Biodesix Announces Presentation on SARS-CoV-2 Neutralizing Antibody Testing for Individual Vaccine Response and Commercial Launch Plans

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Dr. Laura Peek and Dr. Sean Taylor presenting novel data on SARS-CoV-2 Neutralizing Antibody Testing; Commercial Launch Planned for Summer 2021

BOULDER, Colo.--(BUSINESS WIRE)--Apr. 26, 2021-- Biodesix, Inc. (Nasdaq: BDSX), a leading data-driven diagnostic solutions company with a focus in lung disease, today announced in partnership with GenScript Biotech Corporation, a webinar to present novel data on the rapid detection of total SARS-CoV-2 neutralizing antibodies using cPass™ technology. Neutralizing antibodies 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 webinar entitled "SARS-CoV-2 Neutralizing Antibody Testing for Vaccine Efficacy Assessment" will be presented by Dr. Laura Peek from Biodesix, and Dr. Sean Taylor from GenScript®, and is scheduled for 1:00 pm ET on Wednesday May 5, 2021. Participants are encouraged to register here.

The COVID-19 pandemic, caused by SARS-CoV-2, has severely impacted the world and our home country. In record time, three vaccines by Pfizer, Moderna and Johnson & Johnson have been authorized for emergency use by the Food and Drug Administration. The current vaccines are highly effective at generating antibodies against the viral spike protein when administered as recommended. 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. Biodesix and GenScript have come together to offer the blood-based cPass™ SARS-CoV-2 Neutralizing Antibody testing as a service. The test is the first and only surrogate neutralizing antibody test with FDA Emergency Use Authorization (EUA) and uses ELISA technology to qualitatively detect circulating neutralizing antibodies to the receptor binding domain (RBD) in the spike protein of SARS-CoV-2 that are produced in response to vaccination or previous SARS-CoV-2 infection.

This assay is also highly applicable for research purposes to further assess the protection that these novel vaccines may offer, as well as the appropriate timing required between doses or boosters. Biodesix plans to make the test available for broad commercial use in the summer of 2021.

The webinar will present data comparing the cPass SARS CoV-2 Neutralization Antibody test to the gold standard live cell virus neutralization tests. The webinar will also describe how the cPass test is distinguished from IgG binding antibody assays in delineating between vaccinated individuals and how these data compare with published vaccine efficacy data. In addition, the presenters will cover the processes and workflows for integrating cPass into Biodesix's COLA accredited, high-complexity CLIA certified and NYS CLEP approved clinical laboratory, and results from clinical studies of cPass in the real-world and for biopharmaceutical research.

"While the pandemic seems to be ever changing, the need for high quality testing remains," said Scott Hutton, CEO of Biodesix. "We continue to work to support communities both local and across the country by expanding our WorkSafe COVID-19 testing program. In addition to performing onsite rapid antigen testing for schools, athletics, and employers to quickly identify potential cases and utilizing our highly sensitive PCR testing for confirmation and validation, we are excited to add the cPass neutralizing antibody test to our portfolio to help assess vaccine responses and potentially the timing of doses or boosters."

"The cPass test is another important tool to support the fight against COVID-19 and is the first to be able to assess immune responses to today's vaccines," said Laura Peek, PhD, Vice President, Laboratory Operations and New York State Clinical Laboratory Evaluation Program Laboratory Director for Biodesix's Kansas-based clinical laboratory. "The test is a fast and effective way to understand the presence of potentially neutralizing antibodies in a person's immune system, providing important information to help guide immunization decisions."

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 six non-invasive tests for patients with diseases of the lung. Biodesix launched the SARS-CoV-2 ddPCR™ test and the Platelia SARS-CoV-2 Total Ab in response to the global pandemic and virus that impacts the lung and causes COVID-19. The blood based Biodesix Lung Reflex® strategy for lung cancer patients integrates the GeneStrat® and VeriStrat® tests to support treatment decisions with results in 72 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.

About GenScript Biotech Corporation

GenScript Biotech Corporation (Stock Code: 1548.HK) is a global biotechnology group. Based on its leading gene synthesis technology, GenScript has developed four major platforms including the global cell therapy platform, the biologics contract development and manufacturing organization (CDMO) platform, the contract research organization (CRO) platform and the industrial synthesis product platform.

GenScript was founded in New Jersey, U.S. in 2002 and listed on the Hong Kong Stock Exchange in 2015. GenScript's business operation spans over 100 countries and regions worldwide, with legal entities located in the U.S., Mainland China, Hong Kong, Japan, Singapore, Netherlands and Ireland. GenScript has provided premium, convenient, and reliable products and services for over 100,000 customers.

GenScript has a number of intellectual property rights and technical secrets, including more than 100 patents and over 270 patent applications. As of June 30, 2020, GenScript's products and services have been cited by 51,000 peer-reviewed journal articles worldwide.

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. 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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