First Patient Enrolled in Biodesix and Addario Lung Cancer Medical Institute Study Aiming to Predict Patient Survival Using a Blood-based Biomarker

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Study will evaluate the use of a blood-based biomarker to predict outcomes in high PD-L1 expressing non-small cell lung cancer patients treated with immune checkpoint inhibitors plus or minus chemotherapy

SAN CARLOS, Calif. and BOULDER, Colo., May 26, 2021 /PRNewswire/ -- Biodesix, Inc. (Nasdaq: BDSX), a leading data-driven diagnostic solutions company with a focus in lung disease, and Addario Lung Cancer Medical Institute (ALCMI) today announced they will present on the progress of "Biomarker Analysis in High PD-L1 Expressing NSCLC Patients Treated With PD-1/PD-L1 Based Therapy With or Without the Addition of Platinum Based Chemotherapy (BEACON-Lung)." The BEACON-Lung study aims to evaluate biomarkers to predict overall survival and early progression outcomes in treatment-naïve advanced stage non-small cell lung cancer (NSCLC) patients with high PD-L1 expression. The first patient participant enrolled in the study this week.

"The BEACON-Lung study furthers ALCMI's mission to work with partners like Biodesix to overcome barriers to treatment in lung cancer," said Tony Addario, chair and CEO of ALCMI. "This study will enable us to develop a better understanding of how biomarkers can unlock treatment options for patients with NSCLC and improve survivorship."

The study, being conducted through ALCMI's prestigious research consortium of leading US academic centers, launched early this year. Nearly half of the targeted 10 sites are actively enrolling with a target enrollment of 390 patients. BEACON-Lung will use Biodesix's Primary Immune Response (PIR) test to classify patients receiving PD-1/PD-L1 therapy or PD-1/PD-L1 plus carboplatin-based chemotherapy and identify those who may benefit from more aggressive treatment regimens.

"As an oncologist, I am excited by the progress we have made for patients who are now diagnosed with non-small cell lung cancer," said Dr. Mary Jo Fidler, principal investigator for the BEACON trial and associate professor in the Department of Internal Medicine, Division of Hematology, Oncology and Cell Therapy at Rush Medical College. "However, to identify the best treatment course for an individual patient still requires the development of biomarkers, especially in the field of immunotherapy. BEACON-Lung is a study that aims address this current gap in biomarker development and treatment selection for advanced non-small cell lung cancer."

The BEACON-Lung study is designed to generate key data to further the development of immunotherapy biomarkers for treatment naïve NSCLC patients. Currently, PDL1 expression is the only clinically validated biomarker predicting patient response to front line PD-1/L1 directed immunotherapy. However, PD-L1 expression remains an imperfect marker, and this study will also help determine if patients should pursue other treatment regimens.

"We are thrilled that the BEACON-Lung study is now launched," said Dr. James Jett, CMO of Biodesix. "This study will allow us to evaluate performance of Biodesix's PIR test in the treatment naïve NSCLC patient population receiving immunotherapy. We are committed to the advancement of biomarker research and to fulfill an unmet need in the NSCLC treatment landscape."

Presentation Title: *Biomarker Analysis in High PD-L1 Expressing NSCLC Patients Treated With PD-1/PD-L1 Based Therapy With or Without the Addition of Platinum Based Chemotherapy (BEACON-Lung)*
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About ALCMI
The Addario Lung Cancer Medical Institute (ALCMI, voiced as "Alchemy"), founded in 2008 as a 501c(3) non-profit organization by lung cancer survivor Bonnie J Addario, is a patient-centric, international research consortium driving research otherwise not possible. Working in tandem with its "partner" foundation, GO2 Foundation for Lung Cancer, ALCMI powers collaborative initiatives in genetic (molecular) testing, therapeutic discoveries, targeted treatments, and early detection. ALCMI combines scientific expertise found at its network of 26 member academic institutions through its network of community cancer centers to accelerate patient access to research.

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 Bio-Rad 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 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, 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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