Biodesix to Present Data Supporting Proteomic-Based Immunotherapy Diagnostic Tests and AI Explainability in Diagnostic Tests at Society for Immunotherapy of Cancer Annual Meeting

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BOULDER, Colo.--(BUSINESS WIRE)--Nov. 12, 2021-- **Biodesix, Inc**. (Nasdaq: BDSX), a leading data-driven diagnostic solutions company with a focus in lung disease, today announced that the company will co-present with Genentech, a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY), three posters at the 36th Annual Society for Immunotherapy of Cancer (SITC) Nov. 10 – 14, 2021 from research into diagnostic tests of treatment response of NSCLC patients to immune checkpoint inhibitor therapy.

“Biodesix is committed to performing research with biopharma companies, while pursuing, discovering and developing applications that can help physicians and researchers address the needs of patients with lung cancer who will benefit from quick, actionable test results,” said Scott Hutton, CEO, Biodesix. “We are pleased to present data on two tests that have the potential to become instrumental in the care of patients with non-small cell lung cancer (NSCLC). Additionally, our data highlights novel methods that we have developed to provide an explanation as to how our proprietary Diagnostic Cortex Artificial Intelligence (AI) platform combines molecular attributes to produce individual patient results. This data is extremely important because we expect that this will provide clarity and transparency to how our AI-based tests work and how a diagnostic test may better predict efficacy of various treatments in the most appropriate patient populations. We are proud of the data being presented at SITC as it underscores our commitment to the lung cancer community.”

The three Genentech/Biodesix-sponsored posters include the following:

Abstract #26: Validation of the Primary Immune Response (PIR) test in advanced non-small cell lung cancer (NSCLC): blinded retrospective analyses from the POPLAR and OAK trials

Findings will be presented from blinded, retrospective analyses of two Genentech multicenter, open-label RCT clinical studies comparing atezolizumab versus docetaxel in patients with previously treated NSCLC (POPLAR Phase 2 and OAK Phase 3). The Biodesix liquid-biopsy mass spectrometry-based Primary Immune Response (PIR) test stratified outcomes for patients treated with the study drug in second and third line, predicting overall survival, even when adjusted for PD-L1 expression and clinical factors. The importance of understanding who will or will not respond to immunotherapy is critical and identifying predictive biomarkers of immunotherapy response has become a growing focus of immune-oncology research. This study highlights the potential of biomarkers of immune checkpoint inhibitors, such as the PIR test, to support patient stratification.

Abstract #28: Predictions of outcomes and benefit of immune checkpoint inhibitor treatment in non-small cell lung cancer require information on both tumor and host biology

Findings from a Genentech blinded, retrospective study of second- and third-line NSCLC patients in the OAK Phase 3 clinical study comparing atezolizumab versus docetaxel in patients with previously treated NSCLC will be presented. The study demonstrated that the Biodesix Anti-PD-L1 Response Test (ART), based on mass spectrometry of pretreatment serum, stratifies outcomes in both treatment arms overall and in all PD-L1 subgroups. The Biodesix ART test was shown in independent validation to predict outcomes for NSCLC patients treated in a large Phase 3 study and was discovered and developed for Genentech as a part of a partnership between the two companies.

Abstract #831: Exact Shapley Values for explaining complex machine learning based molecular tests of checkpoint inhibitors: potential utility for patients, physicians, and translational research

Data will show how Exact Shapley Values (SVs), a technique developed by Biodesix, can explain how complex machine learning (ML)-based tests combine molecular attributes to produce individual patient results. Exact SVs can be obtained for certain ML architectures used in molecular test development, revealing the overall relative importance of attributes used in such molecular tests. Specifically, this study evaluated SVs for the Biodesix Anti-PD-L1 Response Test (ART), that was shown in independent validation to predict outcomes for NSCLC patients treated in a large Phase 3 study. By subgrouping patients according to ART results, different patterns of SVs were determined, potentially revealing different biologies that were predictive of overall survival outcomes. Exact SVs explain how complex ML-based tests combine molecular attributes to produce individual patient results.

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 seven 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 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. 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. 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 16, 2021, or subsequent quarterly reports on Form 10-Q during 2021, 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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Media
Bobbi Coffin
bobbi.coffin@biodesix.com
(412) 638-2226

Investors
Chris Brinzey
chris.brinzey@westwicke.com
(339) 970-2843

Source: Biodesix, Inc.