ALCMI and Biodesix Initiate Prospective Study to Predict Overall Survival Using Checkpoint Immunotherapy for Front-Line Lung Cancer in Patients with High PDL1 Expression

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Dr. Mary Jo Fidler of Rush University Medical Center Named Principal Investigator

San Carlos, CA and Boulder, CO, August 31, 2019 - Addario Lung Cancer Medical Institute (ALCMI) and Biodesix, Inc. today announced they will begin an observational study to prospectively evaluate the clinical utility of biomarkers, including the proteomic Primary Immune Response (PIR) test, for front-line non-small cell lung cancer (NSCLC) patients receiving immunotherapy with and without the addition of systemic platinum-based chemotherapy who have high expression of program death ligand-1 (PD-L1) on their tumor cells.

Biodesix is a leader in lung cancer diagnostic solutions, and has developed a serum-based proteomic test, Primary Immune Response (PIR) that, in retrospective studies, identified a pretreatment immune profile that predicts response to anti-PD-1 therapy.

ALCMI is a patient-founded not-for-profit global research consortium dedicated to catalyzing and accelerating the discovery, development, and delivery of new and more effective treatment options for lung cancer patients.

Together, they aim to enroll 390 treatment naïve advanced stage non-squamous NSCLC patients with ≥50 percent expression of PD-L1 at leading cancer institutions in the U.S.

“Immunotherapy has revolutionized our treatment of lung cancer patients. Many patients, especially those with high expression of the associated PD-L1 marker, prefer a nonchemotherapy treatment option. Clinical experience, however, suggests that this may not be the best therapy for all of these patients,” said Mary Jo Fidler, MD, Rush University Medical Center.

Adding systemic chemotherapy (carboplatin and pemetrexed) to pembrolizumab, an FDA-approved triplet immunotherapy regimen (Langer Lancet Oncol. 2016) independent of PD-L1 status, may be a way to mitigate rapidly progressive disease in high PD-L1 expressers receiving pembrolizumab monotherapy. However, applying the triplet combination to all patients with PD-L1 ≥50 percent may expose them to increased side effects and cost of therapy without additional benefit.

“ALCMI is dedicated to improving overall survival for all lung cancer patients in the most targeted way possible,” said Tony Addario, ALCMI chair and CEO. “This study reflects that commitment and will drive the pursuit of new and better care options for patients with NSCLC.”

In a study presented at the European Society for Medical Oncology, the Biodesix PIR test demonstrated utility in retrospectively classifying second-line NSCLC patients treated with nivolumab by overall survival. The immunotherapy resistant subgroup in the test demonstrated activation in the complement, acute phase, extra-cellular matrix and wound healing pathways. The proteomic test classification is independent of PD-L1 status and uses mass spectrometry in combination with machine learning to analyze circulating proteins in blood.

“We know that immunotherapy by itself does not work for everyone,” said Scott Hutton, CEO of Biodesix. “With the physical and financial toxicity associated with these therapies, a biomarker that can predict survival or early death would be critical in determining the best therapeutic regimen for lung cancer patients.”

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 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.

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. Moreover, Biodesix operates in a competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for its management to predict all risks, nor can it assess the impact of all factors on its business or the extent to which any factor, or combination of factors, may cause actual results to

differ materially from those contained in any forward-looking statements it may make. 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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