Biodesix Announces Presentation of New Nodify XL2® Data at AABIP Conference Highlighting Increased Proportion of Biopsies Diagnosing Cancer

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Data demonstrates a 51% relative increase in the proportion of lung nodule biopsies diagnosing cancer

BOULDER, Colo.--(BUSINESS WIRE)--Aug. 22, 2023-- Biodesix, Inc. (Nasdaq: BDSX), a leading data-driven diagnostic solutions company with a focus in lung disease, announced today that a new analysis from the post-market, prospective, real-world ORACLE study (An Observational Registry Study to Evaluate the Performance of the Nodify XL2 Test NCT03766958) will be presented at the 6th Annual Conference of the American Association for Bronchology and Interventional Pulmonology (AABIP). The data will be presented by principal investigator of the ORACLE study, Michael Pritchett, DO, MPH, on Thursday, Aug. 24, 2023 in a live poster presentation in Chicago, IL.

The Nodify XL2 test is designed to identify likely benign lung nodules that can be monitored with computed tomography (CT) scans instead of costly invasive procedures. The primary endpoint of the ORACLE study demonstrated that patients with benign lung nodules managed with the test were 74% less likely to undergo an unnecessary invasive procedure compared to the control group. Additionally, the proportion of patients sent to CT surveillance with malignant nodules did not differ between the Nodify XL2 group and the control group.

The analysis to be presented at AABIP investigated the effect of improved identification of benign lung nodules on the remaining patients who received a diagnostic biopsy. Prior to implementation of the Nodify XL2 test, 49% of patients receiving a biopsy had a lung cancer diagnosis compared to 74% when the test was used in clinical decision making, representing a 51% relative increase in the cancer diagnosis rate.

“Finding a suspicious lung nodule can create fear and anxiety for patients, whether it is found through lung cancer screening or an incidental finding from imaging for general medical purposes,” said Dr. Pritchett. “It is very encouraging that the Nodify XL2 test is helping physicians avoid unnecessary invasive procedures on benign lung nodules and prioritize patients with a higher risk of lung cancer. These results offer peace of mind to both patients and providers as they navigate the diagnostic plan.”

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

Investors:
Chris Brinzey
chris.brinzey@westwicke.com
(339) 970-2843

Source: Biodesix, Inc.