HCW Biologics Receives FDA Clearance to Proceed with Phase 1b Clinical Trial for Immunotherapeutic HCW9218 for Pancreatic Cancer

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Company cleared to proceed with first-in-human clinical trial to evaluate HCW9218, Company's lead product candidate, in refractory, advanced/metastatic pancreatic cancer

MIRAMAR, Fla., Oct. 28, 2021 (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 inflammation and age-related diseases, today announced that it has been cleared by the U.S. Food and Drug Administration (FDA) to proceed to evaluate its lead drug candidate, HCW9218, in a first-in-human Phase 1b clinical trial in patients with advanced pancreatic cancer. HCW9218 is an injectable, fusion protein complex designed to drive bifunctional, anti-tumor activity by activating desired immune responses to attack cancer cells while simultaneously blocking unwanted immunosuppressive activities.

Hing C. Wong, Ph.D., Founder and CEO of HCW Biologics, stated, "The FDA's clearance to proceed with our first-in-human trial for HCW9218 in pancreatic cancer is an important milestone for HCW Biologics and our efforts to advance the development of potentially groundbreaking immunotherapy candidates for cancer and other age-related diseases. Advances in immuno-stimulatory and anti-immunosuppressive therapeutics have revolutionized cancer treatment. We have created a bifunctional heterodimeric molecule, HCW9218, that can both stimulate the immune system and block the immunosuppressive activity of transforming growth factor-β. In preclinical studies, we showed that HCW9218 enhanced the anti-tumor efficacy of chemotherapy docetaxel and gemcitabine plus nab-paclitaxel against melanoma and pancreatic cancer, respectively, and simultaneously alleviated the off-target, unwanted effects of chemotherapies on normal tissues. In experimental animal models, HCW9218 was also shown to augment anti-tumor activities of therapeutic and checkpoint antibodies, which are currently standard-of-care anti-cancer treatment for certain solid tumors."

About Pancreatic Cancer:
Pancreatic cancer develops when anomalous cells in the pancreas grow and divide out of control to form a tumor. The American Cancer Society estimates that this year in the U.S. alone, there will be 60,430 new pancreatic cancer cases diagnosed, and 48,220 people will die from the disease, making it the third leading cause of cancer-related death behind lung and colon cancers. Most pancreatic cancer patients are diagnosed at stage IV. Because the pancreas lies deep in the abdomen, a physical examination would not detect the presence of a pancreatic tumor. Pancreatic cancer also has no early symptoms, and there are currently no effective screening tests, so the disease is often discovered after the disease has spread to other areas of the body.

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 TOBITM 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. 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 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; statements regarding the ability of HCW9218 to stimulate the immune system and block the immunosuppressive activity of transforming growth factor-β (TGF-β); and ability of HCW9218 to alleviate the off-target, unwanted effects of chemotherapies on normal tissues and augment anti-tumor activities of therapeutic and checkpoint antibodies. 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 and Quarterly Report on Form 10-Q filed with the SEC on August 13, 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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