Biodesix Announces Issuance of Two U.S. Patents, Expands Coverage of Diagnostic Methods to Improve Care for Cancer Patients

April 6, 2021

Diagnostic Test and Novel Methodologies Designed to Guide Patient Assessment and Treatment Strategies

BOULDER, Colo.--(BUSINESS WIRE)--Apr. 6, 2021-- Biodesix, Inc. (Nasdaq: BDSX), a leading data-driven diagnostic solutions company with a focus in lung disease, today announced that the United States Patent and Trademark Office (USPTO) has issued two patents that will enhance its ability to develop blood-based immunotherapy and pipeline testing strategies. These developments further improve Biodesix's ability to offer rapid, accurate assessment of patients, which guide physician treatment strategies for their cancer patients.

U.S. Patent 10,950,348, titled, "Predictive Test for Patient Benefit from Antibody Drug Blocking Ligand Activation of the T-Cell Programmed Cell Death 1 (PD-1) Checkpoint Protein and Classifier Development Methods," covers a test that classifies patients based on their responses, or failures to respond, to immunotherapies. This diagnostic methodology is designed to stratify patients with lung cancer based on their likelihood to respond to immunotherapies.

"Immunotherapy drugs have made tremendous headway in the treatment of many types of cancers, including lung cancer and melanoma," said Robert Georgantas, III, Ph.D., Senior Vice President of Research and Translational Science at Biodesix. "However, only a subset of patients benefits from these treatments. Predicting who will or will not respond to immunotherapy is imperative for better stratification of patients by immune response to foster treatment personalization and optimal outcome. Additionally, response prediction can help our biopharma research partners develop drug regimens to improve patient survival with these types of drugs."

U.S. Patent 10,870,891, "Diagnostic Test System for Specific, Sensitive and Reproducible Detection of Circulating Nucleic Acids in Whole Blood," covers a novel method for detecting fragmented ribonucleic acid (RNA) in whole blood samples. The method uniquely purifies and amplifies RNA once it is isolated and can ultimately be used in tests that identify or quantify tumor genes and mutations in a host of downstream applications.

"This method is especially valuable because it further improves the performance of our blood-based technologies," Gary Pestano, Ph.D., Chief Development Officer at Biodesix, said of the novel diagnostic test method. "The method is incorporated into multiple diagnostic tests, such as the GeneStrat® test and other pipeline tests. Specifically, the patented methods have applicability across a number of technologies that purify, transcribe and amplify nucleic acids, including polymerase chain reaction (PCR) and next-generation sequencing (NGS), allowing Biodesix to gather important data in a robust and efficient way that can be used to support physicians and patients in making timely treatment decisions."

"Patents have historically driven the biotechnology industry forward, but conversely have become harder than ever to obtain. Our recent issuances, across diverse technology fields are good news in light of the increasingly fast pace of the diagnostics sector," said Scott Hutton, Chief Executive Officer at Biodesix. "There is significant ongoing research activity at Biodesix, which will lead to future patent filings that will continue to strengthen and broaden our position in the market."

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, it's 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20210406005062/en/

Media:
Jordona Jackson Smith
Jordona@jacksonbio.com
(805) 674-7347

Investors:
Chris Brinzey
chris.brinzey@westwicke.com
(339) 970-2843

Source: Biodesix, Inc.