HCW Biologics Designates One of Its Proprietary TRBC-Pembrolizumab-Based Immune Checkpoint Inhibitors as its Franchise Immunotherapeutic for Internal Clinical Development

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Lead product candidate will be advanced to late IND-enabling studies to prepare for clinical trials for evaluation in the treatment of solid tumors

Discovery of unique combination of cytokines in multi-functional fusion protein molecule that exhibits ability to expand TPEX cells without cytokine storm in preclinical studies

Definitive data from preclinical studies shared at Scientific Seminar Series held at Nova Southeastern University on September 12, 2025, in Fort Lauderdale, Florida

MIRAMAR, Fla., Sept. 16, 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 data highlights of its TRBC-based second-generation, pembrolizumab-based immunotherapeutics presented by Dr. Hing C. Wong, the Company's Founder and Chief Executive Officer, at a scientific seminar series held at Nova Southeastern University on September 12, 2025 in Fort Lauderdale, Florida. The presentation featured data on which the Company based its selection of one of its pembrolizumab-based immune checkpoint inhibitors ("ICI") derived from its proprietary TRBC drug discovery and development platform as its lead product candidate to advance as a clinical development program for the treatment of solid tumors.

Dr. Wong's presentation featured the Company's lead product candidate, known as HCW11-040, which is a multi-functional fusion protein constructed with pembrolizumab, commonly known as Keytruda® (a registered trademark of Merck Sharp & Dohme LLC), along with interleukin (IL)-7, IL-15, and TGF-β receptor components (TGF-β traps). Progenitor Exhausted T (TPEX) cells, located in the draining lymph nodes and tumors of the patients, have been implicated as the primary responders to ICI therapy. TPEX cells have self-renewal capacity and vigorously differentiate into effector T cells for providing anti-tumor effects under ICI therapy. In preclinical studies, the Company's scientists recently discovered that IL-7, IL-15, and TGF- β traps in combination can expand the TPEX cells as well as stimulate them to differentiate into anti-cancer effector T cells independent of ICI therapy. Thus, the Company believes that the components of HCW11-040 are able to achieve synergistic effects to expand the TPEX-cell reservoir and promote a larger number of them to differentiate into anti-cancer effector T cells, potentially resulting in a better cancer treatment.

In the presentation, Dr. Wong also highlighted the results of preclinical studies showing that HCW11-040 outperformed pembrolizumab monotherapy in immune-cell activation and expansion, enhancement of immune-cell infiltration into the tumors, and immune-cell cytotoxicity against cancer cells. In other preclinical models, the Company showed that HCW11-040 is not likely to overstimulate the immune system resulting in a cytokine storm when administered by subcutaneous injection using the Company's projected efficacious dose levels.

Dr. Wong stated, "The preclinical data we shared with our colleagues at Nova Southeastern University showed our discovery and selection of HCW11-040 as our franchise-building molecule as a second generation pembrolizumab – namely, preclinical data that demonstrated the ability of HCW11-040 to expand TPEX cells without triggering cytokine storm once administered. Based on this strong data, we will advance HCW11-040 into late phase IND-enabling studies, including the creation of high-expression manufacturing cell bank, chemistry manufacture control 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 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 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 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 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 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, HCW11-006, HCW11-018 and HCW11-040. 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. 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 actual success and potency of pembrolizumab-based TRBC fusion molecules; whether pembrolizumab-based TRBC fusion molecules will exhibit potent anti-pancreatic cancer 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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