



Biodesix Announces Two Presentations on Lung Cancer Treatment Guidance Tests at the IASLC 2023 World Lung Conference on Lung Cancer

September 7, 2023

New data highlights two novel proteomic tests that support treatment decision making in patients with non-small cell lung cancer (NSCLC):

- *Expanded analysis of the VeriStrat® host immune classifier's ability to predict immune checkpoint inhibition (ICI) response in patients with advanced stage NSCLC*
- *The ability of the Risk of Recurrence pipeline test to stratify time to recurrence and overall survival in patients with stage I NSCLC*

BOULDER, Colo.--(BUSINESS WIRE)--Sep. 7, 2023-- Biodesix, Inc. (Nasdaq: BDSX), a leading data-driven diagnostic solutions company with a focus in lung disease, announced today that two abstracts will be presented at the International Association for the Study of Lung Cancer (IASLC) 2023 World Lung Conference on Lung Cancer (WCLC). The first presentation showcases a new analysis of the large multi-center observational registry study INSIGHT (Clinical Effectiveness Assessment of VeriStrat® Testing and Validation of Immunotherapy Tests in NSCLC Subjects, NCT03289780) demonstrating the ability of the VeriStrat host immune classifier to predict response to immune checkpoint inhibitor (ICI) regimens in patients with advanced stage non-small cell lung cancer (NSCLC).

The INSIGHT trial, which recently reached its enrollment goal of 5,000 patients with NSCLC, previously yielded data showing that patients with ≥50% PD-L1 status classified as Host Immune Classifier Cold (HIC-C), also known as VeriStrat Poor, had superior median overall survival when receiving ICI plus chemotherapy versus ICI alone. The expanded analysis confirms these findings and concludes that patients with <50% PD-L1 status classified as Host Immune Classifier Hot (HIC-H), also known as VeriStrat Good, had comparable overall survival when receiving either ICI alone or in combination with chemotherapy.

"These findings highlight the importance of characterizing a patient's immune response to lung cancer to guide immunotherapy treatment decisions," said Wallace Akerley, MD, principal investigator of the INSIGHT study. "The growing body of evidence shows the VeriStrat test is complementary to current standard of care and its use would improve overall patient outcomes by identifying subsets of patients who would benefit from VeriStrat-directed selection of immunotherapy regimen."

The second presentation details the performance of a pre-surgical, blood-based Risk of Recurrence test in three independent cohorts. Patients with early stage lung cancer have favorable outcomes, but many of these patients experience a recurrence which results in a poor prognosis. The test was designed to identify patients with a high probability of recurrence that could be considered for more aggressive treatment or enhanced surveillance. This initial validation study evaluated nearly 800 patients with Stage I NSCLC and demonstrated the test's ability to stratify three distinct groups of patients based on their proteomic profile with high, intermediate, or low risk of recurrence. Furthermore, incorporating the adenocarcinoma grade, a conventional risk factor for recurrence, improved the performance of the test.

"It is crucial to be able to determine which 10-15% of early stage lung cancer patients will recur within 3-5 years after their tumor is completely removed by surgery, and we are encouraged that our model, especially when incorporating the IASLC Histologic Grading System, may lead to more accuracy in this regard," said Harvey Pass, MD lead author of the abstract. "Nevertheless, this work requires further external validation with other cohorts of Stage I lung cancer patients before it could be used clinically to determine who needs appropriate adjuvant therapy."

Following are details about the presentations at the 2023 WCLC:

Title (P2.07-06): Real World Efficacy of First-Line Immunotherapy +/- Chemotherapy in Advanced NSCLC Stratified by Serum Proteomics

Presenter: Wallace Akerley, MD, Director of Lung Cancer Disease Center of Excellence at Huntsman Cancer Institute, University of Utah

Session P2.07: Metastatic Non-small Cell Lung Cancer – Immunotherapy - Retrospective

Date & Time: Monday, Sept. 11, 2023, 18:00 - 20:00 (SGT)

Location: Exhibit Hall, Level 4 (Row 10)

Title (P1.25-13): Enhanced Assessment of Recurrence Risk of Stage I NSCLC by Combined Adenocarcinoma Grading System and Serum Proteomic Testing

Presenter: Harvey Pass, MD, Vice Chair, Research for Cardiothoracic Surgery at NYU Langone Health, and executive committee member for the NYU Lung Cancer Center of the Perlmutter Cancer Institute

Session P1.25: Early-Stage Non-small Cell Lung Cancer - Pushing the Boundaries: Changing Paradigms and Outcomes

Date & Time: Sunday, Sept. 10, 2023, 17:30 - 19:30 (SGT)

Location: Exhibit Hall, Level 4 (Row 32)

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 offers five Medicare-covered 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 pulmonary nodules, enabling physicians to better triage patients to the most appropriate course of action. The blood based IQLung™ strategy for lung cancer patients integrates the GeneStrat® targeted ddPCR™ test, the GeneStrat NGS® test and the VeriStrat® test to support treatment decisions across all stages of lung cancer with results in an average of two to three business days, expediting the 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. For more

information about Biodesix, visit [biodesix.com](https://www.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. The Company's ability to continue as a going concern could cause actual results to differ materially from those contemplated in this press release and additionally, other 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 14, 2022 or subsequent quarterly reports on Form 10-Q during 2022, 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:

Robbie Lunt
robbie.lunt@biodesix.com
1-866-432-5930

Investors:

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

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