HCW Biologics Announces Positive Research Results for CAR-T Cell Therapy Manufactured Utilizing Its Commercial-Ready Proprietary Compound, HCW9206, Published in Science Advances

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Commercialization ready compound supports a new method of generating highly functional human CAR-T cells for treating infectious diseases and cancer

In experimental models, human CAR-T cells manufactured using HCW9206 showed strong anti-tumor activity in leukemia and enhanced antiviral potency in HIV suggesting potential for curative outcomes

Employing HCW9206 as a manufacturing reagent may lower the cost of CAR-T manufacturing

MIRAMAR, Fla., March 16, 2026 (GLOBE NEWSWIRE) -- HCW Biologics Inc. ("HCWB" or the "Company") (NASDAQ: HCWB), is a U.S.-based commercial- and clinical-stage biopharmaceutical company focused on supporting or developing novel immunotherapies to treat autoimmune diseases, cancer, and senescence-associated dysplasia, announced today results of groundbreaking research studies, published in the peer-reviewed, high-impact journal, ***Science Advances (Cole et al., "IL-7/IL-15/IL-21 cytokine-fusion scaffold generates highly functional CAR-T cells enriched in long-lived T memory stem cells" Science Advances, 13 Mar 2026, Vol 12, Issue 11)***. These studies were led by Harris Goldstein, M.D., professor of pediatrics and of microbiology & immunology and director of the Einstein-Rockefeller-CUNY-Mount Sinai Center for AIDS Research and his team of Albert Einstein College of Medicine scientists, most notably Erin Cole, M.S., a graduate student in the Goldstein laboratory.

The study results demonstrated that HCW9206, the Company's proprietary and commercial-stage multi-cytokine fusion protein reagent, provides a revolutionary approach to generate chimeric T-cell receptor - T cells ("CAR-Ts") for immunotherapy with increased function in a cost-effective manner. HCW9206, a first-in-class cytokine-scaffold-based platform, enables production of more potent CAR-T-based immunotherapies by generating a CAR-T population which is highly functional and markedly enriched for long-live T-memory stem cells (T_{scm}). Utilizing HCW9206 as a manufacturing strategy may be broadly applicable to increase persistence and functionality of CAR-Ts.

Dr. Hing C. Wong, the Company's Founder and Chief Executive Officer, stated, "HCW9206 is a novel compound that enables a single molecule to deliver synergistic signals from three different immune-stimulatory cytokines. It is versatile and has shown activity in the creation of memory-like NK-cells for cell-based therapy against cancer, and now we also discovered it has the potential to enhance the production of CAR-T therapies as a promising novel reagent to replace the current industry-standard method that relies on anti-CD3/anti-CD28/IL-2-based approaches. An approach that employs HCW9206 as a reagent is more streamlined and may lower the cost of CAR-T manufacturing. Equally important, based on experimental models, HCW9206 has shown improvement in functional activities and persistence of CAR-Ts following adoptive transfer, a goal the industry has been trying to achieve for the last decade."

Functional persistence of CAR-Ts is limited by conventional and costly manufacturing methods utilizing anti-CD3/CD28 (αCD3/28)/IL-2 stimulation, which generates terminally differentiated and shorter-lived CAR-Ts. Utilizing HCW9206 during the manufacture of CAR-Ts synergizes the effects of IL-7, IL-15 and IL-21 to promote the generation of a CAR-T cell product with a diverse mix of T cell subsets that exhibit a combination of T_{scm} self-renewal capacity and enhanced T cell effector function, likely from the TEM population. In this pivotal publication, the authors show how HCW9206, when used in the manufacture of CAR-T, stimulates proliferation of $CD8^+$T cells, particularly those within the T_{scm} subset. As a result, HCW9206 was shown to generate CAR-Ts without requiring αCD3/28/IL-2 activation which are highly enriched in long-lived T_{scm} (50% or more) and display potent activity across distinct disease experimental models, namely, HIV-1 or B-cell leukemia. In preclinical studies, CAR-Ts manufactured using HCW9206 were significantly superior compared to CART-Ts manufactured using standard methods employing anti-CD3/anti-CD28 and IL-2 reagents for CAR lentiviral transduction and subsequent expansion and persistence of highly active human CAR-Ts. While there is still a need to confirm in clinical studies, this research suggests that CAR-T cells produced with HCW9206 may be a more effective and long-lasting CAR-T cell immunotherapy than conventional CAR-T produced using αCD3/28/IL-2.

In this article, the authors demonstrate in a humanized mouse model of HIV-1 infection utilizing T cells from people living with HIV (PLWH), HCW9206 enabled generation of duoCAR-T cells composed of a highly enriched T_{scm} population, which supported long-term persistence and functional activity *in vivo,* along with the effector memory T cells (T_{EM}) population capable of providing immediate and potent HIV-1 suppression. Utilizing HCW9206 in the manufacture of CAR-Ts may advance HIV immunotherapy by introducing a new strategy that may produce functionally persistent product, thereby extending the lifespan of anti-HIV CAR-T therapy in PLWH and potentially enabling a functional cure. The authors also show how anti-cancer CD19-CAR-T cells manufactured using HCW9206 exhibited a greater capacity to mount a protective proliferative response *in vivo*, as indicated by the effective suppression of tumor cell expansion after rechallenging with $CD19^+$ cancer cells by HCW9206-generated CD19-CAR-T cells compared to the (αCD3/28)-generated CD19-CAR-Tcells in multiple humanized animal models.

