Biodesix Announces the Largest Lung Nodule Biomarker Clinical Validation Study Ever Published Supporting Earlier Lung Cancer Diagnosis

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A retrospective pooled analysis of 1,100 patients demonstrates the Nodify CDT® test's consistent clinical performance across nodule sizes and patient populations

LOUISVILLE, Colo., March 20, 2026 (GLOBE NEWSWIRE) -- Biodesix, Inc. (Nasdaq: BDSX), a leading diagnostics solutions company, announced the publication of the largest lung nodule biomarker clinical validation study ever conducted. This milestone strengthens the clinical foundation for Nodify CDT® tests as a critical decision-support tool in the early detection of lung cancer, addressing a significant unmet need in the management of the millions of lung nodules detected annually in the United States.

The study, published in ***Future Oncology***, February 2026, titled ***Validation of a blood-based autoantibody test to assess lung cancer risk in 4-30mm pulmonary nodules: a retrospective pooled analysis of four cohort studies***, highlights that the Nodify CDT® test offers consistently strong performance in identifying a high risk of lung cancer in patients with lung nodules.

Over 1,100 patients with noncalcified lung nodules ranging in size from 4-30 mm and had Nodify CDT test results were analyzed. The data shows that the Nodify CDT test consistently demonstrated high specificity (91-97%), i.e., low false positive rates, regardless of nodule size or baseline patient risk factors. Test performance was also consistent across four distinct clinical studies with patients enrolled from 48 clinical practices in the US, including the CLARIFY study (NCT06728319) where patients received the Nodify CDT test as part of real-world clinical care. These data substantiate that the Nodify CDT test has strong clinical applicability and consistent performance across diverse practice settings.

"Most small nodules are benign and clinicians must balance patient care decisions … whether to *watch and wait* with imaging surveillance or, instead, to expedite intervention based on the limited insights provided by the CT scan," said Dr. James Jett, Co-Chief Medical Officer at Biodesix, former Pulmonologist at Mayo Clinic, and Professor of Medicine Emeritus of National Jewish Health in Denver, CO.[1] Dr. Jett emphasized, "A recent study reported in the journal *THORAX (by The SUMMIT consortium)* observed that over 40% of malignant pulmonary nodules progressed in tumor size between the time of first detection and the time of definitive treatment.[2] This highlights a clinician's need for more helpful decision-support tools to expedite diagnosis and treatment, such as Nodify Lung® Nodule Risk Assessment."

"The data shows that the Nodify CDT test detected lung cancer with minimal false positives for nodules 4-30 mm in size," confirmed Dr. Luke Yuhico, Pulmonologist, Fort Walton-Destin Hospital, FL. "In my own practice, I have observed that using Nodify Lung testing, in conjunction with the information on the patient's scan, significantly assists in my team's decision-making as we strive to meaningfully impact patient outcomes by finding cancer much earlier, even in very small nodules."

"This comprehensive validation study supports our continued commercial expansion of the Nodify CDT test and reinforces its clinical utility in addressing the substantial market opportunity and system-wide gaps in patient care that are presented by lung nodule management," said Scott Hutton, CEO & President, Biodesix. "The demonstrated consistency of Nodify CDT tests, across real-world practice settings, further strengthens the company's offering with healthcare providers, payers, and clinical guideline committees."

The Nodify CDT test is available for clinical use in patients with 4-30 mm lung nodules. To learn more about Nodify Lung testing, or to order a test for a patient, please visit www.biodesix.com.

Footnotes:

1. **Dr. James Jett, Co-Chief Medical Officer at Biodesix**, is a board-certified physician in pulmonary medicine and served at the Mayo Clinic in Rochester, MN for 28 years. His is also Professor of Medicine Emeritus of National Jewish Health in Denver, CO. He served as the Editor-in-Chief of the *Journal of Thoracic Oncology* and as Co-Editor of the Lung Cancer Section of the premier medical electronic textbook *Up-To-Date*.
2. **Upstaging of screen-detected lung cancers during diagnostic assessment,** published as 10.1136/thorax-2025-224006, 2 Feb 2026**, http://thorax.bmj.com/.** Monica L Mullin, Priyam Verghese, Chuen R Khaw, Andrew Creamer, Amyn Bhamani, Ruth Prendecki, Jennifer L Dickson, Carolyn Horst, Sophie Tisi, Helen Hall, Kylie Gyertson, Esther Arthur-Darkwa, Laura Farrelly, John McCabe, Ricky Thakrar, Arjun Nair, Anand Devaraj, Neal Navani, Allan Hackshaw, The SUMMIT consortium, Sam M Janes.

About Biodesix:

Biodesix is a leading diagnostic solutions company, driven to improve clinical care and outcomes for patients. **Biodesix Diagnostic Tests**, marketed as Nodify Lung® Nodule Risk Assessment and IQLung® Cancer Treatment Guidance, support clinical decisions to expedite personalized care and improve outcomes for patients with lung disease. **Biodesix Development Services** enable the world's leading biopharmaceutical, life sciences, and research institutions with scientific, technological, and operational capabilities that fuel the development of diagnostic tests, tools, and therapeutics. For more information, visit biodesix.com.

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