Biodesix Awarded Advanced Diagnostic Laboratory Test Status for its Nodify CDT® Test by the Center for Medicare and Medicaid Services

July 6, 2023

BOULDER, Colo.--(BUSINESS WIRE)--Jul. 6, 2023-- Biodesix, Inc. (Nasdaq: BDSX), a leading data-driven diagnostic solutions company with a focus in lung disease, today announced that the Centers for Medicare & Medicaid Services (CMS) has designated the Nodify CDT® Test as an Advanced Diagnostic Laboratory Test (ADLT) effective June 30, 2023.

Obtaining ADLT status is a recognition that the Nodify CDT test meets the stringent criteria established under the Protecting Access to Medicare Act of 2014 (PAMA). ADLT status is reserved for innovative tests with Medicare coverage that provide new clinical diagnostic information that cannot be obtained from any other test or combination of tests. The payment amount for the Nodify CDT test as established by the Medicare Administrative Contractor is $649.

"Receiving ADLT status is a major milestone for Biodesix and confirms the clinical value and unique nature of the Nodify CDT test," says Scott Hutton, President and CEO of Biodesix. "We are committed to working closely with CMS and commercial payers to ensure that patients and physicians have access to all tests in the Biodesix portfolio that aid in the diagnosis and treatment of lung cancer."

The Nodify CDT test is used in combination with the Nodify XL2® test, previously awarded ADLT status on May 17, 2019, in Nodify Lung® Nodule Risk Assessment Testing. These tests are designed to help physicians assess the risk of malignancy of pulmonary nodules to identify and prioritize high risk nodules for intervention while avoiding unnecessary invasive procedures on benign nodules.

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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