Biodesix Announces Publication of the ORACLE Clinical Utility Study with the Primary Endpoint Demonstrating that the Nodify XL2® Test Reduced Unnecessary Invasive Procedures on Benign Lung Nodules

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New publication in PLOS ONE, a journal of the Public Library of Science, reaffirms clinical utility of the Nodify XL2® proteomic test in a real-world setting

BOULDER, Colo.--(BUSINESS WIRE)--Jul. 12, 2023-- Biodesix, Inc. (Nasdaq: BDSX), a leading data-driven diagnostic solutions company with a focus in lung disease, announced today that the prospective, real-world ORACLE study (An Observational Registry Study to Evaluate the Performance of the Nodify XL2® Test [NCT03766958]) achieved the primary endpoint of a statistically significant change in the proportion of benign lung nodules managed by Nodify XL2® experiencing invasive procedures. The data was published in PLOS ONE this week.

Lung nodules are a common clinical finding with the increased use of medical imaging for general diagnostic purposes and the expansion of lung cancer screening eligibility. Lung nodules represent an opportunity for early detection of lung cancer but pose a diagnostic dilemma because up to 95% of lung nodules are benign. In this patient population, high rates of invasive procedures, such as biopsies or surgeries, on benign nodules have been documented in the pursuit of lung cancer diagnosis and an analysis of Medicare claims has showed that greater than 40% of the total cost of lung cancer diagnosis was accounted for by biopsied patients without a lung cancer diagnosis.

In ORACLE, the prospective, real-world clinical utility study, patients with benign nodules managed with the Nodify XL2 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 findings from the ORACLE study represent a significant advancement in the clinical evidence for use of the Nodify XL2 test in nodule management,” said Scott Hutton, President and CEO of Biodesix. “Clinical utility is an important step to demonstrate that the test is informing diagnostic decision making in a clinical setting. Avoiding diagnostic procedures on benign nodules reserves healthcare resources for patients with a higher risk of lung cancer, avoids unnecessary interventions for patients, and supports increases in early diagnosis and treatment.”

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 suppor 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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