PDS Biotechnology Corp. Announces Clinical Collaboration with Merck

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PDS0101- KEYTRUDA® (pembrolizumab) Combination to be Evaluated in First Line Treatment of Metastatic Head and Neck Cancer

BERKELEY HEIGHTS, N.J., Oct. 03, 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 a modification of the clinical trial collaboration agreement with a subsidiary of Merck (known as MSD outside the United States and Canada) to evaluate the combination of PDS's lead Versamune®-based immunotherapy, PDS0101, with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in a Phase II clinical trial. The planned clinical trial will now evaluate the efficacy and safety of the combination as a first-line treatment in patients with recurrent or metastatic head and neck cancer and high-risk human papillomavirus-16 (HPV16) infection and is expected to be initiated in the first quarter of 2020.

The modification to the clinical trial design now allowing evaluation of PDS0101 in combination with KEYTRUDA® as first-line treatment comes as a result of Merck's recent approval by the FDA on June 10, 2019 for KEYTRUDA® as monotherapy in patients whose tumors express PD-L1 (CPS ≥1) or in combination with platinum and fluorouracil (FU) for the first-line treatment of patients with metastatic or with unresectable, recurrent head and neck squamous cell carcinoma.

"We are honored to collaborate with Merck, a proven leader in the field of immuno-oncology to evaluate novel investigational combination therapies that have the potential to further improve the lives of cancer patients," said Dr. Lauren V. Wood, Chief Medical Officer of PDS." The recently updated clinical outcome findings of the PDS0101 phase 1 human clinical trial demonstrate unique *in-vivo* systemic induction of high levels of granzyme-b inducing HPV-specific killer T-cells associated with observed clinical responses (regression/ 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 (***PDS press release September 19, 2019***). 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 June 2019 issue of the **Journal of Immunology**.

PDS Biotechnology's lead product candidate, PDS0101 (Versamune®-HPV) is a proprietary clinical stage immunotherapeutic administered by subcutaneous injection being developed to treat HPV-associated cancers. These include cancers such as head and neck cancers and anal cancers, both of which are widely reported to be increasing in frequency over the last decade, and cervical cancer.

Details of the collaboration were not disclosed.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

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

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.

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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