



PDS Biotechnology Announces Principal Investigator and Independent Data Monitoring Committee for its Phase 2 Clinical Collaboration with Merck

December 11, 2019

Study evaluating PDS0101-KEYTRUDA® (pembrolizumab) Combination in First Line Treatment of Metastatic Head and Neck Cancer expected to be initiated in Q1 2020

PRINCETON, N.J., Dec. 11, 2019 (GLOBE NEWSWIRE) -- PDS Biotechnology Corporation (Nasdaq: PDSB), a clinical-stage immuno-oncology company developing multiple therapies based on the Company's proprietary Versamune® T-cell activating technology, today announced that Dr. Jared Weiss, an internationally recognized expert in the field of thoracic and head and neck cancers and Faculty at the University of North Carolina at Chapel Hill School of Medicine and Lineberger Comprehensive Cancer Center, will be the Principal Investigator for the Company's Phase 2 VERSATILE-002 study in collaboration with Merck. In addition, the Company has established an independent Data Monitoring Committee (DMC) that will be responsible for reviewing and evaluating patient safety and efficacy data in the upcoming Phase 2 study.

Dr. Jared Weiss serves as the Section Chief of Thoracic and Head and Neck Oncology and has served as principal investigator on numerous industrial and investigator initiated immunotherapy clinical trials. He is the Vice President of Cancergrace.org, a global resource with the goal of increasing patient education and family information on cancer and is an advocate and board member of the Lung Cancer Initiative of North Carolina. Dr. Weiss holds a Doctor of Medicine from Yale University School of Medicine and a B.S. in neuroscience from Brown University. Dr. Weiss completed his residency in internal medicine at Beth Israel Deaconess Medical Center; and his medical oncology fellowship at the Hospital of the University of Pennsylvania.

The combination study will evaluate the efficacy and safety of PDS Biotech's lead Versamune®-based immunotherapy, PDS0101, in combination with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) in the first-line treatment of patients with recurrent or metastatic human papillomavirus-16 (HPV16) positive head and neck cancer. The study is expected to be initiated in the next three to four months.

"I look forward to working with PDS Biotech in collaboration with Merck on this Phase 2 study to evaluate the novel combination of PDS0101 and KEYTRUDA®," commented Dr. Jared Weiss. "PDS0101's unique ability to promote the *in-vivo* induction of high levels of HVP16-specific CD8+ killer T-cells could hold the potential to overcome a significant limitation of checkpoint inhibitors and potentially play a critical role in expanding their clinical efficacy to a broader population of patients."

PDS Biotech's Data Monitoring Committee (DMC) is comprised of an independent group of clinical and scientific leaders in the field of immuno-oncology and will be responsible for reviewing and evaluating patient safety and efficacy data for the Company's Phase 2 VERSATILE-002 study. The committee will be chaired by Dr. A. Dimitrios Colevas, Professor of Medicine - Head and Neck Surgery at the Stanford University Medical Center. The committee will be comprised of the following members:

Name	Specialty	Organizational Affiliation
A Dimitrios Colevas, MD	Medical Oncologist	Stanford Cancer Center
Lori Julin Wirth, MD	Medical Oncologist	Massachusetts General Hospital
Vlad Sandulache, MD, PhD	Surgical Oncologist	Baylor College of Medicine
Lee-Jen Wei, PhD	Biostatistician	Harvard University
Edward (Ted) Spack, PhD	Immunologist	MedaRed, Inc.

About PDS Biotechnology

PDS Biotechnology is a clinical-stage immuno-oncology company developing multiple therapies based on the Company's proprietary Versamune® T-cell activating technology platform. The Versamune® platform effectively delivers tumor-specific antigens for in-vivo uptake and processing, while also activating a critical immunological pathway, the type 1 interferon pathway, thus resulting in the production of potent tumor-specific killer T-cells. Using Versamune®, PDS Biotechnology is engineering therapies designed to better recognize cancer cells and break down their defense systems to effectively attack and destroy tumors. PDS Biotechnology's pipeline combines the Versamune® technology with tumor-specific antigens across several cancer types. To learn more, please visit www.pdsbiotech.com or follow us on Twitter at [@PDSBiotech](https://twitter.com/PDSBiotech).

About PDS0101

PDS Biotechnology's lead candidate, PDS0101, combines the utility of the Versamune® platform with targeted antigens in HPV-expressing cancers. In partnership with Merck and the National Cancer Institute (NCI), PDS Biotechnology is advancing PD0101 to Phase 2 studies in head and neck cancer and in HPV-related advanced cancer.

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 results 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, including any collaboration studies concerning PDS0101 and the Company's interpretation of the results and findings of such programs and collaborations and whether such results are sufficient to support the future success of the Company's product candidates; 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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Source: PDS Biotechnology Corporation