W biodesix

Biodesix Enhances Access to Nodify Lung® Testing with Launch of New Blood Draw Method

November 14, 2023

Capillary device supports in-office blood collection in diverse practice locations without the need for venipuncture

BOULDER, Colo.--(BUSINESS WIRE)--Nov. 14, 2023-- Biodesix, Inc. (Nasdaq: BDSX), a leading diagnostic solutions company with a focus in lung disease, announced today the validation and launch of a new method of collecting blood specimens for Nodify Lung Nodule Risk Assessment testing. The method uses the FDA-cleared Tasso+TM device, a single-use blood lancing device intended for obtaining capillary whole blood samples from a patient's upper arm.

Blood-based Nodify Lung testing, comprised of the Nodify CDT® and Nodify XL2® tests, addresses a significant unmet need by assessing the risk of cancer in patients with lung nodules. Biodesix offers a range of venous blood draw services, including an extensive network of mobile phlebotomists and independent laboratories. Capillary blood draws using the Tasso+ device enable blood specimen collection for healthcare providers who do not have convenient access to phlebotomy services or a licensed phlebotomist on staff in the clinic or office. The Tasso+ device was validated by Biodesix to be administered in minutes by any healthcare provider at the time of lung nodule evaluation, creating efficiencies in the Nodify Lung workflow.

"The capillary blood collection device has been extremely useful to deliver high quality patient care," said Pedro Del Pino, a Thoracic and General Surgeon who works at Oneida Health and is leading lung nodule management efforts in the Oneida area. "Oneida Health is a referral center serving patients in a wide geographical area. This device has allowed us to order Nodify Lung testing when patients are here for visits, ensuring that we get the critical information to inform the shared decision-making process quickly and accelerate the time to diagnosis."

Biodesix received approval from the New York State Clinical Laboratory Evaluation Program (NYS-CLEP) to use the Tasso+ device as a specimen collection method in support of Nodify Lung testing after entering into a supply agreement with Tasso, Inc. The device is now available for clinical use to collect specimens for Nodify Lung testing.

"Improving patient access to diagnostic tests in all geographies and practice settings is of the utmost importance," said Kieran O'Kane, Chief Commercial Officer of Biodesix. "We know that physicians serve diverse patient populations, some of whom may have to commute hours to access healthcare services. The Tasso+ device provides a convenient option to collect blood specimens, ensuring that the test results are available in a timely manner and preventing patients from having to make a second trip to have their blood drawn."

Tasso+ is a trademark of Tasso, Inc.

About Biodesix

Biodesix is a leading 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 offers five Medicare-covered 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 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 GeneStra[®] targeted ddPCR[™] test, the GeneStrat NGS[®] test and the VeriStrat[®] test to support treatment decisions across all stages of lung cancer with results in an average of two to three business days, expediting the 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. 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 forwardlooking 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. 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 6, 2023 or subsequent quarterly reports on Form 10-Q during 2023, 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20231114108534/en/

Media: Robbie Lunt robbie.lunt@biodesix.com 1-866-432-5930

Investors: Chris Brinzey chris.brinzey@westwicke.com

chris.brinzey@westwicke.com (339) 970-2843

Source: Biodesix, Inc.