Biodesix Announces Commercial Availability of SARS CoV-2 Neutralization Antibody Test

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Detection of circulating neutralizing antibodies produced in response to COVID-19 vaccination and infection may benefit immunocompromised individuals.

BOULDER, Colo.--(BUSINESS WIRE)--Jun. 15, 2021-- Biodesix, Inc. (Nasdaq: BDSX), a leading data-driven diagnostic solutions company with a focus in lung disease, today announced the broad commercial launch of a SARS CoV-2 Neutralization Antibody Test (cPass™ Neutralization Test Kit, GenScript Inc.). The test uses ELISA technology to detect circulating neutralizing antibodies against the receptor binding domain (RBD) of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2 virus) and is the first and only surrogate neutralizing antibody test with FDA Emergency Use Authorization (EUA).The cPass test represents an important diagnostic solution to understanding long-term protective immunity to SARS-CoV.

Current vaccines have been proven highly effective at generating antibodies against the viral spike protein when administered as recommended. However, despite significant research and clinical advances made to combat the SARS-CoV-2 virus, the emergence of new variants and community outbreaks are of continued concern and have been observed in both previously infected and vaccinated individuals. Neutralizing antibodies produced by the body's immune system may specifically block the interaction between the receptor binding protein on SARS-CoV-2, and the host cell's membrane receptor protein, thereby preventing infection of the cell by the virus. The Biodesix SARS CoV-2 Neutralization Antibody Test has the potential to identify in individuals, the presence (or absence) of this important subset of antibodies that arise after previous infection or vaccination. Healthcare providers may use the presence of neutralizing antibodies to understand whether an immunized individual is positive or negative for SARS-CoV-2 neutralizing antibodies, which may be of particular importance on how immunocompromised patients are managed.

"Although current reports generally suggest that vaccines offer the potential for long-lasting protective immunity from the virus infection, the data is only emerging for immunocompromised individuals (autoimmune, cancer patients, transplant recipients and the elderly), and their ability to generate an immune response," said Dr. James Jett, CMO, Biodesix, Inc. "Surveillance programs incorporating the cPass SARS CoV-2 Neutralization Antibody Test could broadly inform the presence or absence of neutralizing antibodies in previously infected or vaccinated individuals in these higher risk populations. This test is also highly applicable for research studies aimed at understanding the immune correlations of protection in the face of previous infection or vaccination. This information could also be useful in planning for potential immunization boosters."

About Biodesix

Biodesix is a leading diagnostic 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 seven non-invasive tests for patients with diseases of the lung. Biodesix launched the Bio-Rad SARS-CoV-2 ddPCR™ test, the Platelia SARS-CoV-2 Total Ab and the cPass SARS CoV-2 Neutralization Antibody Test in response to the global pandemic caused by SARS-CoV-2, the virus that impacts the lung and leads to COVID-19. The antibody tests can detect antibodies that are generated both from infection by the virus and from the vaccines. The blood-based Biodesix Lung Reflex® strategy for lung cancer patients integrates the GeneStrat® and VeriStrat® tests to support treatment decisions with results in 36 hours, expediting time to treatment. 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. Biodesix also collaborates 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. 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 10K, filed March 16, 2021. 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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