



Biodesix Announces New Data on Nodify Lung® Nodule Risk Assessment Testing at the CHEST 2021 Annual Meeting

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First data from the ORACLE prospective clinical utility study highlights reduction of invasive procedures on patients with benign nodules

BOULDER, Colo.--(BUSINESS WIRE)--Oct. 13, 2021-- **Biodesix, Inc.** (Nasdaq: BDSX), a leading data-driven diagnostic solutions company, today announced that multiple data presentations will occur at the 2021 annual CHEST virtual conference. Presentations will include newly emerging data from the post-market, prospective, real-world ORACLE study (*An Observational Registry Study to Evaluate the Performance of the Nodify XL2® Test - ORACLE [NCT03766958]*), demonstrating that incorporation of this blood-based test in the management of patients with newly detected lung nodules modified physician behavior. The prospectively collected data show the ability to reduce unnecessary invasive biopsies and surgeries, through incorporation of the Nodify XL2 test in clinical practice. The ORACLE Study Principal Investigator, Michael Pritchett, DO, MPH, Director, Chest Center of the Carolinas at FirstHealth and past President of the Society for Advanced Bronchoscopy, released new data based on the use of the Nodify XL2® test in a real-world clinical practice setting.

“The results of this real-world study show that with the use of the Nodify XL2 test we are able to reduce the number of invasive procedures on benign lesions by up to 67%,” said Dr. Pritchett. “This further validates the data we saw from the PANOPTIC trial. In my own experience using this test, patients are excited to hear that a simple blood test can give them results in less than a week and can help us avoid an unnecessary invasive procedure. Furthermore, when we find that we have reclassified their lesion as low risk, that finding helps us give them peace of mind while they wait several months for the next follow-up CT scan.”

Abstract #4802 - Impact of a Blood-based Risk Classifier on Management of Benign Pulmonary Nodules ([To view, link here](#)) In this data, Dr. Pritchett presents a first look at the ORACLE study primary objective, which is evaluating healthcare providers utilizing the blood-based Nodify XL2 proteomic test to reduce the number of procedures on benign lung nodules. The author reviewed outcomes data from patients (n = 331) newly identified 8-30mm lung nodules, who were managed with Nodify XL2 testing. The results of this analysis demonstrated that the group of patients managed with the Nodify XL2 test had a 67% reduction in invasive procedures on patients with benign nodules compared to standard of care group (N = 287).

Case Study #4712 – Nodule Dilemma: Proteomic Biomarker Discordance with PET results. ([To view, link here](#)) A real-world patient case study on the impact of the Nodify Lung Nodule Risk Assessment testing strategy will be presented by Jennifer Houpy, MD, internal medicine specialist and pulmonary and critical care fellow, and Ajay Wagh, MD, pulmonologist and assistant professor, from the University of Chicago. This case study highlights the potential value of biomarker testing among other risk information used to inform diagnostic planning. In the case study, the conclusion states that the case highlighted is an example of post-operative morbidity after surgical biopsy of a lung nodule that may have been mitigated by a standardized incorporation of proteomic biomarkers into lung nodule decision-making.

Abstract # 4239 - Blood-based Autoantibody Test to Help Identify Likely Malignant Indeterminate Pulmonary Nodules: An Opportunity for Early Diagnosis of Lung Cancer ([To view, link here](#)) Trevor Pitcher, PhD, Director of Medical Affairs & Medical Information, Biodesix, will present a new analysis of the Nodify CDT® test on the PANOPTIC study population, evaluating the autoantibody profile of patients diagnosed with lung cancer. The data highlights that a majority of the malignant pulmonary nodules with a Nodify CDT positive result were diagnosed with Stage I NSCLC or Limited Stage SCLC, indicating that the autoantibodies in the test are elevated early in lung cancer disease progression and that the test may help physicians achieve the goal of shifting diagnosis to an earlier stage.

Seminar: Monday, October 18th, 5:45 PM: Clinical Utility of a Blood-based Biomarker Test Designed to Reduce Invasive Procedures on Benign Lung Nodules: Institutional Experience from Investigators Participating in the ORACLE Clinical Registry Study: ORACLE study investigators Jonathan Kurman, MD, Director of Interventional Pulmonology, Medical College of Wisconsin and Joshiah Gordon, MD, Program Director of the Pulmonary and Critical Care Fellowship at Parkview Medical Center from Pueblo Pulmonary Associates in Colorado, will be hosting a seminar to present institutional data on how the Nodify Lung Nodule Risk Assessment testing strategy aligns within both community and academic clinical practices. In this seminar, Drs. Kurman and Gordon will both review case studies from their practice as well as aggregate data showing reclassification rates of approximately 200 patients receiving Nodify testing between their two practices.

About Biodesix

Biodesix, Inc. 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 seven 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 Biodesix Lung Reflex® strategy for lung cancer patients integrates the GeneStrat® and VeriStrat® tests to support treatment decisions with results in 36 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 Kit, GenScript, 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. 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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