Biodesix Announces Publication Highlighting Interim Data from the INSIGHT Study Assessing the Clinical Effectiveness of VeriStrat® Proteomic Test in the Journal of Immunotherapy of Cancer

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Data published shows the VeriStrat proteomic test improved overall patient survival by better informing physicians on the selection of immunotherapies to optimally treat NSCLC patients

BOULDER, Colo.--(BUSINESS WIRE)--Nov. 18, 2021-- Biodesix, Inc. (Nasdaq: BDSX), a leading data-driven diagnostic solutions company with a focus in lung disease, announced new interim data published from the large multi-center observational registry study INSIGHT (Clinical Effectiveness Assessment of VeriStrat® Testing and Validation of Immunotherapy Tests in NSCLC Subjects) (NCT03289780) utilizing its novel predictive and prognostic blood-based host immune classifier (the VeriStrat test) to stratify Immune checkpoint inhibition (ICI) treatment response in patients with advanced non-small cell lung cancer(NSCLC). The study, titled "Real-world performance of blood-based proteomic profiling in first-line immunotherapy treatment in advanced stage non-small cell lung cancer," was published in the *Journal of Immunotherapy of Cancer* (JITC) and can be viewed here.

Results from the prespecified INSIGHT interim analysis of approximately 2,000 patients with at least one year of follow up showed that patients classified by VeriStrat as host immune classifier hot (HIC-Hot) had better outcomes, on average living 2-3 times longer when compared to patients classified by VeriStrat as HIC-Cold. A classification of HIC-H, also known as VeriStrat Good, implies that the normal tumor-directed immunity is active and patients are potentially responsive to therapies that boost immune response. HIC "cold" classification, also known as VeriStrat Poor, correlates to what experts refer to as an "immune desert," where tumor-directed immunity is compromised. Results additionally suggest that HIC-C (Veristrat Poor) patients should not be treated with single-agent ICI therapy regardless of their PD-L1 expressions.

"Inflammatory biomarker-driven treatment selection of immunotherapy in lung cancer may further improve upon the already astounding results noted with immunotherapy," said Wallace Akerley, M.D., of Huntsman Cancer Institute. "Further, observational studies, like INSIGHT, offer physicians valuable information gleaned from the broader population when determining optimal treatment approaches for their patients with NSCLC."

ICI either single agent or in combination with chemotherapy has helped advance the management and long-term survival of those living with advanced NSCLC. However, it's not easy to know which patients will experience a favorable response to the various standard of care therapies. There are complex interactions between cancer and the patient's immune system and this data suggests that using an HIC test alongside PD-L1 results and other clinical factors may help inform treatment response and improve outcomes.

"Biodesix is committed to supporting the lung cancer community by discovering, developing and commercializing proteomic tests while conducting supportive studies that aim to strategically inform patient treatment for better outcomes," said Scott Hutton, CEO of Biodesix. "This new INSIGHT Study data demonstrate how our host immune classifier test, VeriStrat, provides valuable information that can help healthcare professionals make informed decisions when evaluating immunotherapy against the increasingly complex treatment landscape for their patients with NSCLC."

About Biodesix

Biodesix is a leading data-driven diagnostic solutions company with a focus in lung disease. The Company develops diagnostic tests addressing important clinical questions by combining multi-omics through the power of artificial intelligence. Biodesix is the first company to offer eight non-invasive tests for patients with lung diseases. The blood based Nodify Lung® nodule risk assessment testing strategy, consisting of the Nodify XL2® and the Nodify CDT® tests, evaluates the risk of malignancy in incidental pulmonary nodules, enabling physicians to better triage patients to the most appropriate course of action. The blood based IQlung™ strategy for lung cancer patients integrates the GeneStrat® targeted test, the GeneStrat NGS ™ test and the VeriStrat® test to support treatment decisions across all stages of lung cancer with results in 36-72 hours, expediting time to treatment. Biodesix also leverages the proprietary and advanced Diagnostic Cortex® AI (Artificial Intelligence) platform, to collaborate with many of the world's leading biotechnology and pharmaceutical companies to solve complex diagnostic challenges in lung disease. Biodesix launched the SARS-CoV-2 ddPCR™ test, the Platelia SARS-CoV-2 Total Ab, and the cPass ™ SARS-CoV-2 Neutralization Antibody test (cPass™ Neutralizatio Test Kit, GenScript, Inc,) in response to the global pandemic and virus that impacts the lung and causes COVID-19. For more information about Biodesix, visit biodesix.com.

Note Regarding Forward-Looking Statements

This press release may contain forward-looking statements that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements contained in this press release other than statements of historical fact, are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "plan," "expect," "predict," "potential," "opportunity," "goals," or "should," and similar expressions are intended to identify forward-looking statements. Such statements are based on management's current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors. Biodesix has based these forward-looking statements largely on its current expectations and projections about future events and trends. These forward-looking statements are subject to a number of risks, uncertainties, and assumptions. Forward-looking statements may include information concerning the impact of the COVID-19 pandemic on Biodesix and its operations, it is possible or assumed future results of operations, including descriptions of its revenues, profitability, outlook, and overall business strategy. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. Factors that could cause actual results to differ materially from those contemplated in this press release can be found in the Risk Factors section of Biodesix's most recent annual report on Form 10-K, filed March 16, 2021, or subsequent quarterly reports on Form 10-Q during 2021, if applicable. Biodesix undertakes no obligation to revise or publicly release the results of any revision to such forward-looking statements, except as required by law. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. All forward-looking statements are qualified in their entirety by this cautionary statement.

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