HCW Biologics Discovers that HCW11-040 Prevents Bronchopulmonary Dysplasia (BPD) During IND-Enabling Studies

May 14, 2026

HCW11-040 is a pembrolizumab-based fusion immunotherapeutic that activates immune cells and eliminates high-oxygen induced senescent cells

BPD is a rare pediatric disease affecting underweight premature infants which the Company believes aligns with newly reauthorized rare pediatric disease and review voucher programs

BPD causes abnormal lung development in premature infants that leads to long-term health problems that persist into adulthood as well as neurodevelopmental delays

MIRAMAR, Fla., May 14, 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, announced today that its scientists and academic collaborators at Queen's University at Kingston, Ontario discover that HCW11-040, a second-generation, pembrolizumab-based fusion immunotherapeutic, prevents bronchopulmonary dysplasia ("BPD") during IND-Enabling studies. The Company expects to complete IND-Enabling studies in the second half of 2027 and intends to immediately file an IND application to evaluate HCW11-040 in patients at a high risk of developing BPD.

BPD in neonates causes long-term health impacts primarily related to chronic lung disease, including reduced lung function, asthma-like symptoms, and higher susceptibility to infections, which can persist into adulthood. Survivors may also face neurodevelopmental delays, impaired exercise tolerance, and in severe cases, pulmonary hypertension, necessitating specialized, multidisciplinary care. There is no known cure for BPD, and it is a high-impact unmet medical need since the premature infants who have BPD have diminished life-long healthspan. In the United States, there are 10,000 – 15,000 cases annually. It is the most common serious complication of prematurity, characterized by lung damage from ventilation and oxygen therapy. Despite advancements in care, the incidence of BPD has remained relatively stable over the last few decades.

On February 3, 2026, President Donald Trump reauthorized the Mikaela Naylon Give Kids a Chance Act and revived the rare pediatric disease ("RPD") priority review voucher program ("PRV"). The RPD program will now be funded through September 2029. The United States Food and Drug Administration grants RPD Designation for rare pediatric disorders to encourage development of treatments for diseases which are life-threatening conditions with no currently approved, specific drug treatments. The Company believes by focusing on the BPD indication, we can align with the Rare Pediatric Disease PRV program.

HCW11-040 is a novel fusion immunotherapeutic that is designed to block the checkpoint receptors and engage the costimulatory receptors, analogous to taking the foot off the brake and simultaneously hitting the gas. It is designed to activate exhausted immune cells. While conducting IND-enabling studies with collaborators at Queen's University at Kingston, Ontario, the Company discovered that a single-dose of HCW11-040 administered subcutaneously also effectively prevented the development of BPD in a clinically relevant and highly stringent animal model.

Dr. Hing C. Wong, the Company's Founder and Chief Executive Officer, stated, "We created HCW11-040 with a generic form of Keytruda®, the clear leader in immune checkpoint inhibitors. We consider our immunotherapeutic as second generation, since in our preclinical studies, it outperformed pembrolizumab as a monotherapy in immune-cell activation and expansion, enhancement of immune cell infiltration into the tumors, and immune cell cytotoxicity against cancer cells."

Dr. Wong continued, "At the outset on the road to our discovery of the potential for HCW11-040 to treat BPD, our hypothesis was that immune checkpoint inhibitors have the potential to treat diseases beyond cancer, since they have also recently been identified as effective senomorphic drugs for senescent cell removal to treat age-related or stressor-induced related diseases. We are very excited to discover that HCW11-040 could indeed be used to prevent senescence-associated dysplasia such as BPD. We will vigorously pursue the clinical development of HCW11-040 for this indication."

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc. and the company is not affiliated with HCWB.

About HCW Biologics:

HCW Biologics Inc. (the "Company") (NASDAQ: HCWB) is a clinical-stage biopharmaceutical company developing transformative fusion immunotherapeutics to support or 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. 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 actual success and potency of the Company’s second generation immune checkpoint inhibitor, TRBC fusion molecules; the ability of HCW11-040 to treat bronchopulmonary dysplasia and cancer; the ability of HCW11-040 to qualify for the RPV program; and HCW11-040’s ability to block the checkpoint receptors and engage the costimulatory receptors. 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:

Dr. Peter Rhode
Chief Scientific Officer and Vice President of Clinical Operations
HCW Biologics Inc.
PeterRhode@HCWBiologics.com