepatitis delta and chronic hepatitis B infections, in addition to multiple oncology programs. Vir also has a preclinical portfolio of programs across a range of other infectious diseases and oncologic malignancies. Vir 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. These forward-looking statements are based on Vir's expectations and assumptions as of the date of this press release. Forward-looking statements contained in this press release include, but are not limited to, statements regarding Vir's strategy and plans; Vir's ability to obtain regulatory approval for the agreement with Sanofi; Vir's ability to realize the anticipated benefits from the exclusive worldwide license agreement with Sanofi; difficulties or unanticipated expenses in connection with the agreement, and the potential effects on Vir's earnings; the risk that Vir's investment in

connection with the agreement will lose value for any number of reasons; the ability of the parties to initiate, progress or complete clinical studies within currently anticipated timelines or at all, and the possibility of unfavorable results from studies, including those involving SAR446309, SAR446329 and SAR446368, and any additional programs that may become subject to the agreement; the potential clinical effects, potential benefits, safety and efficacy of the investigational products that are the subject of these programs; data from ongoing studies evaluating such investigational products and programs; Vir's ability to file applications for regulatory approval or receive regulatory approvals in a timely manner or at all for such investigational products and programs, and the risk that any such approvals may be subject to significant limitations on use; the possibility that closing of the transaction might not occur, that the agreement may be terminated for any number of reasons, or that development of the investigational products and programs subject to the agreement may be discontinued, and therefore may never be successfully commercialized; Vir's ability to successfully commercialize any approved drug products resulting from the agreement; and any assumptions underlying any of the foregoing. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data or results observed during clinical studies or in data readouts; the occurrence of adverse safety events; risks of unexpected costs, delays or other unexpected hurdles; difficulties in collaborating with other companies; successful development and/or commercialization of alternative product candidates by Vir's competitors; changes in expected or existing competition; delays in or disruptions to Vir's business or clinical studies due to geopolitical changes or other external factors; failure to achieve any necessary regulatory approvals; and unexpected litigation or other disputes. 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. You should not place undue reliance on these statements, or the scientific data presented. Other factors that may cause actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Vir's filings with the U.S. Securities and Exchange Commission, including the section titled "Risk Factors" contained therein. Except as required by law, Vir assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

Media

Arran Attridge

Senior Vice President, Corporate Communications

aattridge@vir.bio

Investors

Richard Lepke

Senior Director, Investor Relations

rlepke@vir.bio

Source: Vir Biotechnology, Inc.