HCW Biologics Announces Positive Results of Studies of Proprietary Compound, HCW9206 and Availability for Commercialization

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Addresses key challenges for CAR-T therapies

Potential to significantly reduce costs and improve clinical efficacy of engineered effector T cells

Data Shared at 2025 Annual Meeting of American Association of Immunologists

MIRAMAR, Fla., May 13, 2025 (GLOBE NEWSWIRE) -- HCW Biologics Inc. ("HCWB" or the "Company") (NASDAQ: HCWB), a U.S.-based clinical-stage biopharmaceutical company focused on discovering and developing innovative immunotherapies to extend healthspan by targeting the link between chronic inflammation and disease, announced today presentation of studies showing that its proprietary fusion protein, HCW9206, provides a new pathway for generating chimeric T-cell receptor - T cells (CAR-Ts) for immunotherapy with increased function. HCW9206 is a novel class of immunotherapeutic that enables a single molecule to deliver synergistic signals from three different immune-stimulatory cytokines. The activity of HCW9206 was significantly superior compared to standard methods employing anti-CD3/anti-CD28 and IL-2 reagents for CAR lentiviral transduction and subsequent expansion and persistence of human CAR-Ts. CAR-Ts represent a revolutionary technology with several CD19-specific CAR-T therapies approved by the FDA for the treatment of B-cell malignancies, and CAR-Ts continue to play an increasingly pivotal and expanding role in the treatment of cancer and has significant potential to treat autoimmune diseases and age-related diseases.

The Company's research collaborator Dr. Harris Goldstein's laboratory at the Albert Einstein College of Medicine, Bronx, New York, recently presented findings of these studies at the 2025 Annual Meeting of American Association of Immunologists (AAI 2025), Honolulu, HI. The poster presentation reported that HCW9206 is not only a better reagent than the current anti-CD3/anti-CD28/IL-2 method for CAR-T viral transduction, it also effectively expanded stem cell-like memory T cells (T_{scm}) carrying the CAR constructs. It is well established that the T_{scm} subset of T cells exhibits more in vivo persistence and targeted cell killing than other subsets of T cells, including memory T cells, following adoptive transfer into patients. In experimental humanized models in mice, adoptively transferred HCW9206-generated HIV- and CD19-specific CAR-Ts displayed more potency in suppressing HIV-1 and leukemic cells with enhanced persistence, respectively, when compared with the same CD-19-specific CAR-Ts generated with standard methods. The results of these studies represent an alternative novel strategy for CAR-T cell production with the advantage of generating a large population of CAR-Ts with a T_{scm} cell phenotype, which should enhance the persistence of CAR-Ts in patients. This strategy will likely improve long-term survival of disease-specific CAR-Ts following adoptive transfer and enable sustained suppression of malignancies, chronic infections and autoimmune diseases.

Dr. Hing C. Wong, the Founder and CEO of the Company, commented, "HCW9206 is a promising revolutionary reagent to replace anti-CD3/anti-CD28/IL-2-based approaches to streamline and lower the costs of CAR-T manufacturing. Equally important, HCW9206 can improve the functional activities and persistence of CAR-Ts following adoptive transfer, a goal that has not been achieved for the last decade. Also, it provides us with an in-road opportunity to participate in the development of the highly promising, emergent "in-vivo CAR-T manufacturing technology".

The GMP master cell bank of HCW9206 and its manufacturing process has been established, and its drug master file as an *ex vivo* reagent has also been filed with the US Food and Drug Administration. The Company is now seeking commercial partnerships for HCW9206 reagent sale and/or integration into CAR-T based manufacturing processes.

You could find more about the presentation on HCW9206 at AAI 2025, entitled, "Generation of HIV- and CD19-Specific TSCM CAR-T Cells by a Novel Cytokine-Based Scaffold," using the link below: AAI2025

About HCW Biologics:

HCW Biologics Inc. (NASDAQ: HCWB) is a clinical-stage biopharmaceutical company developing proprietary immunotherapies to treat diseases promoted by chronic inflammation, especially age-related and senescence-associated diseases. The Company's immunotherapeutics represent a new class of drug that it believes have the potential to fundamentally change the treatment of cancer and many other 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 for senescence-associated diseases and conditions that diminish healthspan, including many types of cancer, autoimmune diseases, and neurodegenerative diseases, as well as indications that impact quality-of-life that are not life-threatening. The Company's lead product candidate, HCW9302, was developed using the Company's legacy TOBI™ (Tissue factOr-Based fusIon) platform. The Company has created another drug discovery technology, the TRBC platform, which is not based on Tissue Factor. The TRBC platform has the capability to construct immunotherapeutics that not only activate and target immune responses but are also equipped with receptors that specifically target cancerous or infected cells. This platform is such a versatile scaffold that it enables the creation of multiple classes of immunotherapeutic compounds: Class I: Multi-Functional Immune Cell Stimulators; Class II: Second-Generation Immune Checkpoint Inhibitors; Class III: Multi-Specific Targeting Fusions and Enhanced Immune Cell Engagers. These novel immunotherapeutics can be used to treat a wide range of disease indications, including oncology, autoimmune diseases, and improving quality of life conditions. The Company has constructed over 50 molecules using the TRBC platform, including HCW11-002, HCW11-018 and HCW11-027. Further preclinical evaluation studies are currently being

conducted for these three molecules the Company has selected based on promising early data. The Company has two licensing programs in which it has licensed exclusive 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 efficacy of HCW9206 for generating CAR-T’s for immune cell therapy; and the ability of HCW9206 preclinical studies to translate into human trials to activate 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. 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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