Investigator Sponsor of HCW Biologics' Phase 1 Clinical Trial Presented Human Data Readout and Anti-Cancer Mechanism of Action of HCW9218 at 38th SITC Annual Meeting

November 8, 2023

Showed HCW9218 clinical safety and tumor response endpoints
for 15 patients with heavily pretreated advanced solid tumors

Results in ovarian cancer patients outpace other indications, with 66% stable disease

MIRAMAR, Fla., Nov. 08, 2023 (GLOBE NEWSWIRE) -- HCW Biologics Inc. (the "Company" or "HCW Biologics") (NASDAQ: HCWB), a 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 results from a preliminary human data readout from an ongoing Phase 1 clinical trial sponsored by the University of Minnesota to evaluate HCW9218, the lead drug candidate of HCW Biologics, in patients with solid tumors who failed at least two prior lines of therapy. Data from this study was presented at the 38th Annual Meeting of the Society for Immunotherapy of Cancer ("SITC") by Melissa A. Geller, M.D., M.S., Professor and Division Director of Gynecologic Oncology in the Department of Obstetrics, Gynecology and Women's Health at the University of Minnesota who serves as a Principal Investigator of this trial.

This clinical readout was based on 15 patients who were enrolled in the study as of October 16, 2023, all of whom were patients whose disease had previously progressed after multiple lines of standard-of-care therapy. The trial is now in its final expanded dose level, and the Company expects it to be completed in the fourth quarter of 2023. There has been one dose-limiting toxicity experience in this study, but it did not trigger stopping rules. Highlights of data presented at SITC include:

- HCW9218 was administered subcutaneously once every three weeks for up to six cycles at dose levels 0.25 mg/kg (DL1), 0.5 mg/kg (DL2), 0.8 mg/kg (DL3) or 1.2 mg/kg (DL4). The median number of cycles was three.

- 87% (13/15) had >4 lines of prior therapy. Tumor types included: Ovarian (n=6), Colorectal (n=4), Rectal (n=3), and Liver (n=2).

- 53% (8/15) patients treated with HCW9218 were evaluated in a post-treatment assessment, including biopsies and scanning. Tumor types included: Ovarian (n=3), Colorectal (n=3), Rectal (n= 1) and Liver (n=1).

- 50% (4/8) patients evaluated in post-treatment assessments exhibited stable disease following HCW9218 treatment. Patients showed stable disease lasting over 6 months. Clinical benefit was observed from DL2, DL3 and DL4.

- 66% (2/3) patients with ovarian cancer who underwent post-treatment assessments showed stable disease.

- Analysis of patients' pre- and post-treatment blood and tumor biopsy specimens revealed that HCW9218 induced National Killer ("NK") cell and $CD8^+$ T cell activation, proliferation, and infiltration into the tumor microenvironment which correlated with disease stabilization.

- Repeated HCW9218 administration at up to the highest planned dose level was well tolerated by patients with chemotherapy-refractory advanced solid tumors, which has provided support for the Recommended Phase 2 Dose ("RP2D") level for future Phase 2 studies of HCW9218.

- HCW9218 significantly reduced blood levels of TGF-β in cancer patients in a dose-dependent manner, without causing treatment-emergent skin lesions and bleeding events previously reported with TGF-β antagonists in clinic.

- HCW9218 strongly promotes proliferation and activation of NK and T cells in patients' blood after dosing without causing

cytokine release syndrome. No liver enzyme elevation was observed.

- HCW9218 also showed a substantial increase in blood NK cell counts three weeks after a single dosing.

- Based on the ability of HCW9218 to activate, expand and induce tumor trafficking of progenitor exhausted stem-like and transitory $CD8^+$ T cells, HCW9218 treatment presents a promising approach to enhancing the antitumor activity of immune checkpoint inhibitors in patients with solid tumors.

Dr. Hing C. Wong, Founder and CEO of HCW Biologics, stated, "We believe the findings we shared in the preliminary human data readout at SITC provide support for future Phase 2 studies of HCW9218 in combination with chemotherapy and/or immune checkpoint inhibitors against solid tumors in patients with ovarian cancer. We are pleased to see the consistency of results in humans with those that we saw in our preclinical animal studies. Together, we believe these findings verify the balanced bifunctional activities of HCW9218 in stimulating effector immune cells and reducing TGF-β-mediated responses."

Dr. Wong continued, "Our Company is very fortunate to be working with such high caliber co-principal investigators, Drs. Melissa Geller and Jeffrey Miller, and clinical site at the Masonic Cancer Center. Their work will make it possible for us to achieve our endpoints for evaluating safety and the RP2D ahead of schedule. In addition, we believe, perhaps even more importantly, their extensive correlative studies provide valuable evidence that will inform our Phase 2 clinical studies in cancer indications. With these strong results as a foundation, we believe we will be in a position to pivot to initiate our first Phase 2 clinical trial this year."

About Masonic Cancer Center:
The Masonic Cancer Center, University of Minnesota, is the Twin Cities' only Comprehensive Cancer Center, designated 'Outstanding' by the National Cancer Institute. As Minnesota's Cancer Center, they have served the entire state for more than 25 years. Their researchers, educators, and care providers have worked to discover the causes, prevention, detection, and treatment of cancer and cancer-related diseases.

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, autoimmune diseases, as well as other conditions such as long-haul COVID-19. The Company has combined a 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^{TM} 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, the expected completion date for Phase 1 clinical trial; the ability of HCW9218 to be an effective senescent-cell reducing and senomorphic drug against age-related diseases; the ability of HCW9218 to rejuvenate the immune system, activate and expand NK cells and T cells; statements regarding the ability of HCW9218 to improve the performance of standard-of-care cancer therapies and immune checkpoint inhibitors; statements regarding the ability of HCW9218 to avoid causing negative events related to TGF-β reduction; the timing of the HCW9218 Phase 2 trial; statements comparing HCW9218 to other therapies; that Phase 1 clinical trial may not have satisfactory outcome; that preclinical studies of product candidates may not be predictive of the results of future preclinical studies or trials; that the Company's third party manufacturers may encounter difficulties in production of product candidates for clinical trials; the risk that the Company is unable to file INDs to commence additional trials; the risk the Company is unable to obtain access to check point inhibitors to do a combination trial; timing and ability to identify and discover product candidates; the potential advantages of the Company's current and future product candidates; the Company's anti-inflammaging clinical development strategy and the Company's intellectual property strategy; competition and other risks described in the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's Annual Report on Form 10-K filed with the United States Securities and Exchange Commission (the "SEC") on March 28, 2023, the latest Quarterly Report on Form 10-Q filed with the SEC on August 11, 2023, and in other filings filed from time to time with the SEC. The forward-looking statements in this press release represent the Company's view as of the date of this press release and the Company does not assume any obligation to update any forward-looking statements, except as required by law.

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