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Case Study: bioAffinity Technologies' Positive CyPath® Lung Result Leads to Detecting Breast Cancer Recurrence

Case Demonstrates CyPath® Lung's Potential in Guiding Oncological Care

SAN ANTONIO--(BUSINESS WIRE)-- [bioAffinity Technologies, Inc. \(Nasdaq: BIAF; BIAFW\)](#) today released a [study](#) of a complex clinical case in which [CyPath® Lung's](#) real-time assessment of the lung microenvironment identified a hidden recurrence of breast cancer in an 80-year-old high-risk patient.

"This case exemplifies how CyPath® Lung can play a crucial role not only in lung cancer diagnostics but also in broader oncological decision-making, helping to guide clinical strategies and improve patient outcomes while reducing risky invasive procedures," bioAffinity Technologies' President and Chief Executive Officer Maria Zannes said.

The patient, a former smoker with COPD who was treated successfully for breast cancer in 2019, was under surveillance for lung cancer due to her history. A routine low-dose CT scan detected indeterminate nodules, including an eight-millimeter non-calcified nodule in her left upper lung lobe. "Given her risk factors and the fact that I've been following her with CT scans, this finding was very worrisome," Gordon H. Downie, MD, PhD, Director of the Pulmonary Nodule Clinic at Titus Regional Medical Center in Mount Pleasant, Texas, said.

Traditional diagnostic approaches presented challenges. A PET scan was unlikely to provide clarity due to the lesion's small size, and serum markers were contraindicated because of her prior cancer. "The CyPath® Lung test afforded me the ability in real time to assess a small nodule in a high-risk patient," Dr. Downie said. "The result was likely malignant which launched an aggressive, forward-looking diagnostic approach."

Recognizing the patient's history, her care team conducted a follow-up mammogram, which revealed a new breast cancer confirmed by biopsy.

"Each case study underscores the benefit of adding CyPath® Lung to the standard of care for evaluating indeterminate lung nodules," Zannes said. "By providing earlier and more accurate diagnostic insights, CyPath® Lung can help reduce the need for costly, invasive follow-up procedures, ultimately lowering healthcare costs while improving patient outcomes. This growing body of evidence strengthens the case for broader adoption of CyPath® Lung, highlighting the significant financial and clinical benefits of our technology."

A [study](#) published in the Journal of Health Economics Outcomes and Research and authored by pulmonologists Michael Morris, MD, and Sheila Habib, MD, found that an average cost savings of \$2,773 per patient would have been achieved in 2022 if CyPath®

Lung had been part of the standard of care for Medicare patients with a positive lung cancer screening, for a total of \$379 million. The study attributes the savings to a reduction in follow-up diagnostic assessments, expensive follow-up procedures and procedure-related complications. The study also found that adding CyPath® Lung to the standard of care for private-payer patients with a positive lung cancer screening result could have saved even more, an average of \$6,460 per patient, an estimated total savings of \$895 million if all individuals screened in 2022 were covered by private insurance.

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 CyPath® Lung playing a crucial role in lung cancer diagnostics and broader oncological decision-making, helping to guide clinical strategies and improve patient outcomes while reducing risky invasive procedures, and adding CyPath® Lung to the standard of care for indeterminate nodules lowering healthcare costs for both Medicare and private payers. 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 increase diagnostic accuracy, lower healthcare costs, and the other factors discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, 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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