



HCW Biologics Maintains Momentum Toward Completion of IND Application for Clinical Study to Evaluate Lead T-Cell Engager in Solid Tumors

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Communication with FDA at recent Type B meeting provided clear guidance for next steps to prepare IND application to support first-in-human clinical study in cancer

HCW11-018b is Company's lead candidate in its second-generation T-Cell Engager Program constructed using proprietary non-Fc based TRBC platform technology

Manufacturing of cGMP material for clinical trials is underway

IND application remains on track to be filed in 1H 2027

MIRAMAR, Fla., Oct. 09, 2026 (GLOBE NEWSWIRE) -- HCW Biologics Inc. (the "Company" or "HCW Biologics") (NASDAQ: HCWB), a U.S.-based clinical-stage biopharmaceutical company focused on developing novel fusion immunotherapeutics to treat autoimmune diseases, cancer, and senescence-associated dysplasia, maintains momentum toward filing an IND application to evaluate HCW11-018b, the lead product candidate in its second-generation, non-Fc-based T-Cell Engager Program, in the treatment of solid tumors. The Company's T-Cell Engager Program is derived from its proprietary drug discovery and development TRBC platform, which features a protein-based scaffold that allows for the construction of tetravalent molecules.

T-Cell Engagers, particularly bispecific T-Cell Engagers ("BiTEs"), are promising cancer immunotherapies for hematologic malignancies. However, their success against solid tumors has been limited because the immunosuppressive tumor microenvironments and physical barriers can reduce their effectiveness and impede infiltration by cancer-fighting immune cells.

HCW11-018b incorporates the core features of a BiTE while adding components that alleviate immunosuppression and promote activation and tumor infiltration of cancer-fighting cells. The BiTE component of HCW11-018b contains an anti-CD3 single-chain antibody and an antibody domain that targets human Tissue Factor ("TF"), which is overexpressed in a wide spectrum of solid tumors. In addition, the molecule includes soluble IL-15, an IL-15 receptor α ("IL-15R α ") domain, and a TGF- β receptor II ("TGF β RII") domain trap. The result is a compound that targets TF-positive tumor cells, engages CD3 on T cells, incorporates IL-15/IL-15R α activity, and uses a soluble TGF β RII domain as a TGF- β trap to reduce immunosuppression.

Targeting TGF- β has emerged as a promising strategy in cancer therapy. Besides its direct effects on cancer cells, TGF- β pro-tumorigenic activity includes its immunosuppression effects on CD8⁺ and NK cells, induction of regulatory T cells, and hindrance of effector-cell infiltration into the tumors by modulating monocytes and macrophages in the tumor microenvironment. The Company included IL-15 because it is an attractive immune-stimulatory cytokine that supports CD8⁺ T-cell and NK cell survival, proliferation, and cytotoxic functions without inducing the activation cell death phenomenon mediated by IL-2.

Dr. Hing C. Wong, the Company's Founder and Chief Executive Officer, stated, "Tissue factor has been shown to be highly expressed by various solid tumors. Cancers that hijack the body's TF are very difficult-to-treat cancers. They use TF to avoid immune-cells that would attack them, use extracellular matrix interactions to promote the growth of cancer, increase chances for metastasis, and build resistance to standard-of-care therapies."

Dr. Wong continued, "With our non-Fc based T-Cell Engager program derived from the TRBC platform technology, we have created a second-generation T-Cell Engager, HCW11-018b. HCW11-018b has demonstrated that the addition of TGF β -trap and IL-15 components onto a BiTE domain can overcome the deficiencies of BiTE alone for solid tumor therapy. We are pleased with the clear regulatory guidance provided by the FDA at our recent Type B meeting regarding the preparation of an IND application for a first-in-human clinical study of HCW11-018b in cancer. This guidance enables us to maintain our momentum toward achieving our target to file the IND application in the 1H 2027."

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. HCW Biologics is the leader in creation of multi-valent immunotherapeutics with a unique protein-based scaffold, without the antibody Fc domain. 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, including its commercial-ready reagents to be used in the production of immunotherapeutics for cancer and infectious diseases. To date, the Company has entered into two licensing agreements in which it has licensed exclusive, worldwide rights for some of its proprietary molecules. 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 ability and efficacy of HCW11-018b for the treatment of solid tumors; the ability of HCW11-018b and its components to alleviate immunosuppression and promote activation and tumor infiltration of cancer-fighting cells; the ability of HCW11-018b to overcome the deficiencies of other BiTEs against solid tumors; the ability of the Company to timely file the IND for HCW11-018b trial by 1H 2027; and the probability of receiving a favorable result from the submission of the IND for HCW11-018b based upon FDA Type B meeting response. 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 annual report on Form 10-K filed with the United States Securities and Exchange Commission (the “SEC”) on March 31, 2026 and in other filings filed from time to time with the SEC.

Company Contact:

Peter Rhode, Ph.D.
Chief Scientific Officer and VP Clinical Affairs
HCW Biologics Inc.
PeterRhode@hcwbiologics.com

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