HCW Biologics Reports Third Quarter Financial Results and Recent Business Highlights

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MIRAMAR, Fla., Nov. 12, 2021 (GLOBE NEWSWIRE) -- HCW Biologics Inc. (the “Company” or “HCW Biologics”) (NASDAQ: HCWB), an innovative biopharmaceutical company focused on discovering and developing novel immunotherapies to lengthen health span by disrupting the link between chronic, low-grade inflammation and age-related diseases, today reported recent business highlights and financial results for its third quarter ended September 30, 2021.

“The third quarter of 2021 and recent weeks were an important period for HCW Biologics and our strategy to build a pipeline of first-in-class immunotherapeutic treatments for age-related diseases,” stated Hing C. Wong, Ph.D., founder and CEO of HCW Biologics Inc. “The third quarter provided bookends to what has been a busy time for the Company. In July, we closed our initial public offering and subsequently listed our common stock on Nasdaq. The Company has never been on stronger financial footing, and we believe we now have capital resources sufficient to fund our operations into 2023. During the third quarter, we filed our first IND to evaluate our lead bifunctional molecule, HCW9218, in a pancreatic cancer trial. We completed the regulatory review shortly after the end of the third quarter, and we announced FDA clearance for the Phase 1b clinical trial on October 28, 2021.”

Business Highlights:

- On July 22, 2021, HCW Biologics closed on its IPO, raising $56 million in gross proceeds. The net proceeds of the offering and the Company’s existing cash and cash equivalents are sufficient to fund operating expenses and capital expenditure requirements into 2023.

- HCW Biologics was added to S&P Total Market Index (TMI) on September 20, 2021.

- The Company expanded its Board of Directors with the addition of two new independent directors in October 2021, Lisa M. Giles and Gary M. Winer. Ms. Giles has extensive experience in pharmaceutical, diagnostic, device, and other healthcare industries. She held senior leadership positions in strategic planning, operations, and commercial planning. In addition, she brings a wealth of corporate governance experience, having served as a board member for several public companies. Mr. Winer has led and built successful, multinational businesses in the biopharma and diagnostic healthcare sectors as a Chief Executive Officer or President, including senior leadership positions with AbbVie and Abbott. He brings valuable insights and experience for operations as well as support and advice for strategic transactions.

- On October 28, 2021, HCW Biologics announced that it received clearance from the U.S. Food and Drug Administration (FDA) for an Investigational New Drug (IND) application for a Phase 1b first-in-human clinical trial to evaluate HCW9218 in patients with advanced pancreatic cancer. The Company is in discussions with several leading National Cancer Institute-designated cancer centers as potential clinical trial sites. Discussions are simultaneously underway with a research facility to sponsor an IND for a second, investigator-initiated trial to evaluate HCW9218 in patients with solid tumors (breast, ovarian, prostate, and colorectal cancers).

- HCW Biologics continues IND-enabling studies involving HCW9302, its second lead investigational drug candidate. The Company expects to complete FDA-required preclinical studies in mice by the end of 2021 and non-clinical toxicology studies in non-human primates in the second half of 2022. HCW9302 is an IL-2-based immunotherapeutic designed to stimulate regulatory T (Treg) cells to suppress the activity of inflammasome-bearing cells and inflammatory factors. HCW Biologics intends to evaluate HCW9302 in autoimmune diseases.

- The HCW Biologics’ founder and CEO, Dr. Hing C. Wong, has accepted invitations to present at two noted industry events. Dr. Wong will present at the BioFlorida Annual Conference taking place on December 8-10, 2021, in Orlando, Florida, where he will participate in the featured session, “New Strategies in the Fight Against Cancer.” Dr. Wong will also lead a presentation during the Cambridge Healthtech Institute’s 24 th Annual PepTalk taking place on January 17-19, 2022, in San Diego, California. His presentation, entitled “A Novel Platform to Create Multi-functional Immunotherapies for Cancer,” will focus on the TOBI™ discovery platform and HCW9218.

