



Biodesix Announces Impactful Clinical Data on the Primary Immune Response (PIR) Test at the IASLC 2022 Therapies of Lung Cancer Meeting

March 3, 2022

BOULDER, Colo.--(BUSINESS WIRE)--Mar. 3, 2022-- Biodesix, Inc. (Nasdaq: BDSX), a leading data-driven diagnostic solutions company with a focus in lung disease, today announced impactful data on the Primary Immune Response (PIR) test at the IASLC 2022 Targeted Therapies of Lung Cancer Meeting. In this body of work, the PIR test provided two classifications of PIR-Not Resistant and PIR-Resistant predictive of likely response to immune checkpoint inhibitors (ICIs). The data showed that the Biodesix PIR test was predictive for survival outcomes when tested at baseline (HR=2.36, p=0.02) or 3 weeks after ICI treatment initiation (HR=3.53, p=0.001). Furthermore, the data suggested that patients classified as PIR-Resistant were more likely to experience rapid onset of immune related adverse events (irAE) when treated with ICIs (HR=2.40, p=0.08).

The PIR test is a serum-based proteomic assay that utilizes mass spectrometry and machine learning. The study, titled [Serum Proteomics Analysis as a Potential Predictive Biomarker for Survival Outcomes and Immune-related Adverse Events in Non-Small Cell Lung Cancer Receiving Immune Checkpoint Inhibitors](#) was authored by Leeseul Kim, MD of AMITA Health Saint Francis Hospital, Evanston, Illinois, Myungwoo Nam, MD from Lincoln Medical and Mental Health Center, Bronx, New York, and Dong-Uk Lee, MD and Young Kwang Chae, MD, MPH, MBA, both from Northwestern University Feinberg School of Medicine, Chicago IL. The PIR test was validated on samples from patients receiving second-line nivolumab and was shown to stratify patients based on their outcomes to immunotherapy.

"This data is meaningful for patients with non-small cell lung cancer who are being considered for treatment with ICIs. Immune Checkpoint inhibitor drugs have gained interest in oncology because of their ability to boost a person's immune response against cancer cells. It was recently estimated that nearly half of US patients with cancer are eligible for ICI therapy, however only about 1 in 8 will respond," said Scott Hutton, CEO, Biodesix. "Developing tools that provide a better understanding of a patient's likely overall outcome and adverse events prior to treatment with ICIs will be critical for both the physician and patient, which is the true benefit of the PIR test."

While the PIR test is not yet commercially available, it is being studied further in multiple ongoing clinical studies and is expected to launch commercially in 2023.

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 NGST™ 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 KitGenScript, 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](https://www.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 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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Media:

Bobbi Coffin

bobbi.coffin@biodesix.com

(303) 892-3203

Investors:
Chris Brinzev
chris.brinzev@westwicke.com
(339) 970-2843

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