



HCW Biologics Shares the Latest Data for its Second-Generation Immune Checkpoint Inhibitor Presented at the 40th Annual Meeting of the Society for Immunotherapy of Cancer

November 10, 2025

HCW11-040 is a first-in-class pembrolizumab-based, tetra-valent immune checkpoint inhibitor designated as Company's franchise immunotherapeutic for internal clinical development

MIRAMAR, Fla., Nov. 10, 2025 (GLOBE NEWSWIRE) -- HCW Biologics Inc. (the "Company" or "HCW Biologics"), (NASDAQ: HCWB), a U.S.-based clinical-stage biopharmaceutical company focused on discovering and developing novel immunotherapies to lengthen healthspan by disrupting the link between inflammation and age-related diseases, announced today the latest updated data for its tetra-valent, second-generation pembrolizumab-based Immune Checkpoint Inhibitor ("ICI") Program constructed using the Company's novel TRBC platform, presented at the 40th Annual Meeting of the Society for Immunotherapy of Cancer ("SITC2025") which took place from November 5 to 9, 2025 in National Harbor, MD.

The Company's lead product candidate in its ICI program, HCW11-040, is a novel multi-functional fusion protein molecule, constructed with a unique combination IL-15 and IL-7 domains and a Transforming Growth Factor β ("TGF- β ") trap. It demonstrates PD-1/PD-L1 blocking activity equivalent to pembrolizumab (generic form of Keytruda[®]) in preclinical studies. Results of these preclinical studies also highlight the advantages of HCW11-040 over the first generation immune checkpoint inhibitors:

- 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.
- The mouse homologue of HCW11-040 expands progenitor exhausted T (TPEX) cells significantly better than mouse ICI or pembrolizumab alone. TPEX cells are a key subset of T cells that respond to ICIs. TPEX cells have self-renewal capabilities and are considered a primary driver for the success of ICI therapies, making them an attractive target for improving treatment outcomes.
- HCW11-040 expands and activates human peripheral blood lymphocytes (PBMCs) and memory T cells significantly better than pembrolizumab alone.
- HCW11-040 exhibits significantly better anti-tumor activity of human PBMC against human pancreatic cancer and leukemia cells in organoid models than pembrolizumab alone.
- HCW11-040 leaves no evidence of inducing excessive inflammatory responses from the immune cells after subcutaneous administration.
- Subcutaneous administration expected to improve safety and quality-of-life for patients.
- Streamlined GMP manufacturing process is similar to the process used for therapeutic monoclonal antibodies.

Dr. Hing C. Wong, the Company's Founder and Chief Executive Officer, stated, "The preclinical data we shared at SITC2025 showed the details related to our discovery and selection of HCW11-040 as our franchise-building molecule for cancer and other age-related diseases. Our data shows that we verified the ability of HCW11-040 to expand and activate TPEX cells and promote anti-tumor activity of human peripheral blood mononuclear cells against human cancer cells without triggering cytokine storm side effects. Based on these encouraging results, we will vigorously advance additional IND-enabling studies for HCW11-040, including the creation of a high-expression manufacturing cell bank, manufacturing process development, and preclinical Good Laboratory Practice toxicology studies."

KEYTRUDA[®] is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc. and the company is not affiliated with HCWB.

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 drugs 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 potentially extend longevity. Chronic inflammation, including inflammaging, is believed to be a significant contributing factor to senescence-associated diseases and conditions that diminish healthspan, including many types of cancer, autoimmune diseases, and neurodegenerative diseases, as well as many 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 fuslon) 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 a versatile scaffold that 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 are being developed for treatment of 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. Further preclinical evaluation studies are currently being conducted for these molecules the Company has selected based on promising preclinical data. The Company has two licensing programs in which it has licensed exclusive rights for some of its proprietary molecules.

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 actual success and potency of pembrolizumab-based TRBC fusion molecules; the ability of pembrolizumab-based TRBC fusion molecules to be equivalent to pembrolizumab alone including the ability of HCW11-040 to expand TPEX cells more effectively and expand and activate PBMCs more effectively; whether pembrolizumab-based TRBC fusion molecules will exhibit potent anti-pancreatic cancer and anti-leukemia activities and continue to outperform pembrolizumab both *in vitro* and in humanized mouse models; or whether pembrolizumab-based TRBC fusion molecules are effective in treatment of solid tumors and pancreatic cancers. 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, the latest Form 10-Q filed with the SEC on August 18, 2025 and in other filings filed from time to time with the SEC.

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