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Case Study: CyPath® Lung Detects Neuroendocrine Tumor Missed by Other Diagnostic Tools

bioAffinity Technologies' noninvasive sputum test flagged difficult-to-diagnose cancer at earliest Stage 1A

SAN ANTONIO--(BUSINESS WIRE)-- **bioAffinity Technologies, Inc. (Nasdaq: BIAF; BIAFW)**, a biotechnology company addressing the need for noninvasive, accurate tests for the detection of early-stage cancer, today released a compelling new case study in which CyPath® Lung identified a Stage 1A neuroendocrine tumor in the patient's lung after PET scan, bronchoscopies and a serum tumor marker test suggested it was non-cancerous inflammation.

"We believe that this patient's experience demonstrates the high added value that CyPath® Lung brings to the diagnostic pathway. Multiple procedures and diagnostic tools were inconclusive, failing to identify the 13mm lung nodule as cancer," said Gordon Downie, MD, PhD, bioAffinity Technologies' Chief Medical Officer. "So when her CyPath® Lung test returned a 'likely cancer' result, it clarified appropriate next steps. The end result was surgical removal of a Stage 1A neuroendocrine tumor, a cancer type that can be difficult to detect by imaging and bronchoscopy alone, early enough for potentially life-saving treatment."

The female patient, an 80-year-old former smoker, had less than a 15-pack-year history and quit smoking in 1999. She had stable pulmonary function until a COVID-19 infection left her with asthma symptoms, including wheezing, coughing and shortness of breath, which responded to inhalers. A low dose CT in October 2023 revealed a 13mm nodule in the right lower lobe, but a PET scan showed low metabolic activity and risk models placed the likelihood of malignancy around 16%.

Initial diagnostic workups – including bronchoscopy and serum markers – indicated inflammation or infection without malignancy, and the patient was placed on a surveillance plan with antibiotics and asthma management. Follow-up LDCT scans in January and July 2024 were stable.

In early 2025, a new upper respiratory infection prompted repeat imaging, which showed that the nodule was growing. A second bronchoscopy again returned no evidence of malignancy. Her physician ordered CyPath® Lung for further risk assessment. The CyPath® Lung test, reported on March 4, 2025, returned a high score of 0.72, indicating the likelihood of cancer.

Based on the CyPath® Lung result, the patient was referred for robotic wedge resection in

June 2025, and pathology confirmed a Stage 1A neuroendocrine tumor.

“We believe that this case underscores CyPath® Lung’s growing importance as an essential adjunct to low-dose CT scans for patients with indeterminate pulmonary nodules when imaging and traditional tools leave questions unanswered,” bioAffinity Technologies President and CEO Maria Zannes said.

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 indicate a high probability of lung cancer, 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 and when other adjuvant diagnostics are contraindicated. 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 indicate a high probability of lung cancer, 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 and when other adjuvant diagnostics are contraindicated, 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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