PDS Biotech Announces Release of Abstract for PDS0101 in NCI-Led Phase 2 Clinical Study for Oral Presentation at 2021 ASCO Meeting

Objective responses (tumor reduction) observed in 83% (5 of 6) of HPV16-positive relapsed or refractory checkpoint inhibitor naïve patients and 63% (5 of 8) of HPV16-positive relapsed or refractory advanced cancer patients who have also failed checkpoint inhibitor therapy

Florham Park, NJ, May 20, 2021 - PDS Biotechnology Corporation (Nasdaq: PDSB), a clinical-stage immunotherapy company developing novel cancer therapies based on the Company’s proprietary Versamune® T-cell activating technology, today announced publication of abstract #2501 by the American Society of Clinical Oncology (ASCO). The abstract summarizing interim data from the National Cancer Institute (NCI)-led phase 2 trial has been accepted for oral presentation at the 2021 ASCO Annual Meeting taking place June 4-8. The presentation, scheduled for June 7, is expected to include results from a larger sample than the 14 patients included in the abstract.

Additional data highlights from abstract #2501 include:

- An overall objective response rate of 71% (10/14) in patients with refractory HPV16-associated cancers
  - 1 complete response (anal cancer)
  - 9 partial responses (3 cervical cancer, 2 vulvar/vaginal cancer, 2 anal cancer, 2 oropharyngeal cancer)
- 90% of these of these responses are ongoing after a median 5 months of follow up (9/10)

The NCI Center for Cancer Research’s Laboratory of Tumor Immunology and Biology (LTIB) and Genitourinary Malignancies Branch (GMB) are jointly leading this Phase 2 trial (NCT04287868), which studies PDS0101 in combination with two investigational immune-modulating agents: bintrafusp alfa (M7824), a bifunctional “trap” fusion protein targeting TGF-β and PD-L1, and NHS-IL12 (M9241), a tumor-targeting immunocytokine. Bintrafusp alfa is being jointly developed by Merck KGaA, Darmstadt, Germany, and GlaxoSmithKline; NHS-IL12 is being developed by Merck KGaA, Darmstadt, Germany.

The trial is evaluating the treatment combination in both checkpoint inhibitor naïve and refractory patients with advanced human papillomavirus (HPV)-associated cancers that have progressed or returned after treatment. Objective response is measured by radiographic tumor responses according to RECIST 1.1. These reported data validate the preclinical studies published by the NCI demonstrating that the complementary mechanisms of action of the three immunotherapies which involve potent in-vivo HPV16-specific killer and helper T-cell induction with effective T-cell tumor infiltration, blocking of immune checkpoints as well as targeting of TGF-β resulted in superior tumor regression.

“The achievement of a 71% objective response rate in a difficult to treat patient population continues to strengthen the evidence of our novel Versamune® platform’s potential ability to induce high levels of tumor-specific CD8+ killer T-cells that attack the cancer resulting in strong synergy with Bintrafusp alfa and NHS-IL12, thus leading to effective tumor regression,” commented Dr. Lauren Wood, Chief Medical Officer of PDS Biotech. “The initial data solidifies our belief that PDS0101’s published preclinical efficacy,
when combined with these two immune-modulating agents, demonstrates the potential to significantly improve clinical outcomes for patients with advanced, refractory HPV-associated cancers who have limited treatment options.”

There are more than 630,000 cases of HPV-associated malignancies including cervical, oropharyngeal and anal cancer worldwide annually. HPV 16 is responsible for most of these cases. About 15-20% of HPV-associated malignancies respond to PD-(L)1 inhibitors. However, for the overwhelming majority of patients who progress on these immunotherapies there is no effective standard of care therapy.

The abstract is now available online on the ASCO conference website: https://am.asco.org/.

Abstract Number: 2501
Abstract Title: Phase II evaluation of the triple combination of PDS0101, M9241, and bintrafusp alfa in patients with HPV 16 positive malignancies.

Presenting Author: Julius Strauss, MD, National Cancer Institute
Session: Developmental Therapeutics—Immunotherapy
Date: June 7, 2021
Time: 3:00 PM-6:00 PM EDT

Dr. Julius Strauss, Staff Clinician, LTIB, is serving as the Principal Investigator of this phase 2 clinical trial in advanced HPV-associated cancers. For patients interested in enrolling in this clinical study, please call NCI’s toll-free number 1-800-4-Cancer (1-800-422-6237) (TTY: 1-800-332-8615), email NCIMO_Referrals@mail.nih.gov, and/or visit the website: https://trials.cancer.gov.

About PDS Biotechnology

PDS Biotech is a clinical-stage immunotherapy company developing a growing pipeline of cancer immunotherapies and infectious disease vaccines based on the Company’s proprietary Versamune® T-cell activating technology platform. Our Versamune®-based products overcome the limitations of current immunotherapy by inducing in vivo, large quantities of high-quality, highly potent polyfunctional tumor specific CD4+ helper and CD8+ killer T-cells. PDS Biotech has developed multiple therapies, based on combinations of Versamune® and disease-specific antigens, designed to train the immune system to better recognize diseased cells and effectively attack and destroy them. Our immuno-oncology product candidates are initially being studied in combination therapy to potentially enhance efficacy without compounding toxicity across a range of cancer types. The company’s lead investigational cancer immunotherapy product PDS0101 is currently in Phase 2 clinical studies in HPV-associated cancers. To learn more, please visit www.pdsbiotech.com or follow us on Twitter at @PDSBiotech.

About PDS0101

PDS Biotech’s lead candidate, PDS0101, combines the utility of the Versamune® platform with targeted antigens in HPV-expressing cancers. In partnership with Merck and Co., PDS Biotech is evaluating a combination of PDS0101 and KEYTRUDA® in a Phase 2 study in first-line treatment of recurrent or metastatic head and neck cancer. PDS Biotech is also conducting two additional Phase 2 studies in advanced HPV-associated cancers and advanced localized cervical cancer with the National Cancer Institute (NCI) and The University of Texas MD Anderson Cancer Center, respectively.
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,” “forecast,” “guidance”, “outlook” and other similar expressions among others. 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 Company’s ability to protect its intellectual property rights; 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 Company’s dependence on additional financing to fund its operations and complete the development and commercialization of its product candidates, and the risks that raising such additional capital may restrict the Company’s operations or require the Company to relinquish rights to the Company’s technologies or product candidates; the Company’s limited operating history in the Company’s current line of business, which makes it difficult to evaluate the Company’s prospects, the Company’s business plan or the likelihood of the Company’s successful implementation of such business plan; the timing for the Company or its partners to initiate the planned clinical trials for PDS0101, PDS0203 and other Versamune® based products; 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, PDS0203 and other Versamune® based products 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, including unforeseen circumstances or other disruptions to normal business operations arising from or related to COVID-19. 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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*Updated data and results to be presented in June at the ASCO meeting


2S. Gandhapudi et al, J. Immunology, 2019 (202), 1215