Biodesix Announces Intent to Launch Liquid Biopsy Next Generation Sequencing Test with Unprecedented Turnaround Time

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Blood-based NGS Test is Shown in Recent Publication to Provide Critical Data in 72 Hours; Launch Planned for First Half of 2022

BOULDER, Colo.--(BUSINESS WIRE)--Apr. 28, 2021-- Biodesix, Inc. (Nasdaq: BDSX), a leading data-driven diagnostic solutions company with a focus in lung disease, has announced their plan to add a blood-based 52-gene next generation sequencing (NGS) test to their portfolio of molecular testing based on a recent publication. Of critical importance, the publication, "Targeted Next-Generation Sequencing of Liquid Biopsy Samples from Patients with NSCLC," in *Diagnostics* showed that the rapid liquid biopsy testing was able to detect actionable genomic alterations in patients with non-small cell lung cancer (NSCLC) with an unmatched turnaround time of only 72 hours.

The test has been in use for biopharma research testing and is performed in Biodesix's ISO 13485-certified, New York Clinical Laboratory Evaluation Program (CLEP)-approved, College of American Pathologists (CAP)-accredited, Clinical Laboratory Improvement Amendments (CLIA)-high complexity certified clinical testing laboratory. With the turnaround time for existing, on-market liquid biopsy NGS tests ranging from 7-14 days, improving turnaround time to three days can be critical for patients with advanced NSCLC who are unable to undergo biopsy or whose biopsies have yielded insufficient test results.

"We observed significant agreement (95.7%–100%) with an orthogonal, high-sensitivity Droplet Digital™ Polymerase Chain Reaction (ddPCR) test," said Gary Pestano, Ph.D., Chief Development Officer at Biodesix. "This method offers a valuable supplement to assessing targeted mutations from blood while conserving specimens and maintaining sensitivity, with rapid turnaround time to actionable results."

The NGS test will complement the now 36-hour turnaround time that GeneStrat® ddPCR and VeriStrat® tests currently offer with the expanded coverage of 52-genes and broader molecular markers. The 52-gene NGS test will be used for advanced, late-stage, or recurrent cancer mutation detection, and the targeted 6-gene GeneStrat test can be used for identification of the select mutations for treatment guidance, recurrence monitoring, and detection of the development of resistance mutations over time. The company expects to begin offering this testing strategy in the first half of 2022.

"This test allows Biodesix to offer comprehensive molecular test results, with small and large genomic testing panels in combination with our immune profiling test for early and advanced NSCLC," said Scott Hutton, CEO of Biodesix. "We believe that by adding this NGS test to our current portfolio and multi-omics approach, we can enable physicians to make critical treatment decisions for their patients across the continuum of care in the shortest amount of time available today."

About Biodesix

Biodesix is a leading diagnostic 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 six non-invasive tests for patients with diseases of the lung. Biodesix launched the SARS-CoV-2 ddPCR™ test and the Platelia SARS-CoV-2 Total Ab in response to the global pandemic and virus that impacts the lung and causes COVID-19. The blood based Biodesix Lung Reflex® strategy for lung cancer patients integrates the GeneStrat® and VeriStrat® tests to support treatment decisions with results in 72 hours, expediting time to treatment. 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. Biodesix also collaborates 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, its 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 10K, filed March 16, 2021. 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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