Biodesix Presents New Data from the INSIGHT Study at the 2022 Society for Immunotherapy of Cancer (SITC) 37th Annual Meeting

November 10, 2022

Data confirms the ability of the VeriStrat® test to predict outcomes in patients with Non-small Cell Lung Cancer treated with immunotherapy regimens

BOULDER, Colo.--(BUSINESS WIRE)--Nov. 10, 2022-- Biodesix, Inc. (Nasdaq: BDSX), a leading data-driven diagnostic solutions company with a focus in lung disease, announced today that Wallace Akerley, MD, medical oncologist at the University of Utah Huntsman Cancer Institute, will present new interim data from the large multi-center prospective observational registry study INSIGHT (Clinical Effectiveness Assessment of VeriStrat® Testing and Validation of Immunotherapy Tests in NSCLC Subjects) (NCT03289780) at the Society for Immunotherapy of Cancer (SITC) 37th Annual Meeting. The data highlights the ability of the VeriStrat® test, a novel predictive and prognostic blood-based host immune classifier, to stratify immune checkpoint inhibition (ICI) treatment response in patients with advanced non-small cell lung cancer (NSCLC). The poster, titled "Host Immune Profiling in First-line Immunotherapy Treated Advanced Stage Non-Small Cell Lung Cancer: Results from the INSIGHT Registry Study," will be presented on Friday, November 11th, 2022.

Results from a prior analysis of the VeriStrat test published in the Journal for ImmunoTherapy of Cancer (JITC) in October 2021 demonstrated that approximately 2,000 patients with at least one year of follow up 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 host immune classifier cold (HIC-C). 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-C classification, also known as VeriStrat Poor, correlates to what experts refer to as an "immune desert," where tumor directed immunity is compromised.

The new data expands the analysis population to a total of 3,040 patients and confirms the ability of the VeriStrat test to predict outcomes in patients treated with immunotherapy regimens. Patients with HIC-C classification had superior median overall survival when receiving ICI plus chemotherapy versus ICI alone (8.2 months versus 5.6 months, respectively). Furthermore, patients with high PD-L1 expression and with HIC-C classification had superior median overall survival when receiving ICI plus chemotherapy versus ICI alone (14.3 months versus 3.3 months, respectively).

"Real World data can answer questions not addressed by registrational studies. HIC (VeriStrat) is a biomarker of immune therapy and these results suggest that HIC-C (VeriStrat Poor) patients should not be treated with single agent ICI therapy regardless of their PD-L1 expression," said Dr. Akerley, principal investigator of the INSIGHT study. "Immunotherapy has transformed treatment options for patients with non-small cell lung cancer, but it is challenging to know which standard of care regimens will be most effective. This new data from the INSIGHT study shows how a biomarker-driven strategy can help determine optimal treatment approaches for these patients."

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 offers five Medicare-covered 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® ddPCR™ test, the GeneStrat NGS™ test an the VeriStrat® test to support treatment decisions across all stages of lung cancer with results in an unprecedented average of 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. 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. The Company's ability to continue as a going concern could cause actual results to differ materially from those contemplated in this press release and additionally, other 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 14, 2022 or subsequent quarterly reports on Form 10-Q during 2022, 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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