HCW Biologics Announces Initiation of First-In-Human Clinical Trial to Evaluate HCW9302 in an Autoimmune Disease

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First Patient Dosed at The Ohio State University Wexner Medical Center in this Multi-Center Trial

Active component of HCW9302 is interleukin-2 -- cytokine that maintains proper numbers and functions of regulatory T cells to control excessive inflammation

Gateway to development of a first-in-kind immunotherapeutic for autoimmune and pro-inflammatory diseases

MIRAMAR, Fla., Nov. 18, 2025 (GLOBE NEWSWIRE) -- HCW Biologics Inc. ("HCWB" or the "Company") (NASDAQ: HCWB), a U.S.-based clinical-stage biopharmaceutical company focused on discovering and developing innovative immunotherapies to extend healthspan by targeting the link between chronic inflammation and disease, today announced the first patient was dosed at The Ohio State University Wexner Medical Center for the Company-sponsored, multi-center first-in-human clinical trial to evaluate HCW9302 in patients with alopecia areata (NCT07049328). This marks a major milestone in the Company's clinical development program in autoimmune diseases.

HCW9302 is the Company's lead product candidate for its clinical program to develop treatments for autoimmune diseases and inflammatory conditions. It is a subcutaneously injectable, first-in-kind interleukin-2 ("IL-2") fusion molecule constructed using the Company's legacy TOBI™ platform technology. IL-2, the active component of HCW9302, is the cytokine in humans and other vertebrates responsible for maintaining the proper numbers and functions of regulatory T ("T_{reg}") cells in the body. T_{reg} cells control excessive inflammation caused by other immune cells, which is the etiology of autoimmune diseases. The breakthrough discovery of the critical function of T_{reg} cells by Drs. Mary E. Brunkow, Fred Ramsdell and Shimon Sakaguchi was recently acknowledged with the 2025 Nobel Prize in Physiology or Medicine for their groundbreaking work which was the discovery that T_{reg} cells are the immune system's security guards which prevent immune cells from attacking our own body.

The Company believes that HCW9302 has the potential to activate and expand T_{reg} cells in patients, reducing inflammation, while minimizing the risk of broad immunosuppression or unwanted side effects caused by the activation of immune effector cells. For alopecia areata, the Company believes that HCW9302 can suppress the hair-follicle killing activities of the auto-reactive immune cells by activating and expanding T_{reg} cells. There is no curative FDA approved treatments of this indication. Alopecia areata causes sudden hair loss and can have a significant negative impact on patients' quality of life and psychological health. The National Alopecia Areata Foundation estimates approximately 160 million people worldwide and 7 million people in the United States have alopecia areata. The condition affects about 2% of the global population at some point in their lifetime.

Dr. Hing C. Wong, the Company's Founder and Chief Executive Officer, commented, "While not life-threatening, alopecia areata has no cure. For those who suffer from the burden of this disease, it can severely impact a person's quality of life and self-esteem, leading to increased rates of anxiety and depression. Existing off-label treatments may provide some relief of symptoms, but there are often dangerous side effects. HCW9302, a novel IL-2 based fusion molecule, has been demonstrated to be well tolerated in non-human primate studies, which is an important improvement compared to conventional IL-2 therapies. We are excited to be the sponsor of this clinical study to evaluate this promising new treatment for alopecia areata."

Dr. Wong continued, "The goal of this initial trial is to establish the safe recommended Phase 2 dose of HCW9302 that effectively increases T_{reg} cell activity in patients. Once we achieve this objective, we hope to rapidly expand clinical development of HCW9302 in Phase 2 studies in patients in alopecia areata as well as other autoimmune diseases and inflammatory dermatological conditions, such as vitiligo and atopic dermatitis. Additionally, we plan to explore the potential benefit that HCW9302 may have in a wide variety of inflammatory conditions, such as graft vs. host disease and neurodegenerative diseases, such as Alzheimer's Disease, where HCW9302 has been shown to have activity in relevant animal models."

The Phase 1 multi-center dose-escalation study of HCW9302is designed to treat up to 30 patients with alopecia areata. The primary objectives of the study are to evaluate the safety of HCW9302, injected under the skin (subcutaneously), and to determine the recommended dose level to advance to later phase clinical studies. Secondary objectives include assessment of disease responses and the effects of HCW9302 on proliferation and function of immune cells, particularly T_{reg} cells. Depending on the results of this study, multi-dose studies of HCW9302 in expanded cohorts of patients with alopecia areata and in patients with other inflammatory dermatological conditions are expected to be initiated.

