PDS Biotechnology Completes Manufacturing of Clinical Batches of PDS0101

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Clinical batches support upcoming Phase 2 PDS101 combination trials with Merck and National Cancer Institute

PRINCETON, N.J., Oct. 22, 2019 (GLOBE NEWSWIRE) -- PDS Biotechnology Corporation (Nasdaq: PDSB), a clinical-stage immuno-oncology company pioneering development of multi-functional novel immunotherapies, today announced that it has completed manufacturing of clinical batches of PDS0101 with its partner BSP Pharmaceuticals S.p.A, a leading manufacturer of anticancer drugs.

The clinical batches of PDS0101 will be used in the Company's two upcoming Phase 2 studies, which are expected to start in the first quarter of 2020. The trials include a combination study with Merck to evaluate PDS0101 in combination with KEYTRUDA® in first-line treatment of head and neck cancer and a study to evaluate PDS0101 in combination with two novel clinical-stage immunotherapies in advanced HPV associated cancers with the National Cancer Institute.

"We are pleased to have completed the manufacturing of the clinical batches of PDS0101 with our partner BSP Pharmaceuticals and are honored to be collaborating with two leaders in the field of immuno-oncology," said Dr. Frank Bedu-Addo, CEO of PDS. "Based on our recently announced Phase 1 clinical outcome data which demonstrated PDS0101's unique ability to promote the *in-vivo* induction of high levels of HPV-specific CD8+ killer T-cells as well as the regression of pre-cancerous lesions in 60% of patients, we believe that PDS0101 could expand the clinical efficacy of checkpoint inhibitors such as KEYTRUDA®. We are now working diligently to qualify clinical sites for our combination trial with KEYTRUDA® in first line treatment of head and neck cancer and look forward to initiating both our planned combination trials by the first quarter of 2020."

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 HPV16-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 HPV16 expressed in patients with HPV16-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, Princeton, 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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