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bioAffinity Technologies Announces Validation Study with Brooke Army Medical Center to Expand Sample Collection Options for the CyPath® Lung Noninvasive Early Detection Lung Cancer Test

Validating sample collection by deep suction has potential to accelerate and expand adoption of CyPath® Lung

SAN ANTONIO--(BUSINESS WIRE)-- **bioAffinity Technologies, Inc.** **(Nasdaq: BIAF; BIAFW)**, a biotechnology company focused on noninvasive diagnostics and early cancer detection, today announced a new study with Brooke Army Medical Center (BAMC) to validate the clinical utility of using the CyPath® Lung diagnostic test to assess sputum samples obtained by tracheal and bronchial suctioning for early detection of lung cancer.

The study is designed to enroll approximately 30-50 patients undergoing routine tracheal or bronchial suctioning, with results from the study expected by mid-year 2026. Validating the performance of CyPath® Lung analysis on deep suction samples has the potential to expand the versatility of CyPath® Lung and support broader use in the detection of early-stage lung cancer.

"CyPath® Lung is a novel, noninvasive adjuvant diagnostic for patients at high risk for lung cancer," said Michael J. Morris, MD, pulmonology and critical care physician at BAMC. "The ability to use CyPath® Lung to analyze suctioned sputum collected during bronchoscopy and other procedures would leverage samples that we are already obtaining and expand access to earlier, more informed decision-making for patients at risk."

"Clinicians who have patients scheduled to undergo diagnostic bronchoscopy have told us that CyPath® Lung could be very helpful by providing an independent and complementary test for diagnosis," said Gordon Downie, MD, PhD, Chief Medical Officer of bioAffinity Technologies. "Physicians tell us they need additional tools for diagnosing indeterminate lung nodules, and this study demonstrates that we are listening to the clinicians using CyPath® Lung and responding to their needs."

Under the standard protocol for the CyPath® Lung test, patients with suspicious pulmonary nodules collect a sputum sample at home and send the sample overnight to the lab for processing. The deep suction study is designed to expand the options for sample collection

by validating the use of CyPath® Lung with suctioned sputum samples, conducted in the clinic while patients undergo bronchial and tracheal suction procedures. Bronchial and tracheal suction may be used to clear airways and improve oxygenation. When used in conjunction with bronchoscopy, a suction catheter gently aspirates secretions from areas of concern within the lungs which can provide robust samples to obtain diagnostic information.

Bronchoscopy is used commonly in the United States, with approximately 500,000 procedures performed annually. The U.S. bronchoscopy procedure market, including devices and related technologies, is valued at $700–$920 million and continues to grow, driven by the rising prevalence of lung disease, including cancer and COPD, and adoption of innovative diagnostic tools. The CyPath® Lung study with BAMC will explore an approach that could expand the utility of bronchoscopy-collected samples for earlier, noninvasive lung cancer detection.

"BAMC is a leader in medical research with access to a large patient population representing the full range of pulmonary health," said Maria Zannes, President and CEO of bioAffinity Technologies. "We look forward to collaborating with BAMC and the potential to expand the reach of the AI-driven technology behind CyPath® Lung to detect lung cancer at the earliest, most treatable stage."

About Brooke Army Medical Center (BAMC)

Brooke Army Medical Center (BAMC), located at Joint Base San Antonio-Fort Sam Houston, Texas, is the United States Army's premier academic medical center and the Department of War's largest hospital. BAMC provides comprehensive inpatient and outpatient care to active-duty service members, veterans, their families, and civilian patients, supported by more than 8,000 military and civilian personnel. The center also serves as a teaching hospital and research institution with advanced specialty services, graduate medical education, and rehabilitation programs.

About CyPath® Lung

CyPath® Lung is a noninvasive test designed to improve the early detection of lung cancer in patients at high risk for the disease. CyPath® Lung uses advanced flow cytometry and proprietary artificial intelligence (AI) to identify cell populations in patient sputum that indicate malignancy. CyPath® Lung incorporates a fluorescent porphyrin that is preferentially taken up by cancer and cancer-related cells. Clinical study results demonstrated 92% sensitivity, 87% specificity and 88% accuracy in detecting lung cancer in patients at high risk for the disease who had small indeterminate lung nodules less than 20 millimeters.

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 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 timing, design, enrollment, conduct and anticipated results of the Brooke Army Medical Center study; the clinical utility, performance, versatility, or broader adoption or use of CyPath® Lung, including use with deep suction samples; the potential benefits, applications, market opportunity, or impact of CyPath® Lung or related technologies; 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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