Biodesix Initiates Biomarker Study to Affirm Nodify XL2® Test's Importance in Clinical Decision Making

December 23, 2020

Dr. Gerard A. Silvestri of Medical University of South Carolina Named Principal Investigator

BOULDER, Colo.--(BUSINESS WIRE)--Dec. 23, 2020-- Biodesix, Inc. (Nasdaq: BDSX), a leading data-driven diagnostic solutions company, is proud to announce the launch and active recruitment of a first-in-class biomarker study aligned with the recommendations from the official 2018 American Thoracic Society (ATS) policy statement on the early detection of lung cancer. The Nodify XL2 Classifier Clinical Utility Study in Low to Moderate Risk Lung Nodules (ALTITUDE), titled "A Multicenter, Randomized Controlled Trial, Prospectively Evaluating the Clinical Utility of the Nodify XL2 Proteomic Test in Incidentally Discovered Low to Moderate Risk Lung Nodules," is a randomized blinded controlled study with the objective of assessing how clinical decision making is impacted by the introduction of Nodify Lung test results into risk assessment. The study will focus on new, incidentally identified patients with lung nodules that are estimated to have low to moderate risk of lung cancer using the current standard of care.

The study is designed to generate key data to provide further support for a testing strategy that improves on the current standard of care and that significantly enhances guidelines. Biodesix has selected Dr. Gerard Silvestri, Hillenbrand Professor of Thoracic Oncology at the Medical University of South Carolina, to lead this trial. Dr. Silvestri is an internationally recognized researcher in all aspects of lung cancer care but with focused expertise in the early detection, evaluation and management of pulmonary nodules.

"I am excited to serve as principal investigator for the ALTITUDE trial, a study that I consider to be the first of its kind," said Dr. Silvestri. "We expect the trial to demonstrate that having the results of the Nodify XL2 Lung tests will lead to patients with benign disease avoiding unnecessary and invasive procedures. I believe that it will establish a new standard for future biomarker studies for the early detection of lung cancer."

With a total enrollment goal of 2,000 patients, Biodesix anticipates publishing interim results in 2022 and expects to complete the study in late 2023.

"As a data-driven company, Biodesix is committed to continuing to study our tests and their impact on patients and the healthcare system. Through the ALTITUDE study, we want to better understand the impact on real-world decisions made in the clinic every day with the Nodify Lung test," said Scott Hutton, CEO of Biodesix. "We are proud that this important study will include leading experts in early detection of lung cancer from some of the most prestigious academic centers in the U.S."

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. Moreover, Biodesix operates in a competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for its management to predict all risks, nor can it assess the impact of all factors on its business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements it may make. 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/20201223005046/en/

Jordona Jackson Smith
Jordona@jacksonbio.com
805-674-7347

Source: Biodesix, Inc.