HCW Biologics Participating at H.C. Wainwright 25th Annual Global Investment Conference in New York on September 11 – 13, 2023

September 6, 2023

Company will provide an update for clinical development and intellectual property programs, Including recent achievements and expected milestones in the next 12 months

MIRAMAR, Fla., Sept. 06, 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, will participate in the H.C. Wainwright 25th Annual Global Investment Conference in New York City. On September 12, 2023, the Company will be meeting individual investors in person at the conference venue, the Lotte New York Palace Hotel in New York. In addition, a pre-recorded, virtual Company update will be available on demand beginning at 7:00 a.m. EDT on September 11, 2023 for all who register for the conference.

The update on clinical development will include a Phase 1 clinical trial to evaluate HCW9218 in solid tumors, sponsored by The Masonic Cancer Center, University of Minnesota ("UMN"). UMN is now dosing patients at the highest dose level. Due to clinical protocol requirements, dosing of the remaining patients is expected to take place in the next 3 to 6 months. The trial participants include patients with refractory/chemo-resistant ovarian cancer and colorectal cancer. There has been no dose-limiting toxicity observed in this study.

The Principal Investigator of the UMN study is 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. Dr. Geller stated, "Our team is very excited to bring this clinical trial to patients who have recurrent cancer. With the ease of a subcutaneous injection, this innovative immunotherapeutic can stimulate the immune system while at the same time inhibiting proteins that cause immunosuppression. This unique combination could provide cancer patients with a novel immune-based therapy when previous treatments have failed."

"HCW9218 may define a new category of cancer treatment through modifying factors related to drug resistance and disease recurrence. In our clinical trial, we have conducted correlative studies to evaluate this potential. We look forward to presenting our findings at a major industry conference in the fall," noted Jeffrey A. Miller, M.D., Deputy Director of the Masonic Cancer Center, and Co-Principal Investigator for the UMN study.

In a second ongoing clinical study, a Company-sponsored Phase 1b/2 clinical trial to evaluate HCW9218 in advanced pancreatic cancer, the Company expects this study to be completed in the first half of 2024. There has been no dose-limiting toxicity observed in this study. This is a multi-center trial, led by the Center for Cancer Research at the National Cancer Institute ("NCI"). Dr. Christine Camp Alewine, M.D., Ph.D., is the principal investigator for the NCI clinical site. She is a Lasker Clinical Research Scholar in the Laboratory of Molecular Biology at the Center for Cancer Research at NCI and a foremost expert in pancreatic cancer research.

Dr. Hing C. Wong, Founder and CEO of HCW Biologics, stated, "The preliminary results of the initial phases for the clinical trials to evaluate HCW9218 in solid tumor cancers have been encouraging. We are on track to quickly pivot to Phase 2 clinical trials, which are likely to be in ovarian, colorectal, and pancreatic cancers in combination with chemotherapies. Our preclinical research has shown that HCW9218 enhances the anti-tumor activities of standard of care chemotherapies by potentially reducing chemotherapy-induced senescent cancer cells and alleviating the side effects of chemotherapy by eliminating the senescence-associated secretory phenotype."

Dr. Wong continued, "Recently, we also revealed the underlying mechanism of action of HCW9218 against cancer and aging. HCW9218 stimulates and expands stem-like progenitor exhausted $CD8^+$ T cells and the differentiation of exhausted transitory effector $CD8^+$ T cells, which are known as targets of immune checkpoint inhibitors. We believe this positions HCW9218 as a potential powerful immunotherapeutic to improve the potency of immune checkpoint inhibitor treatment for solid tumors."

Novel immunotherapeutics, processes, and methods invented by the Company are supported by a robust intellectual property program creating a strong backstop to protect the underlying technology comprising its clinical and strategic development programs. In the past 12 months, the Company was awarded five patents from the United States Patent and Trademark Office, the first patents granted from an extensive set of patent filings filed in the United States as well as many other jurisdictions around the world.

The Company now holds fundamental patents that protect its lead product candidates, HCW9218 and HCW9302, as well as its proprietary TOBI™ discovery platform and its novel tissue factor scaffold. In addition, the Company now holds patents that protect proprietary processes for the treatment of cancer and other age-related diseases by reducing the number of senescent cells and the pro-inflammatory factors they secrete, through treatment with its immunotherapeutic, HCW9218. Most recently, the Company was awarded two patents to protect methods for activating and expanding Natural Killer ("NK") cells and T cells ex vivo using a number of its proprietary molecules, which are U.S. Patent No. 11,730,762 and U.S. Patent No. 11,738,052.

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™ 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 1/1b clinical trials and the initiation of Phase 2 clinical trials; 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, and create systemic changes that reduce senescence and SASP factors without compromising the healthspan; statements regarding the ability of HCW9218 to improve the performance of ADCC therapies and immune checkpoint inhibitors through activation of exhausted T cells; statements regarding the potential for HCW9218 to redefine or fundamentally change the approach for treating aging conditions and age-related diseases, or constitute a new class of immunotherapeutics; that trials may not have satisfactory outcomes; 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 timing and ability of the Company to raise additional capital; the risk that costs required to develop or manufacture the Company's products will be higher than anticipated, including as a result of delays in development and manufacturing resulting from COVID-19 and other factors; 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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