About Alopecia Areata:

Alopecia areata ("AA") is one of the most prevalent autoimmune diseases in the world, affecting approximately 1 in 1,000 people, with a lifetime incidence of 2% worldwide, or 160 million people. According to the National Alopecia Areata Foundation, about 7 million people in the United States have alopecia areata. The condition primarily affects individuals under the age of 30, occurring at similar rates in both males and females. AA is characterized by hair loss in localized areas, the entire scalp, or, in some cases, the whole body. It occurs when the immune system mistakenly attacks hair follicles, leading to hair loss without causing permanent damage to the follicles. Patients often experience recurring episodes of hair loss throughout their lives. Existing treatments, such as corticosteroids, immunotherapy, Janus kinase inhibitors, and topical solutions, focus on managing the severity and duration of episodes of hair loss. However, these therapies primarily address symptoms rather than providing a cure or consistent,

long-term hair regrowth. Currently, there is no cure for alopecia areata.

About HCW Biologics:

HCW Biologics Inc. (NASDAQ: HCWB) is a clinical-stage biopharmaceutical company developing proprietary immunotherapies to treat diseases promoted by chronic inflammation, especially age-related and senescence-associated diseases. The Company's immunotherapeutics represent a new class of drugs that it believes have the potential to fundamentally change the treatment of cancer and many other diseases and conditions that are promoted by chronic inflammation — and in doing so, improve patients' quality of life and potentially extend longevity. Chronic inflammation, including inflammaging, is believed to be a significant contributing factor to senescence-associated diseases and conditions that diminish healthspan, including many types of cancer, autoimmune diseases, and neurodegenerative diseases, as well as many indications that impact quality-of-life that are not life-threatening. The Company's lead product candidate, HCW9302, was developed using the Company's legacy TOBI™ (Tissue factOr-Based fusIon) platform. The Company has created another drug discovery technology, the TRBC platform, which is not based on Tissue Factor. The TRBC platform has the capability to construct immunotherapeutics that not only activate and target immune responses but are also equipped with receptors that specifically target cancerous or infected cells. This platform is a versatile scaffold that enables the creation of multiple classes of immunotherapeutic compounds: Class I: Multi-Functional Immune Cell Stimulators; Class II: Second-Generation Immune Checkpoint Inhibitors; Class III: Multi-Specific Targeting Fusions and Enhanced Immune Cell Engagers. These novel immunotherapeutics are being developed for treatment of a wide range of disease indications, including oncology, autoimmune diseases, and improving quality of life conditions. The Company has constructed over 50 molecules using the TRBC platform. HCW9302 is the lead product candidate for the Company's clinical development program for autoimmune diseases and other proinflammatory conditions. The Company has dosed the first patient in a Company-sponsored, multi-center Phase 1 clinical trial to evaluate HCW9302 in an autoimmune disease (NCT07049328). The IND-enabling process is underway for three TRBC-based molecules which were selected as the lead product candidates for other clinical development programs in cancer and age-related diseases based on promising preclinical data. The Company has two licensing programs in which it has licensed exclusive rights for some of its proprietary molecules.

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, the actual success and potency HCW9302, possible delays in patient enrollment and recruitment that could prevent the timeliness of completing the study, ability of the clinical sites to recruit the number of patients needed to complete the trial, whether any of the patients participating in the trial will suffer adverse effects, events that could possibly delay or cause the Company to suspend or end the trial, the Company's plans and ability to identify a recommended Phase 2 dose, to rapidly expand clinical development of HCW9302 into Phase 2 studies for alopecia areata, vitiligo, atopic dermatitis and other autoimmune or inflammatory dermatological conditions, or whether HCW9302 is effective in the treatment of alopecia areata or other autoimmune diseases and inflammatory conditions; and the ability of the Company to expand the trial and treat additional conditions. 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 annual report on Form 10-K filed with the United States Securities and Exchange Commission (the "SEC") on March 28, 2025, the latest Form 10-Q filed with the SEC on November 14, 2025 and in other filings filed from time to time with the SEC.

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