

HCW Biologics is Granted Second Fundamental Patent: U.S. Patent for Multi-Chain Chimeric Polypeptide Created with TOBI™ Platform

December 7, 2022

Allowed Claims for Novel Immunotherapeutic Compound Constructed with Tissue Factor as Platform for Target Binding Domains

Patent for Underlying Intellectual Property for HCW9218 Currently in Clinical Development for Cancer

MIRAMAR, Fla., Dec. 07, 2022 (GLOBE NEWSWIRE) -- <u>HCW Biologics Inc.</u> ("HCW Biologics" or the "Company") (NASDAQ: HCWB), a clinical-stage biopharmaceutical company focused on discovering and developing novel immunotherapies to lengthen healthspan by disrupting the link between chronic, low-grade inflammation and age-related diseases, was granted U.S. Patent No. 11,518,792 on December 6, 2022, which contains composition claims for a novel multi-function fusion immunotherapeutic. With the issuance of this patent, along with the previously granted U.S. Patent No. 11,401,324 issued on August 2, 2022, the Company has secured intellectual property for use of its TOBI™ platform technology to create bi-specific and multi-specific immunotherapeutic compounds without using the traditional Fc domain of an antibody. The Company has created over thirty multi-functional immunotherapeutic compounds with its TOBI™ platform technology, four of which have been cGMP manufactured at large-scale in support of current and future clinical development programs against cancer and autoimmune indications.

This patent specifically provides intellectual property protection for the Company's lead drug candidate, HCW9218, a heterodimeric, bifunctional fusion protein complex comprising an extracellular domain of human tissue factor as a scaffold with target binding domains of TGF- β receptor II, as a TGF- β trap for TGF- β neutralization, and a human interleukin ("IL")-15/IL-15 receptor α complex for immune cell stimulation. HCW9218 is currently being evaluated in two early-stage clinical trials for the treatment of patients with chemo-refractory/chemo-resistant solid tumors, including pancreatic cancer (Clinicaltrials.gov Identifier: NCT05322408 and Clinicaltrials.gov Identifier: NCT05304936).

Hing C. Wong, Ph.D., Founder and CEO of HCW Biologics, stated, "Being granted our second fundamental patent marks an important step in the evolution of our patent portfolio for our TOBI™ platform technology, and the novel immunotherapeutic compounds we have created with it. This patent supports our commitment to treat diseases driven by chronic inflammation typical of aging and age-related diseases, including cancer."

HCW Biologics is represented by a leading global intellectual property law firm, Fish & Richardson P.C. "We are pleased that the U.S. Patent and Trademark Office recognized the novel technology of the TOBI™ platform and its lead molecule HCW9218," observed Tiffany A. Reiter, Ph.D., Principal in the Boston office of Fish & Richardson P.C. Dr. Reiter continued, "Fish & Richardson has advised HCW Biologics in developing a robust intellectual property strategy. With this patent, the Company now has U.S. patents issued for the underlying intellectual property for its lead molecules, HCW9218 and HCW9302. These patents provide vital recognition and protection for these novel immunotherapeutics."

About HCW Biologics:

HCW Biologics is a clinical-stage biopharmaceutical company focused on discovering and developing novel immunotherapies to lengthen healthspan 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 has combined deep understanding of disease-related immunology with its expertise in advanced protein engineering to develop the TOBI™ (Tissue factOr-Based fusIon) discovery platform. The Company uses its TOBI™ discovery platform to generate designer, novel multi-functional fusion molecules with immunotherapeutic properties. The invention of HCW Biologics' two lead molecules, HCW9218 and HCW9302, was made via the TOBI™ discovery platform. The Masonic Cancer Center, University of Minnesota, has initiated a Phase 1 clinical trial to evaluate HCW9218 in chemo-refractory/chemo-resistant solid tumors that have progressed after prior chemotherapies (Clinicaltrials.gov: NCT05322408). The Company is also enrolling patients in a Company-sponsored Phase 1b/2 clinical trial to evaluate HCW9218 in chemo-refractory/chemo-resistant advanced pancreatic cancer (Clinicaltrials.gov: NCT05304936). The Company's lead molecule for its regulatory T cell expansion program, HCW9302, is currently undergoing IND-enabling studies 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 the initiation and completion of our solid tumor cancer studies, and the ability to protect our intellectual property through issued patents or otherwise. 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, potential delays in clinical and pre-clinical trials and IND-enabling studies; other potential adverse impacts due to the COVID-19 pandemic, geopolitical or macroeconomic factors such as delays in regulatory review, manufacturing and supply chain interruptions, staffing shortages, and our ability to enroll patients in our ongoing and future clinical trials; the success of our current and future licensing arrangements; our reliance on third parties for the manufacture and supply of our product candidates for clinical trials; our reliance on third parties to conduct our clinical trials; difficulties protecting or enforcing our intellectual property rights; and those other risks and uncertainties that are described in the section titled "Risk Factors" in the quarterly report on Form 10-Q filed with the United States Securities and Exchange Commission (the "SEC") on November 7,

2022 and in other filings filed from time to time with the SEC. 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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