Biodesix Obtains Medicare Coverage for the Nodify CDT® Lung Nodule Test

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BOULDER, Colo.--(BUSINESS WIRE)--Jun. 7, 2022-- Biodesix, Inc. (Nasdaq: BDSX), a leading data-driven diagnostic solutions company with a focus in lung disease, announced that WPS Government Health Administrators, the Medicare Administrative Contractor with jurisdiction for Biodesix's De Soto, Kansas laboratory, has provided coverage for the Nodify CDT® lung nodule test.

The Nodify CDT test is a part of the Biodesix's blood-based Nodify Lung® Nodule Risk Assessment testing strategy consisting of two tests to aid physicians in stratifying patients into distinct nodule management treatment pathways: diagnostic procedure or imaging surveillance. The Nodify CDT test helps identify patients with lung nodules that are likely malignant or higher risk of cancer, and the Nodify XL2® test conversely helps identify those that are likely benign or lower risk of cancer.

"Medicare coverage is a significant milestone for the Nodify CDT test to ensure access and availability for patients with lung nodules. Medicare coverage for both the Nodify CDT and Nodify XL2 tests leverages our capability to ensure physicians have access to these insightful and valuable tests to help determine if a lung nodule is likely malignant or likely benign and help guide to best course of action for each individual patient," said Robin Harper Cowie, Chief Financial Officer, Biodesix. "This important coverage and our increasing physician adoption of the Nodify CDT test further demonstrates the clinical relevance of our nodule risk assessment testing. Biodesix is strongly positioned to continue driving adoption of Nodify Lung testing in 2022," said Kieran O'Kane, Chief Commercial Officer, Biodesix.

Now, all five Biodesix blood-based lung diagnostic tests within the Nodify Lung Nodule Risk Assessment testing strategy and IQLung™ strategy for lung cancer patients are now covered by Medicare. The blood based IQLung strategy for lung cancer patients integrates the GeneStrat® ddPCR™ test, the GeneStrat NGS™ test and the VeriStrat® test to support treatment decisions across all stages of lung cancer with results in an unprecedented 36-72 hours, expediting time to 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 is the first company to offer eight non-invasive 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 and the VeriStrat® test to support treatment decisions across all stages of lung cancer with results in an unprecedented 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. Biodesix launched the SARS-CoV-2 ddPCR™ test, the Platelia SARS-CoV-2 Total Ab, and the cPass™ SARS-CoV-2 Neutralization Antibody test (cPass™ Neutralization Test Kit, GenScript, Inc,) in response to the global pandemic and virus that impacts the lung and causes COVID-19. 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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