



bioAffinity Technologies Adds to Growing Number of Case Studies Demonstrating Clinical Value of CyPath® Lung

Noninvasive diagnostic test again leads to detecting Stage 1A lung cancer

SAN ANTONIO--(BUSINESS WIRE)-- [bioAffinity Technologies, Inc.](#) (Nasdaq: BIAF; BIAFW), a biotechnology company advancing noninvasive diagnostics for lung cancer and other lung diseases, today released three additional case studies – one in which use of CyPath® Lung led to detecting lung cancer at Stage 1A, its earliest and possibly curative stage, and two where risky invasive procedures were avoided for patients facing difficult healthcare choices.

“These three new cases, provided by a Texas pulmonologist who has been using CyPath® Lung for more than a year, reflect what we're hearing from many physicians – CyPath® Lung enhances clinical decision-making by personalizing care and playing a critical role in refining the diagnostic pathway,” said Dr. Gordon Downie, Chief Medical Officer of bioAffinity Technologies. “We believe CyPath® Lung can be a transformative tool in the lung cancer diagnostic pathway, especially when imaging results are inconclusive. A positive CyPath® Lung result can lead to earlier diagnosis and treatment, and a negative result can spare patients from unnecessary invasive procedures.”

Patient Case Study Highlights

Case Study “Samuel”: Prompting Action in a Hesitant Patient Led to Detecting Stage 1A Lung Cancer

This 68-year-old smoker's CT showed a 1.8 cm spiculated lesion in the right upper lobe. The nodule was categorized as suspicious but relatively low risk for malignancy. The patient was hesitant to undergo a biopsy. However, a positive CyPath® Lung result shifted the clinical picture, convincing him to proceed with biopsy. Pathology confirmed Stage 1A lung cancer, allowing for timely and potentially life-saving treatment. bioAffinity previously released three case studies detailed in the article [“From Uncertainty to Clarity and Confidence: Cases 5-7”](#) in which positive CyPath® Lung results led to detecting lung cancer at Stage 1A.

Case Study “David”: Avoiding Unnecessary Biopsy When the Path Forward is Otherwise Unclear

This patient's low-dose CT revealed a 1.2 x 0.5 cm nodule with associated lymphadenopathy (enlarged lymph nodes), leading to a Lung-RADS 4A classification, a suspicious but relatively low-risk prognosis. Though a biopsy was considered, CyPath® Lung returned a negative result, suggesting a low likelihood of cancer. The patient was comfortable being followed, as per the practice's lung nodule algorithm, with 3-month serial

CT scans.

Case Study “Lisa”: A Positive CyPath® Lung Result Leads to Radiation Treatment for a Patient with a History of Lung Cancer when Biopsy Posed Significant Risk

With a history of end-stage COPD and a previous diagnosis of lung cancer, this patient's incidental CT finding of a pulmonary nodule presented a complex decision: pursue a risky biopsy on a patient who may not be healthy enough for the procedure or monitor the nodule over time to determine if it grows. A positive CyPath® Lung result gave the patient's care team the confidence to proceed with radiation therapy without performing a biopsy. One year later, the lesion remains stable.

Maria Zannes, President and Chief Executive Officer of bioAffinity Technologies, said, “As more and more physicians use CyPath® Lung, it is both gratifying and humbling to see how our test can help patients and their physicians navigate the diagnostic uncertainty that often surrounds the increasing number of indeterminate, small pulmonary nodules found by imaging.”

About CyPath® Lung

CyPath® Lung uses proprietary advanced flow cytometry and artificial intelligence (AI) to identify cell populations in patient sputum that indicate malignancy. Automated data analysis helps determine if cancer is present or if the patient is cancer-free. CyPath® Lung incorporates a fluorescent porphyrin that is preferentially taken up by cancer and cancer-related cells. [Clinical study results](#) demonstrated that CyPath® Lung had 92% sensitivity, 87% specificity and 88% accuracy in detecting lung cancer in patients at high risk for the disease who had small lung nodules less than 20 millimeters. Diagnosing and treating early-stage lung cancer can improve outcomes and increase patient survival. For more information, visit www.cypathlung.com.

About bioAffinity Technologies, Inc.

bioAffinity Technologies, Inc. addresses the need for noninvasive diagnosis of early-stage cancer and other diseases of the lung and broad-spectrum cancer treatments. The Company's first product, [CyPath® Lung](#), is a noninvasive test that has shown high sensitivity, specificity and accuracy for the detection of early-stage lung cancer. CyPath® Lung is marketed as a Laboratory Developed Test (LDT) by [Precision Pathology Laboratory Services](#), a subsidiary of bioAffinity Technologies. For more information, visit www.bioaffinitytech.com.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements" within the meaning of the federal securities laws. Words such as "may," "might," "will," "should," "believe," "expect," "anticipate," "estimate," "continue," "predict," "forecast," "project," "plan," "intend" or similar expressions, or statements regarding intent, belief, or current expectations, are forward-looking statements. These forward-looking statements are based upon current estimates and assumptions and include statements regarding the ability of CyPath® Lung to identify lung cancer in difficult-to-diagnose patients, the benefits of adding CyPath® Lung to the standard of care for evaluating indeterminate lung nodules, and CyPath® Lung providing clarity when imaging and risk models are inconclusive. These forward-looking statements are subject to various risks and uncertainties, many of which are difficult to predict, that could cause actual results to differ materially from current expectations and assumptions from those set forth or implied by any forward-looking

statements. Important factors that could cause actual results to differ materially from current expectations include, among others, the ability of CyPath® Lung to identify lung cancer in difficult-to-diagnose patients, the benefits of adding CyPath® Lung to the standard of care for evaluating indeterminate lung nodules, CyPath® Lung providing clarity when imaging and risk models are inconclusive, and the other factors discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2024, and its subsequent filings with the SEC, including subsequent periodic reports on Forms 10-Q and 8-K. Such forward-looking statements are based on facts and conditions as they exist at the time such statements are made and predictions as to future facts and conditions. While the Company believes these forward-looking statements are reasonable, readers of this press release are cautioned not to place undue reliance on any forward-looking statements. The information in this release is provided only as of the date of this release, and the Company does not undertake any obligation to update any forward-looking statement relating to matters discussed in this press release, except as may be required by applicable securities laws.

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