HCW Biologics Inc. Announces its Lead Product Candidate Shown to Augment Anti-Tumor Activity and Reduce Side Effects of Chemotherapy Regimens

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Preclinical Data for HCW 9218 Included in Pivotal Scientific Paper Published in Molecular Therapy

MIRAMAR, Fla., Jan. 20, 2022 (GLOBE NEWSWIRE) -- HCW Biologics Inc. (the "Company") (NASDAQ: HCWB), a biopharmaceutical company focused on discovering and developing novel immunotherapies to lengthen health span by disrupting the link between chronic, low-grade inflammation and age-related diseases, today announced the publication of a scientific paper, authored by the Company's scientific research team, in the peer-reviewed journal, *Molecular Therapy*. The paper is entitled, "Immunotherapeutic HCW9218 augments anti-tumor activity of chemotherapy via NK cell mediated reduction of therapy-induced senescent cells." It highlights preclinical data from *in vivo* animal studies demonstrating the ability of the Company's lead investigational candidate, HCW9218, to both enhance the anti-tumor efficacy of chemotherapy drugs and diminish their harmful side effects by reducing therapy-induced senescence (TIS).

Cellular senescence is an essential mechanism for tumor suppression. However, an increasing body of evidence has shown that chemotherapy and radiation, standard-of-care anti-cancer regimens, cause the accumulation of senescent cells both in tumor and normal tissue. Paradoxically, cellular senescence protects non-dividing cancer cells by limiting the effect of chemotherapeutic drugs and radiation and contributes to chemoresistance, radiation resistance, disease relapse, and systemic side effects. The Company's data presented in this publication shows that HCW9218 activated immune response can significantly reduce cellular senescence induced by current chemotherapy to improve the anti-tumor efficacy and alleviate the unwanted side effects.

Dr. Hing C. Wong, the Founder and CEO of HCW Biologics, and the corresponding author of this published article, stated, "We believe our preclinical research findings are groundbreaking and among the very first studies that show our immunotherapeutic can enhance the efficacy of chemotherapy. We are also interested in the collateral damage caused by chemotherapy treatment that has such a detrimental impact on health span and quality of life for millions of cancer patients."

Dr. Wong continued, "We believe the findings reported in this paper could have broad implications in the future of chemotherapy. Multiple studies have revealed that increased cellular senescence in normal tissues can promote tumor progression, creating a link between aging and cancer. We have demonstrated with this data that targeting senescence cells with an immunotherapy could create an exciting clinical opportunity to maximize the anti-tumor efficacy of chemotherapies and minimize their negative side effects on normal tissues. In addition, we found that HCW9218 in combination chemotherapies can further augment the anti-cancer activities of therapeutic and immune-checkpoint antibodies against solid tumors. These encouraging preclinical results further support our decision to advance clinical development of HCW9218 for chemotherapy-refractory pancreatic cancer and other solid tumors."

HCW9218 is a heterodimeric, bifunctional fusion protein complex engineered using the company's proprietary TOBI™ platform technology. As detailed in the paper published today, data from *in vivo* animal studies demonstrated that HCW9218 improved the efficacy of the chemotherapy agent docetaxel against B16F10 melanoma, and anti-cancer agents gemcitabine combined with nab-paclitaxel against SW1990 pancreatic tumors by augmenting the metabolic and cytotoxic activities of immune cells and reducing TIS tumor cells that play a role in cancer recurrence, metastasis, and resistance to chemotherapy and radiation.

As demonstrated in the paper, HCW9218 treatment in animal models reduced the immunosuppressiveness of the tumor microenvironment and enhanced immune-cell infiltration and cytotoxicity in tumors to eliminate TIS cancer cells. Immunodepletion analysis suggested that natural killer (NK) cells activated by HCW9218 played a pivotal role in TIS cancer cell removal. HCW9218 treatment following docetaxel chemotherapy further enhanced the efficacy of tumor antigen-specific and anti-PD-L1 antibodies in B16F10 melanoma tumor-bearing mice. Data also demonstrated that tumor-bearing mice treated with chemotherapy and HCW9218 showed decreased TIS cells and proinflammatory senescence-associated secretory phenotype (SASP) factors in off-target tissues. SASP factors are believed to contribute to chemoresistance, disease relapse, and chemotherapy's negative side effects.

HCW Biologics received clearance in October 2021 from the U.S. Food and Drug Administration (FDA) of an Investigational New Drug (IND) application for a first-in-human Phase 1b clinical trial to evaluate HCW9218 in patients with advanced pancreatic cancer. The Company is in discussions with several leading National Cancer Institute-designated cancer centers as potential clinical trial sites. Discussions are simultaneously underway with a research facility to sponsor an IND for a second, investigator-initiated trial to evaluate HCW9218 in patients with breast, ovarian, prostate, colorectal and other solid tumors.

About the TOBI™ platform:
HCW Biologics has combined deep understanding of disease-related immunology with its expertise in advanced protein engineering to develop the TOBI™ discovery platform. The TOBI™ platform is a proprietary immunotherapeutic drug design and discovery platform. The Company has utilized this modular, tunable technology to generate a novel pipeline of immunotherapeutic candidates capable of activating and targeting desired immune responses while blocking unwanted immunosuppressive activities. The balancing of these two activities is believed to be the key to developing immunotherapeutic agents that will be safe, well tolerated and efficacious.

About HCW Biologics:
HCW Biologics is a transformative immunotherapy company that focuses on inflammaging, a state of unresolved inflammatory responses and chronic inflammation. The Company is developing novel immunotherapies designed to improve health span by disrupting the link between chronic, low-grade inflammation and age-related diseases such as cancer, cardiovascular diseases, diabetes, neurodegenerative diseases and autoimmune diseases. The Company uses its TOBI™ discovery platform to generate designer, novel multi-functional fusion molecules with immunotherapeutic properties for the treatment of inflammaging. The invention of HCW Biologics' two lead molecules, HCW9218 and HCW9302, was made via the TOBI™ discovery platform. The FDA has cleared HCW Biologics to initiate a first-in-human Phase 1b clinical trial for HCW9218 in patients with advanced pancreatic cancer. The Company is also advancing IND-enabling studies for HCW9302 for an autoimmune indication.

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, without limitation, statements regarding immunotherapeutic candidates capable of activating and targeting desired immune responses while blocking unwanted immunosuppressive activities; the balancing of certain activities believed to be the key to developing immunotherapeutic agents that are expected to be safe, well tolerated and efficacious; the development of novel immunotherapies expected to improve health span by disrupting the link between chronic, low-grade inflammation and age-related diseases, and the Company's intention to use TOBI™ technology to develop the next generation of cancer immunotherapeutics, the ability of HCW9218 to augment and enhance the anti-tumor efficacy of chemotherapy drugs and diminish their harmful side effects by reducing or eliminating TIS, the ability of HCW9218 to significantly reduce senescence, the potential clinical opportunity with chemotherapies and therapeutic and immune-checkpoint antibodies, the ability of HCW9218 to drive significant bifunctional antitumor activity and augment the metabolic and cytotoxic activities of immune cells, the ability of HCW9218 to reduce immunosuppressiveness of tumor microenvironment and enhanced immune-cell infiltration and cytotoxicity in tumors. 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 final prospectus related to the Company's initial public offering filed with the Securities and Exchange Commission on July 21, 2021. Forward-looking statements contained in this press release are made as of this date, and the Company undertakes no duty to update such information except as required under applicable law.

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