



HCW Biologics Showcases Scientific Paper in Molecular Therapy Highlighting Potential of HCW9218 as Novel, Bifunctional Cancer Immunotherapeutic

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Lead Drug Candidate Engineered Using Tissue Factor-Based Fusion (TOBI™) Platform

Preclinical Data Demonstrated HCW9218 Antitumor Activity as Single-Agent Monotherapy and as an Adjunct to Enhance Potency of Therapeutic Antibodies

Investigational New Drug Application ("IND") for Chemotherapy-Refractory Pancreatic Cancer Expected to be Filed by Year-End 2021

MIRAMAR, Fla., Aug. 24, 2021 (GLOBE NEWSWIRE) -- HCW Biologics Inc. (the "Company") (NASDAQ: HCWB), an innovative, 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*. Entitled, "Bifunctional TGF- β trap/IL-15 Protein Complex Elicits Potent NK Cell and CD8⁺ T Cell Immunity Against Solid Tumors," the paper highlights preclinical data from *in vivo* studies demonstrating the potential of the Company's lead investigational candidate, HCW9218, as a novel immunostimulant with the ability to simultaneously lessen immunosuppression in patients with cancer.

This novel immunotherapeutic, HCW9218 is a heterodimeric, bifunctional fusion protein complex comprising extracellular domains of the human transforming growth factor- β (TGF- β) receptor II, as TGF- β trap for TGF- β neutralization, and a human interleukin (IL)-15/IL-15 receptor α complex for immune-cell stimulation. HCW9218 was engineered using the TOBI™ platform technology developed internally by HCW Biologics with Company-owned technology. The unique combination of a TGF- β receptor that neutralizes a highly immunosuppressive cytokine secreted by tumors, combined with IL-15, a potent cytokine that stimulates the NK- and CD8⁺ cell cytotoxicity, creates an immunotherapeutic with the potential to drive significant bifunctional antitumor activity.

As detailed in the paper, preclinical data demonstrated that HCW9218, administered as a monotherapy, was well tolerated and showed potent anti-cancer activity in animal models of melanoma. The data showed limited side effects, with none of the bleeding episodes often associated with high doses of other antibody-based TGF- β neutralizers. HCW9218 showed an ability to promote proliferation and metabolic activity of immune cells as well as enhance the cells' cytotoxicity with tumor targets. Importantly, we presented data from mouse animal models in melanoma which demonstrated that HCW9218 slowed tumor growth and prolonged survival in mice treated with HCW9218 as a monotherapy. This antitumor activity was mediated by immune cells and correlated with increased immune cell infiltration into tumors. HCW9218 demonstrated a 10-fold stronger TGF- β 1 neutralizing activity than a molecule containing two TGF- β receptor II dimers with the Fc scaffold; a high level of potency that could be driven by the unusual property of HCW9218 to bind the latency-associated protein/TGF- β complexes.

HCW9218 was also observed to enhance the antibody dependent cell mediated toxicity of rituximab against human lymphoma cells. Antibody therapies are commonly used in cancer treatment.

"The HCW team is excited by the publication of its latest scientific paper in *Molecular Therapy*, which marks yet another important milestone for our team. This paper validates the potential clinical utilities of our lead molecule, HCW9218, created with our TOBI™ discovery platform. With this technology, we intend to develop additional next-generation cancer immunotherapeutics," stated Hing Wong, Ph.D., Founder and CEO of HCW Biologics and the paper's corresponding author. "Advances in immunostimulatory and anti-immunosuppressive treatments have revolutionized cancer treatment, but few of these therapies are able to do both. We believe we may have created such an immunotherapeutic with our bifunctional molecule, HCW9218. These encouraging preclinical results support our decision to advance clinical development of HCW9218 for chemotherapy-refractory pancreatic cancer and other solid tumors."

HCW Biologics expects to submit an Investigational New Drug (IND) application to the U.S. Food and Drug Administration for a Phase 1b/2 clinical trial to evaluate HCW9218 in chemotherapy-refractory pancreatic cancer by year-end 2021. The Company is in the final stages of IND-enabling activities.

About TOBI™:

HCW Biologics has combined deep understanding of disease-related immunology with its expertise in advanced protein engineering to develop the TOBI™ discovery platform. TOBI™ is a proprietary immunotherapeutic drug design and discovery platform. HCW 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 by disrupting the link between chronic, low-grade

inflammation and age-related diseases such as cancer, cardiovascular diseases, diabetes, neurodegenerative diseases and autoimmune diseases. HCW uses its TOBI™ discovery platform to generate designer, novel multi-functional fusion molecules with immunotherapeutic properties for the treatment of inflammation. Two of HCW Biologics lead inventions via TOBI™ include molecules HCW9218 and HCW9302, both currently undergoing IND-enabling studies.

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; and the Company’s intention to use TOBI™ technology to develop the next generation of cancer immunotherapeutics, expectations to submit an IND to the US Food and Drug Administration for a Phase 1b/2 clinical trial to evaluate HCW9218 in chemotherapy-refractory pancreatic cancer by the end of the year. 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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