Biodesix to Present Data at the CHEST 2022 Annual Meeting Demonstrating High Sensitivity of the Nodify XL2® Blood-Based Lung Nodule Test in Various Patient Populations, Including Individuals Participating in Lung Cancer Screening Programs

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New data reinforces the performance of the Nodify XL2® proteomic test in assessing risk of malignancy of pulmonary nodules in different patient populations

BOULDER, Colo.--(BUSINESS WIRE)--Oct. 12, 2022-- Biodesix, Inc. (Nasdaq: BDSX), a leading data-driven diagnostic solutions company with a focus in lung disease, announced today that three data presentations will occur at the CHEST 2022 Annual Meeting which will be held live and in-person for the first time since 2019. Presentations will include a sub-group analysis of 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 the Nodify XL2 test has equivalent performance in identifying patients with benign nodules discovered through lung cancer screening programs, compared to those discovered incidentally through medical imaging for unrelated diagnostic purposes. This prospectively collected data reinforces the potential of the Nodify XL2 test to identify high-risk individuals participating in lung cancer screening who have a likely-benign lung nodule and can avoid an unnecessary invasive biopsy.

"Last year, the United States Preventative Services Task Force (USPSTF) expanded the screening criteria, doubling the population eligible for low-dose computed tomography (LDCT) screening in the U.S. to an estimated 16 million people" said James Jett, MD, Co-Chief Medical Officer at Biodesix. "One out of four LDCT scans reveal a new lung nodule, most of which are benign. Determining which patients require a prompt biopsy and which can be monitored with routine surveillance is critical to the goal of optimal management of indeterminate pulmonary nodules."

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 this data based on the use of the Nodify XL2 test in a real-world clinical practice setting.

"As expected, the data shows that we can use biological information from patients' blood as a complement to standard risk assessment methods to better stratify patients with lung nodules, possibly avoid invasive procedures on those that have benign nodules and focus on the patients who may benefit from interventions," said Dr. Pritchett.

Rapid Fire Oral Presentation, Monday, October 17, 1:30 PM, Exhibit Hall Rapid Area 4C:
Comparison of the Performance of a Blood-Based Integrated Classifier in Risk Stratifying Incidental and Screening-Detected Pulmonary Nodules.

Dr. Pritchett will present a sub-group analysis from the ORACLE study, which is evaluating healthcare providers utilizing the blood-based Nodify XL2® proteomic test to reduce the number of invasive procedures on benign lung nodules. The author reviewed the test's ability to identify benign lung nodules from patients (n = 280) who had a newly identified, 8-30 mm lung nodule discovered incidentally (n = 211) or through a lung cancer screening program (n = 69). The results demonstrate that the Nodify XL2 test did not differ between the two populations, maintaining a high sensitivity and negative predictive value (NPV) as previously reported in the PANOPTIC clinical study (NCT01752114).

Oral Presentation, Monday, October 17, 1:30 PM, Convention Center Room 104DE:
Impact of the Nodify® Biomarker Panel for Risk Stratification of Pulmonary Nodules at an Academic Medical Center.

Jonathan Kurman, MD, MBA, FCCP, Director of Interventional Pulmonology at the Medical College of Wisconsin and ORACLE study investigator, reviewed 110 patients with 8-30 mm lung nodules receiving Nodify Lung® testing in his clinical practice to assess the reclassification rates from intermediate (5-65% probability of cancer [pCA]) into high (>65% pCA) or very low (<5% pCA) groups. In the oral presentation, Bailey Ray, MD from the Medical College of Wisconsin will present the results of this analysis demonstrating that approximately one-third of all patients were reclassified into the high or very low risk group, further informing diagnostic decisions through shared decision-making discussions with patients.

Rapid Fire Oral Presentation, Wednesday, October 19, 11:15 AM, Exhibit Hall Rapid Area 3A:
Impact of a Blood-Based Integrated Classifier to Reclassify Lung Nodule Risk Across Nodule Size Spectrum.

Dr. Kurman will present a sub-group analysis from the ORACLE study assessing the performance of the Nodify XL2 proteomic test in identifying benign lung nodules across nodule size groups: <10 mm (n = 92), 10-15 mm (n = 124), and >15 mm (n = 64). The results demonstrate that the performance of the test is similar across size groups with high sensitivity and NPV as previously reported in the PANOPTIC clinical study (NCT01752114), identifying patients who may benefit from CT surveillance independent of nodule size.

About Biodesix
Biodesix 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 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 incidental 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 GeneStrat® ddPCR™ test, the GeneStrat NGS™ test an the VeriStrat® test to support treatment decisions across all stages of lung cancer with results in an unprecedented average of 36-72 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. 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 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. 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 14, 2022 or subsequent quarterly reports on Form 10-Q during 2022, 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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