Biodesix Announces Publication of a New Nodify CDT® Clinical Validation Study

January 7, 2025

Analysis of 447 patients receiving the Nodify CDT blood-based lung nodule test published in CHEST Pulmonary Journal reaffirms test performance

LOUISVILLE, Colo., Jan. 07, 2025 (GLOBE NEWSWIRE) -- Biodesix, Inc. (Nasdaq: BDSX), a leading diagnostic solutions company with a focus in lung disease, announced a new post-market clinical validation study was published in ***CHEST Pulmonary Journal*** that reaffirms the previously established performance of the Nodify CDT® blood-based lung nodule test. Clinical data is one of the foundational pillars driving the success of Biodesix through market adoption and payor coverage of its diagnostic tests.

The Nodify CDT test measures levels of seven autoantibodies associated with lung cancer that can be detected in blood samples of patients with indeterminate lung nodules. Prior studies have demonstrated that elevated levels of the autoantibodies indicate a likely cancerous nodule (referred to as a “rule in” test) and may lead to escalation of care to diagnose lung cancer earlier. The test is often ordered in conjunction with the Nodify XL2 ® blood-based lung nodule test, designed to identify likely benign nodules (referred to as a “rule out” test). The combination of the two tests, marketed as Nodify Lung® Nodule Risk Assessment, reclassifies the risk of lung cancer to help identify the most appropriate diagnostic pathway.

The newly published study included 447 patients with lung nodules managed conventionally without the use of the Nodify CDT or Nodify XL2 tests. In this cohort, 33% of patients with cancerous nodules received a diagnosis more than three months after lung nodule detection, representing a missed opportunity for early detection, which may have improved patient outcomes. The Nodify CDT test was performed retrospectively to analyze test performance.

The primary findings of the study demonstrated that the Nodify CDT test maintained a high specificity, meaning that a very low percentage of benign nodules were misclassified as high risk. The Nodify CDT test performance was also compared to that of positron emission tomography (PET) scans, an imaging modality commonly used to assess lung nodule risk. In the 222 patients receiving PET scans, the Nodify CDT test demonstrated higher specificity, meaning that PET scans had significantly more false positive results. Because PET scans are often used to guide clinical decision making in patients with lung nodules, a false positive can lead to an unnecessary invasive procedure that carries the risk of complications and cost to the patient and healthcare system.

“It is very encouraging to see that the performance of the test is robust in further validation studies,” commented Gerard A. Silvestri, MD, MS, Hillenbrand Professor of Thoracic Oncology at the Medical University of South Carolina. “Clinicians often rely on PET scans for risk classification, but this study demonstrates that the performance of PET alone is insufficient for diagnostic decision making. In comparison, the Nodify CDT test may be a useful adjunct in clinical practice given its high specificity and low false positive rate. The goal of using this *rule in test* is to avoid delays in getting patients with cancer to definitive treatment options.”

About Biodesix
Biodesix is a leading diagnostic solutions company with five Medicare-covered tests available for patients with lung diseases. The blood-based Nodify Lung® Nodule Risk Assessment, 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™ test portfolio for lung cancer patients integrates the GeneStrat® targeted ddPCR™ test, the GeneStrat NGS® test, and the VeriStrat® test to support treatment decisions across all stages of lung cancer and expedite personalized treatment. In addition, Biodesix collaborates with the world’s leading biopharmaceutical companies to provide biomarker discovery, diagnostic test development, and clinical trial support services. 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 backlog and the timing and assumptions regarding collection of revenues on projections, availability of funds and future capital including under the term loan facility, expectations regarding revenue and margin growth and its impact on profitability, and the impact of a pandemic, epidemic, or outbreak, including the COVID-19 pandemic, on Biodesix and its operations and financial performance. 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 most recent annual report on Form 10-K, filed March 1, 2024 or subsequent quarterly reports on Form 10-Q during 2024, 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.

Media:
Natalie St. Denis
Natalie.StDenis@biodesix.com

1-720-925-9285

Investors:
Chris Brinzey
chris.brinzey@icrhealthcare.com
1-339-970-2843