Biodesix Announces Publication Further Validating the Use of Liquid Biopsies and NGS Techniques to Provide Clinical Information for Patients With Cancer

March 29, 2022

Additionally, data associated with the GeneStrat® ddPCR ™ and Genestrat NGS ™ blood tests will be presented at the American Association for Cancer Research (AACR)

BOULDER, Colo.--(BUSINESS WIRE)--Mar. 29, 2022-- Biodesix, Inc. (Nasdaq: BDSX), a leading data-driven diagnostic solutions company with a focus in lung disease, today announced that new data were published in the peer-reviewed journal, Diagnostics (Basel), in an article titled, “Analytic and Clinical Validation of a Pan-Cancer NGS Liquid Biopsy Test for the Detection of Copy Number Amplifications, Fusions and Exon Skipping Variants.” This peer-reviewed publication further validates the GeneStrat NGS test and the use of multiple classes of tumor markers in circulating free nucleic acid analysis as a surrogate for tumor tissue biopsies. [i]

“These data extend on Biodesix’ testing of plasma for somatic nucleotide variants and indels in circulating nucleic acids by detecting amplifications, fusions and exon skipping. We can broadly assay for the major variant classes which includes actionable mutations in support of comprehensive molecular testing in lung cancer,” said Gary Pestano, Ph.D., Chief Development Officer, Biodesix.

Additionally, Biodesix will present data associated with the GeneStrat ddPCR and NGS blood tests in a poster presentation focused on reporting validation studies of key actionable mutations in NSCLC entitled: Analytic and clinical validation of a new pan-cancer NGS liquid biopsy test for the detection of copy number variations, fusions/exon skipping, somatic variants and indels (Abstract number 5323), at the American Association for Cancer Research (AACR) Annual Meeting from April 8-13, 2022. The full abstract can be found on the official AACR website here. Poster presentations will be viewable after April 8th, 2022.

The company believes that the coupling of highly sensitive, rapid stand-alone droplet digital ™ PCR (ddPCR) and the NGS techniques offers more comprehensive blood-based testing support for patients with non-small cell lung cancer (NSCLC) and provides clinically relevant information both before and after targeted treatment of patients with cancer.

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® ddPCR ™ test, the GeneStrat NGS ™ test and the VeriStrat® test to support treatment decisions across all stages of lung cancer with results in an unprecedented 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 ™ Neutralization 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. 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. 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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[i] Analytic and Clinical Validation of a Pan-Cancer NGS Liquid Biopsy Test for the Detection of Copy Number Amplifications, Fusions and Exon Skipping Variants. Diagnostics 2022, 12(3), 729; https://doi.org/10.3390/diagnostics12030729 - 17 Mar 2022
Targeted Next-Generation Sequencing of Liquid Biopsy Samples from Patients with NSCLC. Diagnostics 2021, 11(2), 155; https://doi.org/10.3390/diagnostics11020155 - 21 Jan 2021

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