HCW Biologics Reports Fourth Quarter and Full Year 2021 Financial Results and Business Highlights for 2021

March 28, 2022

$56 Million IPO Completed in July 2021 Expected to Fund Operating Expenses through 2023

FDA Clearance for Initial Clinical Trials in Two Difficult-to-Treat Cancer Indications

Publication of Three Pivotal Scientific Papers in Peer-Reviewed Journals

MIRAMAR, Fla., March 28, 2022 (GLOBE NEWSWIRE) -- HCW Biologics Inc. (the "Company" or "HCW Biologics") (NASDAQ: HCWB), a 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 fourth quarter and full year ended December 31, 2021.

Dr. Hing C. Wong, the Founder and CEO of HCW Biologics, stated, "We accomplished a number of significant achievements in the past year. We fortified our balance sheet through an initial public offering. We advanced our clinical development programs, overcoming headwinds from the COVID-19 pandemic, supply chain disruptions, and critical supply shortages. We begin 2022 poised to initiate multiple clinical trials to evaluate HCW9218 in cancer indications. We are hopeful later this year we begin to see human data that demonstrate the potential for our immunotherapeutics in the treatment of chemotherapy-resistant cancer, and validate our focus on the elimination of cellular senescence, which is the etiology for many age-related diseases."

Year in Review – Business Highlights:

In the year ended December 31, 2021, the Company achieved several milestones:

- **IPO.** On July 22, 2021, the Company closed its IPO resulting in net proceeds of approximately $49.2 million, after deducting underwriting discounts and commissions and offering expenses paid by the Company.

- **HCWB added to Total Market Index.** The Company was added to the S&P Total Market Index ("TMI") on September 20, 2021.

- **FDA clearance for Company-sponsored Phase 1b clinical trial in cancer.** On October 28, 2021, the Company announced that it was cleared by the FDA to proceed to evaluate its lead drug candidate, HCW9218, in a first-in-human Phase 1b clinical trial in patients with advanced pancreatic cancer.

- **FDA clearance for Investigator-sponsored Phase 1 clinical trial in cancer.** On January 24, 2022, the Company announced that the Masonic Cancer Center at the University of Minnesota, a National Cancer Institute designated Comprehensive Cancer Center, was cleared by the FDA to proceed to evaluate the Company's lead drug candidate, HCW9218, in a Phase 1 clinical trial in patients with advanced solid tumors with progressive disease after prior chemotherapies.

- **Two new independent board members.** The Company increased the skill set of its Board of Directors with the addition of two new board members: Lisa M. Giles and Gary M. Winer. Ms. Giles has extensive experience in pharmaceutical, diagnostic, device, and other healthcare industries. Mr. Winer has led and built successful, multinational businesses in the biopharma and diagnostic healthcare sectors as a Chief Executive Officer or President, and has held senior leadership positions with AbbVie and Abbott.

- **Dr. Hing C. Wong, Company's Founder and CEO, Weaver H. Gaines Entrepreneur of the Year.** Hing C. Wong, Ph.D., the Company's CEO and Founder, was named the 2021 Weaver H. Gaines Entrepreneur of the Year by BioFlorida. Presented annually at the BioFlorida Conference, the award recognizes an individual who has made extraordinary contributions to the growth of life sciences in the leadership of a company or institution. This marks the second time Dr. Wong was recognized for his outstanding contributions with this award.

- **Expanding IP Portfolio.** The Company continues to expand its intellectual property portfolio through filing provisional and utility U.S. applications based upon new research, filing non-U.S. national stage phase patent applications, and filing U.S. trademark applications. The Company's earlier filed applications are progressing through the prosecution phase.

- **Three publications in peer-reviewed journals.** Publications in peer-reviewed journals, which are based on inventions and discoveries made by the Company, are a pillar in the Company's strategy to establish leadership in oncology and other age-related diseases especially with the scientific and clinical communities. As of today, the Company has published three papers:

    - An article in *Cancer Immunology Research* describing its platform: Becker-Hapak MK, et al. A Fusion Protein Complex Combines IL-12, IL-15, and IL-18 Signaling to Induce Memory-like NK Cells for Cancer Immunotherapy. September 9, 2021.

    - An article in *Molecular Therapy* on the characterization of its lead molecules, HCW9218: Liu B et al., Bifunctional TGF-ß Trap/IL-15 Protein Complex Elicits Potent NK Cell and CD8 + T Cell Immunity Against Solid Tumors. October 6, 2021.

    - An article in *Molecular Therapy* which discusses HCW9218 and its ability to augment anti-tumor activity and reduce side effects of chemotherapy regimens: Chaturvedi, P et al., Immunotherapeutic HCW9218 Augments Anti-tumor Activity of Chemotherapy via NK Cell Mediated Reduction of Therapy Induced Senescent Cells, January 17, 2022.

Fourth Quarter and Year-End Financial Results:

- Cash and cash equivalents: On December 31, 2021, the Company's cash balance was $11.7 million, short-term investments were $25.0 million and long-term investments were $9.9 million. The net proceeds from the IPO were $49.2 million. The Company estimates that it has sufficient cash to fund operation expenses to the end of 2023. This estimated cash runway does not include potential sources of non-dilutive financing, which may be obtained from new or existing out-licensing agreements.

- Revenues: Revenues for the fourth quarter and year ended December 31, 2020 and 2021 were $4.1 million and none, respectively. On December 24, 2020, the Company entered an exclusive worldwide licensing agreement granting Wugen, Inc. limited rights to two of our molecules. Revenues were generated from the sale of cGMP clinical materials, R&D knowledge transfer, and an in-kind payment consisting of shares of Wugen common stock. In the year ended December 31, 2021, the Company recognized $1.8 million in deferred revenue to the extent cash was received for sales of clinical and research-grade materials to Wugen prior to the finalization of contractual terms of purchase.

- Research and development (R&D) expenses: R&D expenses for the fourth quarter ended December 31, 2020 and 2021 were $1.4 million and $1.5 million, respectively. R&D expenses for the year ended December 31, 2020 and 2021 were $7.3 million and $8.2 million, respectively. The annual increase of 13% was primarily attributable to an increase in expenses associated with IND-enabling activities, offset by a reimbursement for certain R&D expenses as provided for in the Wugen license.

- General and administrative expenses (G&A): G&A expenses for the fourth quarter ended December 31, 2020 and 2021 were $1.0 million and $1.6 million, respectively. G&A expenses for the year ended December 31, 2020 and 2021 were $2.7 million and $5.2 million, respectively. The annual increase of 93% was primarily due to an increase in costs related to operating as a public company, including legal fees for corporate work, intellectual property protection, other professional services, and insurance.

- Net income (loss): Net income for the fourth quarter ended December 31, 2020 was $2.1 million. Net loss for the fourth quarter ended December 31, 2021 was $3.2 million. Net loss for the year ended December 31, 2020 and 2021 was $5.8 million and $12.9 million, respectively.

About HCW Biologics:

HCW Biologics is a 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, 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. 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. The FDA has cleared the Masonic Cancer Center at the University of Minnesota to initiate a Phase 1 clinical trial for HCW9218 in patients with advanced solid tumors with progressive disease after prior chemotherapies. 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 immunotherapies that are able to lengthen health span by disrupting the link between chronic, low-grade inflammation and age-related diseases; sufficient capital resources through 2023; potential clinical trial sites at certain NCI-Cancer Centers; ability to initiate trials in first half of 2022; the timing of preclinical and toxicology studies in HCW9302; and the Company’s ability to secure intellectual property rights from applications. 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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