

Reach: For immediate release

NetScientific plc

("NetScientific" or the "Company")

PDS Biotechnology Announces Achievement of Efficacy Threshold in Stage 2 of the VERSATILE-002 Trial Evaluating PDS0101 and KEYTRUDA® in Head and Neck Cancer

14 patients in the immune checkpoint inhibitor naïve arm of VERSATILE-002 have experienced either a complete response or partial response on two consecutive scans, thus constituting a confirmed objective response

Efficacy and safety continue to be monitored as additional patients have yet to undergo imaging evaluation

NetScientific Plc (AIM: NSCI), the investment and commercialisation group with an international portfolio of innovative life science, sustainability and technology companies, reports that its portfolio company, PDS Biotechnology Corporation (Nasdaq: PDSB), a clinical-stage immunotherapy company developing a growing pipeline of targeted immunotherapies for cancer and infectious disease, has today announced the achievement of an important efficacy threshold.

PDS Biotechnology has achieved the threshold for efficacy as per investigator assessment in Stage 2 of the VERSATILE-002 ([NCT04260126](#)) Phase 2 clinical trial investigating PDS0101 in combination with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), for the treatment of unresectable, recurrent or metastatic human papillomavirus (HPV)16-positive head and neck cancer. [The achievement of full recruitment of 54 patients in the ICI naïve arm was announced in May 2023.](#) The threshold for efficacy, as defined in the clinical protocol, was achieved when 14 out of the 54 immune checkpoint inhibitor (ICI) naïve patients enrolled achieved a confirmed objective response. Additional patients in the trial have yet to undergo imaging evaluation.

Per RECIST 1.1, the standard to classify oncologic imaging outcomes in clinical trials, patients are considered to have achieved an objective response when imaging studies document tumor shrinkage of 30% or more. In VERSATILE-002, the primary endpoint requires two consecutive scans 9 to 12 weeks apart, rather than one, to be considered a confirmed objective response. Confirmation with two consecutive scans is not required to achieve an objective response in every clinical trial per RECIST 1.1.

At the recent [2023 American Society of Clinical Oncology \(ASCO\) Annual Meeting](#) PDS Biotechnology presented data showing 9 confirmed responses among 34 evaluable patients. Median progression-free survival (PFS) of 10.4 months was also presented at the 2023 ASCO Annual Meeting along with a 12-month overall survival (OS) rate of 87.1% for patients with a CPS \geq 1. Additional patients have been assessed since data was presented at the 2023 ASCO Annual Meeting. With these additional data, a total of 14 patients have now achieved a confirmed response to date. The achievement of this endpoint suggests an additive effect of PDS0101 over published results with ICI monotherapy and is based on statistical calculations using the appropriate power and alpha.

The primary endpoint in the VERSATILE-002 study is the best overall response (BOR) of confirmed complete response (CR) or confirmed partial response (PR) per RECIST 1.1. The key secondary endpoints are progression-free survival (PFS), OS at 12 and 24 months, safety, and tolerability. The study utilizes a Simon's 2-stage optimum design.

Dr. Frank Bedu-Addo, President and Chief Executive Officer of PDS Biotechnology said:

"We are highly encouraged by the growing set of PDS0101 efficacy and safety data being generated in multiple independent trials by leading experts in the field. The consistency in PDS0101 induced HPV16-specific immune responses, the response rates and [survival benefit](#) observed [in multiple types of HPV cancer](#) and at [different stages](#) of disease, aligns with both the preclinical and Phase 1 monotherapy results. Multiple studies have demonstrated the induction of high levels of active and potent, HPV16-specific CD4 and CD8 T cells, as well as long-lasting memory CD8 T cells by PDS0101."

Lauren V. Wood, M.D., PDS Biotechnology's Chief Medical Officer said:

"Achieving the efficacy threshold in VERSATILE-002 is an important milestone for us, especially as it has been achieved ahead of the full efficacy evaluation for this cohort. With our Phase 2 trial near completion, and our planned global Phase 3 confirmatory randomized, controlled trial, VERSATILE-003, actively advancing, we believe we are closer to our goal of providing a well-tolerated, safe and effective therapy for those who suffer from head and neck cancer, a critical unmet medical need."

Dr. Ilian Iliev, CEO of NetScientific, added:

"Congratulations to Frank and his team for reaching this important milestone as they continue their important work in the battle against head and neck cancer."

PDS Biotech plans to initiate the VERSATILE-003 as a result of the successful completion of an End-of-Phase 2 meeting in the third quarter of 2022 with the FDA, during which PDS Biotech received guidance on key elements of the Phase 3 program that will support the submission of a Biologics License Application (BLA). The planned primary endpoints for VERSATILE-003 are OS and PFS. In preparation for the VERSATILE-003 trial, PDS Biotech plans to submit an amended Investigational New Drug (IND) application to the FDA in the third quarter of 2023.

A full version of PDS Biotech's announcement can be accessed here:

<https://www.pdsbiotech.com/index.php/investors/news-center/press-releases/press-releases1/125-2023-news/840->

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About NetScientific

NetScientific plc (AIM: NSCI) is an investment and commercialisation group with an international portfolio of innovative life science, sustainability and technology companies.

NetScientific identifies, invests in, and builds high growth companies in the UK and internationally. The company adds value through the proactive management of its portfolio, progressing to key value inflection points, and delivering investment returns through partial or full liquidity events.

NetScientific differentiates itself by employing a capital-light investment approach, making judicious use of its balance sheet and syndicating investments through its wholly owned VC subsidiary, EMV Capital. The group secures a mixture of direct equity stakes and carried interest stakes in its portfolio of companies, creating a lean structure that can support a large portfolio.

NetScientific is headquartered in London, United Kingdom, and is admitted to trading on AIM, a market operated by the London Stock Exchange.

www.netscientific.net

About PDS Biotechnology

PDS Biotech is a clinical-stage immunotherapy company developing a growing pipeline of targeted cancer and infectious disease immunotherapies based on our proprietary Versamune[®], Versamune[®] plus PDS0301, and Infectimune[™] T cell-activating platforms. We believe our targeted immunotherapies have the potential to overcome the limitations of current immunotherapy approaches through the activation of the right type, quantity and potency of T cells. To date, our lead Versamune[®] clinical candidate, PDS0101, has demonstrated the ability to reduce and shrink tumours and stabilize disease in combination with approved and investigational therapeutics in patients with a broad range of HPV16-associated cancers in multiple Phase 2 clinical trials and will be advancing into a Phase 3 clinical trial in combination with KEYTRUDA[®] for the treatment of recurrent/metastatic HPV16-positive head and neck cancer in 2023. Our Infectimune[™] based vaccines have also demonstrated the potential to induce not only robust and durable neutralizing antibody responses, but also powerful T cell responses, including long-lasting memory T cell responses in pre-clinical studies to date. To learn more, please visit www.pdsbiotech.com or follow us on Twitter at @PDSBiotech.

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