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Case Study: bioAffinity Technologies' CyPath® Lung Detects Second Primary Lung Cancer in Patient With History of Lung Cancer

Case Demonstrates Benefit of Integrating CyPath® Lung into Standard of Care for Patients Under Surveillance After Treatment for Previous Lung Cancer

SAN ANTONIO--(BUSINESS WIRE)-- **bioAffinity Technologies, Inc. (Nasdaq: BIAF; BIAFW)** today released a case study in which a positive CyPath® Lung result led to the detection of a second primary lung cancer in a high-risk patient who was previously diagnosed with stage 1A non-small cell lung cancer and underwent successful surgery in 2023.

"The CyPath® Lung test provided real-time information that was pivotal in identifying a second primary lung cancer, which might have been missed with standard follow-up protocols," bioAffinity Technologies President and CEO Maria Zannes said. "This case underscores the test's potential to significantly impact patient outcomes by enabling early and accurate detection, especially when imaging reveals small indeterminate nodules that would not immediately lead to invasive diagnostic procedures."

The patient is a 72-year-old with a 50 pack-year smoking history and significant COPD and chronic respiratory failure who had a wedge resection to remove a non-small cell lung cancer tumor. Postoperative surveillance included regular computed tomography (CT) scans that revealed changes in the scar tissue, raising concerns about potential recurrence.

"Subtle changes post-op are common and present a diagnostic dilemma. Due to her previous cancer diagnosis, serum markers were contra-indicated, and a PET scan may be inconclusive on smaller nodules," said Gordon H. Downie, MD, PhD, Director of the Pulmonary Nodule Clinic at Titus Regional Medical Center in Mount Pleasant, Texas. "But now we have CyPath® Lung. Her CyPath® result came back as likely cancer, which told me in real time that there were new malignant cells in her lungs."

Prompted by the CyPath® score, Dr. Downie ordered a PET scan that revealed significant avidity in the mediastinum and right hilum, along with a new nodule in the right upper lung. A subsequent bronchoscopy confirmed a diagnosis of small cell carcinoma, distinct from the initial NSCLC. This early detection facilitated timely and appropriate treatment for the second primary cancer.

“Each case study illustrates how CyPath® Lung provides actionable information to the physician who can then move forward in the best interest of each patient,” Ms. Zannes said. “By providing earlier and more accurate diagnostic insights, CyPath® Lung improves patient outcomes that can lead to lower healthcare costs for both public and private insurers. We are seeing both clinical and financial benefits with the broader adoption of CyPath® Lung.”

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. 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. The study attributes the savings to a reduction in follow-up diagnostic assessments, expensive follow-up procedures and procedure-related complications.

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’s potential to significantly impact patient outcomes by enabling early and accurate detection,

especially when imaging reveals small indeterminate nodules that would not immediately lead to invasive diagnostic procedures; and CyPath® Lung improving patient outcomes that can lead to lower healthcare costs for both public and private insurers with projected cost savings of $2,773 per Medicare patient and $6,460 per private payer patient, an estimated total savings of $895 million if all individuals screened in 2022 were covered by private insurance. 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 significantly impact patient outcomes by enabling early and accurate detection, 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. 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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