HCW Biologics Reaches Milestones for Its Proprietary Tetravalent Second-Generation T-Cell Engager Program On Track To Initiate Clinical Trials in First Half 2027

July 23, 2026

Company requested Type B pre-IND meeting with U.S. FDA to discuss development and regulatory strategy for its investigational tetravalent T-cell engager, HCW11-018b

HCW11-018b has demonstrated potential for treating solid tumors that overexpress human tissue factor, including gynecologic and pancreatic cancers

Company has developed a streamlined, robust manufacturing process designed to produce high-quality cGMP material at a lower cost than current methods

MIRAMAR, Fla., July 23, 2026 (GLOBE NEWSWIRE) -- HCW Biologics Inc. (the “Company” or “HCW Biologics”), (NASDAQ: HCWB), a U.S.-based clinical-stage biopharmaceutical company developing transformative fusion immunotherapeutics to treat diseases promoted by chronic inflammation, focusing on autoimmune disorders and other inflammatory diseases, cancer and senescence-associated dysplasia, today announced that it has requested a Type B (pre-IND application) meeting with the U.S. FDA to discuss the development and regulatory strategy for its investigational lead product candidate, HCW11-018b, a tetravalent T-cell engager (“TCE”) constructed with the Company’s proprietary TRBC drug development platform.

HCW11-018b is intended to treat solid tumors and is administered by subcutaneous injection. In preclinical studies, it has shown the ability to target tissue factor-expressing cancer cells and activate CD3-positive effector T cells, while simultaneously reducing immunosuppression in the tumor microenvironment. Immunosuppression in the tumor microenvironment can limit effector T-cell infiltration and antitumor activity in solid tumors, particularly in gynecologic and pancreatic cancers.

TCEs have emerged as a potent therapeutic modality to treat cancer. First-generation TCEs represented a breakthrough in immunotherapy but they continue to face significant challenges, including antigen selection, limited efficacy in solid tumors, tolerability and safety concerns, and require a complex manufacturing process. Extensive preclinical studies of HCW11-018b --including assessments of *in vitro* and *in vivo* potency, antigen specificity, pharmacokinetics, toxicity in nonhuman primates, and its therapeutic window -- suggest that it may be able to overcome the limitations of earlier-generation TCEs.

Currently, the U.S. FDA and other regulatory agencies have approved eight TCEs to be used to treat 12 indications. Even with a very limited number of approved indications, approved TCEs generate multi-billion-dollar annual sales. The level of interest for this area from major pharmaceutical companies remains strong over many years, as indicated by the large number of high-value partnerships formed with innovative biotechnology companies developing second-generation TCEs. These partnerships have likely been driven by TCE’s potential in both oncology and autoimmune diseases.

Dr. Hing C. Wong, the Company’s Founder and CEO, stated, “We are pleased to have reached this important milestone in the development of HCW11-018b and look forward to discussing our proposed clinical trial designs, nonclinical testing programs, and CMC data with the FDA. HCW11-018b exhibits remarkable anti-tumor activities with high tolerability in animal models. We discovered that it can penetrate into the tumor microenvironment with potent and antigen-specific anti-pancreatic cancer activities.”

Dr. Wong continued, “We believe we have established a robust, streamlined, and cost-efficient manufacturing process capable of producing high-quality cGMP material to support HCW11-018b in clinical development and potential future commercialization. Our manufacturing process is based on high-producing recombinant CHO cell lines and a proprietary monoclonal antibody needed for the affinity purification process. The monoclonal antibody is currently being manufactured under GMP standards using a top-tier CDMO.”

About HCW11-018b:

HCW11-108b is designed to treat a wide spectrum of solid tumors with enhanced anti-tumor activities and tolerability. HCW Biologics has identified HCW11-018b as the lead candidate in its Tetravalent T-Cell Engager Program, known as the “Big BiTE.” The unique structure of the Big BiTE combines a tumor-associated tissue factor-targeting BiTE with IL-15 immune stimulation, in addition to a TGF-β trap to address immunosuppression in the tumor microenvironment. HCW11-018b was created using the Company’s proprietary TRBC drug development platform, without using the Fc fusion technology commonly found in bi-specific or tri-specific fusion molecules. In extensive preclinical studies, HCW11-018b demonstrated that it induces robust, sustained, antigen-specific tumor killing, enhances $CD8^+$ T-cell activation, survival, and effector functions and promotes tumor infiltration into solid tumors. Further, HCW11-018b demonstrated in preclinical studies that it does not trigger cytokine release syndrome, a major concern of using BiTEs, when used in its therapeutic dose range.

About HCW Biologics:

HCW Biologics Inc. (the “Company”) (NASDAQ: HCWB) is a clinical-stage biopharmaceutical company developing transformative fusion immunotherapeutics to treat diseases promoted by chronic inflammation, including autoimmune diseases, cancer, and senescence-associated dysplasia. The Company’s immunotherapeutics represent a new class of drugs that it believes have the potential to fundamentally change the

treatment of proinflammatory and senescence-associated diseases and conditions that are promoted by chronic inflammation —and in doing so, improve patients' quality of life and possibly extend longevity. A key aspect of the Company's clinical development and financing strategy is to focus on its business development programs. See the Company Pipeline at https://hcwbiologics.com/pipeline/

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 of the Company's TCE-based TRBC fusion molecules, including HCW11-018b, the ability of the Company's TCE's to target cancer antigens, CD3 activation of effector T cells, and reduce immunosuppression in the tumor microenvironment; the ability of the Company's TCEs to exhibit potent and antigen-specific anti-pancreatic cancer activities both *in vitro* and in humanized mouse models; the ability realize cost savings in the manufacture of HCW11-018b; and whether the Company's TCEs are effective in treatment of solid tumors and pancreatic cancers. 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 31, 2026, the quarterly report on Form 10-Q filed with the SEC on May 14, 2026, and in other filings filed from time to time with the SEC.

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