- The Company continues to expand its intellectual property portfolio through filing provisional U.S. applications based upon new research, filing non-U.S. national stage phase patent applications, and filing U.S. trademark applications. As of September 30, 2021, HCW Biologics is the owner of record of 60 pending patent applications worldwide, including 11 pending U.S. utility patent applications, two pending provisional U.S. patent applications, seven pending PCT applications, 36 pending non-U.S. national phase patent applications, and four pending Hong Kong patent applications. The Company also owns five U.S. trademark applications related to its corporate name and logo, and the TOBI™ platform.

Third Quarter Financial Results:

- Cash and cash equivalents: On September 30, 2021, the Company's cash balance was $15.1 million, short-term investments were $25.0 million and long-term investments were $10.0 million. The net proceeds from the IPO were $49.0 million. The Company estimates that it has sufficient cash to fund operations and capital expenditures into 2023. This estimated cash runway does not include potential sources of non-dilutive financing, which may be obtained from existing or new out-licensing agreements.

- Research and development (R&D) expenses: R&D expenses were $2.7 million for the three-month period ended September 30, 2021, as compared to $2.1 million for the three-month period ended September 30, 2020. Higher costs in the third quarter of 2021 were primarily the result of higher manufacturing and IND-enabling activity costs. During the nine-month period ended September 30, 2021, R&D expenses were $6.7 million versus $5.8 million during the nine-month period ended September 30, 2020. The 14% increase in expense was driven primarily by an increase in IND-enabling and preclinical activities.

- General and administrative expenses (G&A): G&A expenses were $1.4 million for the three-month period ended September 30, 2021, as compared to $0.6 million for the three-month period ended September 30, 2020. This reflects an increase in compensation expense including salaries, performance-based bonuses and board compensation, and an increase in certain operating expenses including higher insurance costs, professional fees, and legal services expenses. For the nine-month period ended September 30, 2021, G&A expenses were $3.6 million versus $2.0 million for the same period ended September 30, 2020. The 75% increase was primarily driven by an increase in expenses for salaries, performance-based bonuses, employee benefits, professional fees, and other expenses.

- Net loss: Net loss was $4.1 million for the three-months ended September 30, 2021, compared to $2.7 million for the three-months ended September 30, 2020. For the nine-months ended September 30, 2021, net loss was $9.7 million, compared to $7.9 million for the same period in the prior year.

About the TOBI™ platform:
HCW Biologics has combined deep understanding of disease-related immunology with its expertise in advanced protein engineering to develop the TOBI™ discovery platform. The TOBI™ platform is a proprietary immunotherapeutic drug design and discovery platform. The Company has utilized this modular, tunable technology 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 span by disrupting the link between chronic, low-grade inflammation and age-related diseases such as cancer, cardiovascular diseases, diabetes, neurodegenerative diseases and autoimmune diseases. The Company uses its TOBI™ discovery platform to generate designer, novel multi-functional fusion molecules with immunotherapeutic properties for the treatment of inflammaging. The invention of HCW Biologics' two lead molecules, HCW9218 and HCW9302, was made via the TOBI™ discovery platform. The FDA has cleared HCW Biologics to initiate a first-in-human Phase 1b clinical trial for HCW9218 in patients with advanced pancreatic cancer. HCW9302 is currently undergoing IND-enabling studies for an autoimmune indication.

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; the balancing of certain activities believed to be the key to developing immunotherapeutic agents that are expected to be safe, well tolerated and efficacious; the Company's intention to use TOBI™ technology to develop the next generation of cancer immunotherapeutics; expectations to submit a second IND to the FDA sponsored by a research facility in connection with an investigator-initiated trial to evaluate HCW9218 in solid tumors; sufficient capital resources through 2023; potential clinical trial sites at NCI Cancer Centers; the timing of preclinical and toxicology studies in HCW9302; and the Company's intellectual property applications which are subject to approval. 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 (the "SEC") on July 21, 2021 and in other filings filed from time to time with the SEC. 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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