PDS Biotechnology Prioritizes Development of PDS0101 in Advanced Cancers Following Promising Phase 1 Clinical Outcome Data

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Data demonstrated regression of lesions in 60% of patients

BERKELEY HEIGHTS, N.J., Oct. 01, 2019 (GLOBE NEWSWIRE) -- PDS Biotechnology Corporation ("PDS Biotechnology") (Nasdaq: PDSB), a clinical-stage immuno-oncology company pioneering the development of multi-functional immunotherapeutic products, today announced it will prioritize clinical development of PDS0101 in advanced cancers following its recent reporting of promising PDS0101 Phase 1 clinical trial outcome data.

On September 19, 2019, PDS reported clinical outcome data from a Phase 1 clinical trial of PDS0101 in patients with cervical intraepithelial neoplasia (CIN) infected with multiple high-risk, cancer-causing types of human papillomavirus (HPV). The study demonstrated robust treatment-induced HPV16-specific killer T-cell (CD8+) responses as well as clearance of the disease and regression of lesions in 60% of patients. These *in-vivo* PDS0101-induced T-cells were demonstrated to induce granzyme-b thus confirming their cytolytic/killing potency. This clinical data supports the superior CD8+ T-cell induction and anti-tumor efficacy of the Company's Versamune® platform, as published based on the results of preceding preclinical studies in the June 2019 Issue of the ***Journal of Immunology***.

"Our intent is to continue to advance our previously announced combination studies with PDS0101 in various advanced HPV-associated cancers. These phase 2 clinical studies are partnered with top leaders in the field. We also intend to rapidly progress PDS0102 (targeting prostate and breast cancers), PDS0103 (targeting colon, lung, ovarian cancers) and PDS0104 (targeting melanoma) into human clinical trials in combination with checkpoint inhibitors. This approach has been recently supported by promising Phase 1 clinical outcome data," said Dr. Frank Bedu-Addo, CEO of PDS. "The unique ability of PDS0101 to promote *in-vivo* induction of high levels of CD8+ T-cells overcomes a significant limitation of many current immunotherapy approaches such as checkpoint inhibitors. Checkpoint inhibitors have a proven ability to induce effective anti-tumor responses in approximately 20% of patients by "releasing the brakes" of the immune system that have been activated by cancer. It has been reported that there is a strong correlation between the presence of tumor-targeting CD8+ T-cells and the efficacy of checkpoint inhibitors. We believe that the Versamune® platform, by promoting induction of these tumor-specific cytolytic CD8+ killer T cells, could be critical to substantially expanding clinical efficacy of checkpoint inhibitors into a larger percentage of the population, which could address unmet patient needs for improved treatment options across a range of advanced cancer indications."

As a result of the recent data showing strong CD8+ T-cell induction and the subsequent decision to prioritize the platform's application in combination therapies addressing advanced cancer, the Company no longer anticipates starting a Phase 2 study to evaluate PDS0101 monotherapy in CIN2/3 as previously reported.

About the Versamune® Platform Technology
Versamune® is a proprietary, synthetic lipid-based T-cell activating platform. PDS Biotechnology's pipeline of Versamune®-based products, which are administered by subcutaneous injection, provides strong activation of type I interferon genes. The Versamune® mechanism of action also involves effective presentation of tumor antigens via the MHC Class I and Class II pathways. These mechanisms together promote strong *in-vivo* induction of polyfunctional tumor-targeting CD8+ T-cells. Versamune®-based immunotherapies have been demonstrated to alter the tumor micro-environment in preclinical mechanism of action studies, thus further enhancing the ability of Versamune®-induced T-cells to effectively kill tumor cells. Preclinical data demonstrating the novel multi-functional mechanism of action of the Versamune® platform technology and the resulting superior T-cell induction and unique regression of advanced tumors were published in the Journal of Immunology (***Journal of Immunology, Vol. 202, Issue 1215 June 2019)***.

About PDS Biotechnology and PDS0101
PDS Biotechnology is a clinical stage immuno-oncology company with a growing pipeline of clinical-stage immunotherapies to treat various HPV-associated cancers, including head and neck cancer, cervical and anal cancers. PDS0101 includes the Versamune® immune-activating platform and a mixture of HPV16 E6 and E7 peptide antigens designed to induce cytolytic T-cell responses against HPV expressed in patients with HPV-associated cancers. Clinical outcome findings from the PDS0101 Phase 1 clinical study demonstrated unique *in-vivo* systemic induction of high levels of granzyme-b inducing HPV-specific killer T-cells associated with observed clinical responses (regression and elimination of pre-cancerous lesions) in the majority of evaluable patients treated with PDS0101 monotherapy, and a lack of dose limiting toxicities at all tested doses.

Versamune® is a registered trademark of PDS Biotechnology Corporation, Berkeley Heights, NJ, USA.

For additional information about PDS, please visit www.pdsbiotech.com.

Forward Looking Statements
This communication contains forward-looking statements (including within the meaning of Section 21E of the United States Securities Exchange Act of 1934, as amended, and Section 27A of the United States Securities Act of 1933, as amended) concerning PDS Biotechnology Corporation (the "Company") and other matters. These statements may discuss goals, intentions and expectations as to future plans, trends, events, results of operations or financial condition, or otherwise, based on current beliefs of the Company's management, as well as assumptions made by, and information currently available to, management. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "would," "expect," "anticipate," "plan," "likely," "believe," "estimate," "project," "intend," and other similar expressions among others. Statements that are not historical facts are forward-looking statements. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties and are not guarantees of future performance. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: the ability of the Company to integrate Edge and PDS Biotechnology following the merger; the Company's ability to protect its intellectual property rights; competitive responses to the completion of the merger; potential adverse reactions or changes to business relationships resulting from the completion of the merger; the Company's anticipated capital requirements, including the Company's anticipated cash

runway and the Company's current expectations regarding its plans for future equity financings; the timing for the Company or its partners to initiate the planned clinical trials for its lead assets, PDS0101 and PDS0102; the Company's interpretation of the results of its Phase 1 trial for PDS0101 and whether such are sufficient to support additional trials or the future success of such trials; the successful implementation of the Company's research and development programs and collaborations; the acceptance by the market of the Company's product candidates, if approved; the timing of and the Company's ability to obtain and maintain U.S. Food and Drug Administration or other regulatory authority approval of, or other action with respect to, the Company's product candidates; and other factors, including legislative, regulatory, political and economic developments not within the Company's control. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors included in the Company's annual and periodic reports filed with the SEC. The forward-looking statements are made only as of the date of this press release and, except as required by applicable law, the Company undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

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