The authors of this article also reported that antigen stimulation of duoCAR-T produced with HCW9206 significantly upregulated the expression of SATBI1 (special AT-rich sequence-binding protein 1), a gene previously reported to be a key determinant in linage commitment through chromatin reorganization. Specifically, SATB1 has been shown to be a key regulator of $CD8^+$ T-cell quiescence and stemness, as well as promoting early effector

cell expansion and differentiation to support both effector responses and long-term T-cell persistence.

Taken together, these data demonstrate that manufacturing human T cells with HCW9206 produces HIV- and CD19-specific CAR-T cells that are highly enriched for the T_{scm} memory phenotype, as well as human effector T cells capable of maintaining suppression of HIV and leukemic cell proliferation in experimental models. Therefore, generating human CAR-T cells utilizing HCW9206 could provide a new, improved, and highly scalable method for generating human CAR-T cells to treat patients with infectious disease and cancer and replace standard CAR-T cell production using αCD3/28 activation. This has widespread implications for the generation of more robust CAR-T cell-based immunotherapies with the potential to improve CAR-T cell functional persistence and efficacy for treatment of HIV and cancer.

The authors are Natalia Valderrama Pena, B.S., Niraj Shrestha, Ph.D., and Hing Wong, Ph.D. at HCW Biologics; along with Sara Lamcaj, Ph.D., Agnes Sydenstricker, B.S., Adilyn Voss, B.S., Christopher Hiner, Ph.D., and Jian Hua Zheng, B.S., Harris Goldstein, M.D. at Albert Einstein College of Medicine; Ying Xiong, Ph.D., Zhongyu Zhu, Ph.D., and Boro Dropulić, Ph.D., at Caring Cross; and Cheng Cheng Zhang, Ph.D. at University of Texas Southwestern Medical Center, Dallas, TX.

Links for Articles Referenced in Press Release:

IL-7/IL-15/IL-21 cytokine-fusion scaffold generates highly functional CAR T cells enriched in long-lived T memory stem cells | Science Advances

A “Prime and Expand” strategy using the multifunctional fusion proteins to generate memory-like NK cells for cell therapy | Cancer Immunology, Immunotherapy | Springer Nature Link

About HCW Biologics:

HCW Biologics Inc. (“HCWB” or the “Company”) (NASDAQ: HCWB) is a U.S.-based commercial- and clinical-stage biopharmaceutical company focused on supporting or developing novel immunotherapies to treat autoimmune diseases, cancer, and senescence-associated dysplasia. The Company’s immunotherapeutics represent a new class of drugs that it believes have the potential to fundamentally change the treatment of proinflammatory and senescence-associated diseases and conditions that are promoted by chronic inflammation — and in doing so, improve patients’ quality of life and possibly extend longevity. Chronic inflammation, including inflammaging, is believed to be a significant contributing factor to the cause conditions that diminish healthspan, including many types of cancer, autoimmune diseases, and neurodegenerative diseases, as well as indications, such as bronchopulmonary dysplasia, that impact quality-of-life that are not life-threatening. HCW9206, the Company’s commercial asset, is a commercialization-ready compound that supports a new method of generating highly functional human CAR-T cells for treating infectious diseases and cancer. The Company’s lead product candidate for its autoimmune program is HCW9302, which is subcutaneously injectable, first-in-kind interleukin-2 (“IL-2”) fusion molecule constructed using the Company’s TOBI™ platform technology. HCW9302 is currently being evaluated in a Phase 1 clinical study in patients with alopecia areata, which initiated in November 2025 (NCT07049328). The Company has identified two preclinical lead product candidates which are currently in IND-enabling stage for internal development constructed with its proprietary TRBC drug discovery and development platform. HCW11-018b (“Big BiTE”) is a tetra-valent T-cell engager designed to address shortfalls of bi-specific T-cell engagers (“BiTE”) related to manufacturability, safety profile, and ability to treat a wide spectrum of solid tumors. HCW11-040 is a pembrolizumab-based, tetra-valent immune checkpoint inhibitor. To improve efficacy, HCW11-040 is equipped with other moieties in addition to pembrolizumab which neutralizes the immunosuppressive cytokine, TGF-β, and activates effector immune cell responses. A key aspect of the Company’s clinical development and financing strategy is to focus on its business development programs. To date, the Company has entered into two licensing agreements in which it has licensed exclusive, worldwide rights for some of its proprietary molecules. See the Company Pipeline at https://hcwbiologics.com/pipeline/

Forward Looking Statements:

Statements in this press release contain “forward-looking statements” that are subject to substantial risks and uncertainties. These statements are made under the “safe harbor” provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements contained in this press release may be identified by the use of words such as “anticipate,” “expect,” “believe,” “will,” “may,” “should,” “estimate,” “project,” “outlook,” “forecast” or other similar words and include, the ability and efficacy of HCW9206 for generating CAR-T’s for immune cell therapy with increased persistence and functionality at a lower cost; the ability of HCW9206 preclinical studies to translate into human trials to activate long-lived T-memory stem cells (“T_{scm}”) cells in patients; the ability of HCW9206 to improve long-term survival of disease- specific CAR-Ts following adoptive transfer and enable sustained suppression of malignancies, chronic infections and autoimmune diseases; the availability for a license and supply HCW9206 for commercial use for certain indications. Forward- looking statements are based on the Company’s current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. Factors that could cause actual results to differ include, but are not limited to, the risks and uncertainties that are described in the section titled “Risk Factors” in the annual report on Form 10-K filed with the United States Securities and Exchange Commission (the “SEC”) on March 28, 2025 and in other filings filed from time to time with the SEC.

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