

# HCW Biologics' Article Published in Cancer Immunology Research Validates Novel Tissue Factor Scaffold Fusion Protein (TOBI™) Discovery Platform

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TOBI™Discovery Platform Creates GMP-Scale Heteromeric Fusion Protein Complexes (HFPCs)

That Solve Issues with Multi-Signal Receptor Engagement on Immune Cells

MIRAMAR, Fla., Aug. 17, 2021 (GLOBE NEWSWIRE) -- HCW Biologics Inc. (NASDAQ: HCWB), an innovative biopharmaceutical company, is focused on discovering and developing novel immunotherapies to lengthen health span by disrupting the link between chronic, low-grade inflammation and age-related diseases. The Company featured its internally-developed Tissue factOr-Based fusIon (TOBI<sup>TM</sup>) discovery platform in a recent research article published online in the peer-reviewed journal *Cancer Immunology Research*. Using the TOBI<sup>TM</sup> discovery platform, the Company has created novel multi-functional immunotherapeutics to rejuvenate the immune system to reduce the accumulation of senescent cells and suppress the activity of inflammasomes. These fusion immunotherapeutics are comprised of cytokines, chemokines, ligands, receptors, and single-chain antibodies carefully selected and designed to work in tandem to stimulate, inhibit, or target specific immune responses.

The key aspect of the unique TOBI<sup>TM</sup> platform is that it uses a novel tissue factor ("TF") protein scaffold. The extracellular domain of human TF was selected as it has a rigid elongated structure comprised mainly of ß-sheets with its N- and C-termini located at distal ends of the polypeptide, permitting genetic fusions of other protein domains without anticipated steric interference. This TF domain does not interact with the cell membrane phospholipid bilayer and, as a result, does not exhibit procoagulant activity. Consistent with these properties, the Company found that genetic fusion to the TF domain promoted increased production of difficult-to-express proteins, such as IL-15. Additionally, the TF fusion proteins could be readily purified by affinity chromatography using anti-TF antibodies and low pH elution conditions, like those used in Protein A-based affinity purification of therapeutic antibodies.

As a proof of concept, HCW Biologics' published scientific article describes the creation of the molecules HCW9201 and HCW9207 as well as their individual functionality which mimic a cocktail of cytokines IL-12, IL-15, and IL-18 to prime memory-like natural killer (NK) cells for cell-based cancer therapy. However, use of the IL-12/IL-15/IL-18 cocktail for generation of memory-like NK cells for adoptive therapies is limited by the lack of available, scalable GMP-grade reagents for advancing this approach beyond early-phase clinical trials. HCW9201 and HCW9207 are expected to overcome such a production problem in the large-scale GMP manufacturing process. HCW9201 is already in clinical development to replace the IL-12/IL-15/IL-18 cocktail for patients with relapsed/refractory ("R/R") acute myeloid leukemia ("AML").

"HCW Biologics has invented a unique solution for providing clinical-grade fusion proteins to replace the IL-12/IL-15/IL-18 cocktail to prime memory-like NK cells for clinical use," stated Todd A. Fehniger, M.D., Ph.D., Professor of Medicine at Washington University School of Medicine in St. Louis, and the corresponding author of the scientific article. "We discovered the approach using IL-12/IL-15/IL-18-priming to generate a superior memory-like NK cellular therapy for cancer. We are very excited that the availability of HCW9201 is expected to enable us to overcome the regulatory hurdles associated with the use of multiple individual GMP-grade cytokines to prepare memory-like NK cells. Washington University is now sponsoring two Phase 2 clinical trials to assess HCW9201 in the treatment of AML using this cell therapy-based approach." (See NCT01898793 (R/R AML) <a href="https://clinicaltrials.gov/ct2/show/NCT01898793">https://clinicaltrials.gov/ct2/show/NCT01898793</a> and NCT03068819 (combined with donor lymphocyte infusions for post-transplant relapse in AML) <a href="https://clinicaltrials.gov/ct2/show/NCT03068819">https://clinicaltrials.gov/ct2/show/NCT03068819</a>.)

Hing C. Wong, Ph.D., the Founder and Chief Executive Officer of HCW Biologics, stated, "The TOBI<sup>TM</sup> platform technology was invented and developed entirely in-house by HCW Biologics. The HCW Biologics team is extremely proud of its latest scientific paper which marks yet another important milestone for our team. This article validates what we have accomplished in the creation of a completely new approach to drug development based upon a TF scaffold. Using the power of the TOBI<sup>TM</sup> platform technology, we intend to create the next generation of cancer and anti-aging immunotherapeutics."

# About TOBI<sup>TM</sup>:

HCW Biologics has combined deep understanding of disease-related immunology with its expertise in advanced protein engineering to develop the TOBI<sup>TM</sup> discovery platform. TOBI<sup>TM</sup> is a proprietary immunotherapeutic drug design and discovery platform. This modular, tunable technology HCW has utilized to generate a novel pipeline of immunotherapeutic candidates capable of activating and targeting desired immune responses while blocking unwanted immunosuppressive activities. The balancing of these two activities is believed to be the key to developing immunotherapeutic agents that will be safe, well tolerated and efficacious.

# **About HCW Biologics:**

HCW Biologics is a transformative immunotherapy company that focuses on inflammaging, a state of unresolved inflammatory responses and chronic inflammation. The Company is developing novel immunotherapies designed to improve health by disrupting the link between chronic, low-grade inflammation and age-related diseases such as cancer, cardiovascular diseases, diabetes, neurodegenerative diseases and autoimmune diseases. HCW uses its TOBI<sup>TM</sup> discovery platform to generate designer, novel multi-functional fusion molecules with immunotherapeutic properties for the

treatment of inflammaging. Two of HCW Biologics lead inventions via TOBI<sup>TM</sup> include molecules HCW9218 and HCW9302, both currently undergoing IND-enabling studies.

#### **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, statements regarding immunotherapeutic candidates capable of activating and targeting desired immune responses while blocking unwanted immunosuppressive activities; balancing developing immunotherapeutic agents that are expected to be safe, well tolerated and efficacious; intend to create the next generation of cancer and anti-aging immunotherapeutics; expect to overcome (i) certain production problems in the large-scale GMP manufacturing process and (ii) the regulatory hurdles associated with the use of multiple individual GMP-grade cytokines to prepare memory-like NK cells. 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 final prospectus related to the Company's initial public offering filed with the Securities and Exchange Commission on July 21, 2021. Forward-looking statements contained in this press release are made as of this date, and the Company undertakes no duty to update such information except as required under applicable law.

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