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Independent White Paper Highlights Real-World Impact of bioAffinity Technologies' CyPath® Lung in Diagnosing Early-Stage Lung Cancer

Dr. Gordon Downie shares case-based evidence demonstrating how CyPath® Lung improves diagnostic confidence and guides care in high-risk patients

SAN ANTONIO--(BUSINESS WIRE)-- [bioAffinity Technologies, Inc. \(Nasdaq: BIAF; BIAFW\)](#), a biotechnology company focused on the need for noninvasive, accurate tests for the detection of early-stage lung cancer, today announced the release of a white paper authored by Dr. Gordon Downie, MD, PhD, Director of the Lung Nodule Clinic and Interventional Pulmonology at Titus Regional Medical Center.

The paper, titled "[CyPath® Lung in Practice: Cases 1-4](#)," details real-world clinical cases in which [CyPath® Lung](#), a noninvasive sputum-based test, significantly influenced clinical decision-making for patients with indeterminate pulmonary nodules. A majority of nodules discovered incidentally or through low dose CT screening programs are less than 20 mm. They are considered indeterminate if they cannot be definitively classified as malignant or benign based on imaging alone.

"Over the past year, CyPath® Lung has become an active component in our clinical assessment of newly discovered non-calcified pulmonary nodules. It has accelerated diagnosis, helped guide difficult clinical discussions, and prevented unnecessary invasive procedures," Dr. Downie said.

The white paper presents four cases involving high-risk patients, including those with:

- Sub-8 mm nodules in hard-to-biopsy locations
- A prior cancer history complicating imaging interpretation
- Post-COVID pulmonary changes and indeterminate PET scans
- A previous lung cancer diagnosis with new suspicious imaging findings

In each scenario, CyPath® Lung played a pivotal role in determining next steps for patients ranging from the active surveillance of the "watch and wait" approach to more proactive invasive procedures that carry their own risks.

"As more high-risk patients are screened, we are seeing an explosion in lung nodules, 98% of which we know are benign. But we don't want to miss that remaining 2%," Dr. Downie said. "Adding CyPath® Lung as an adjuvant after imaging by low dose CT and PET provides real-time information about the likelihood of malignancy. Now my patients and I can make a

more informed decision about whether to continue to monitor the nodules or proceed with further evaluation, including biopsy.”

“Dr. Downie’s clinical insights and impactful white paper confirm the value of adding CyPath® Lung to the standard of care for physicians navigating the complexities of pulmonary nodules in high-risk patients,” said Maria Zannes, President and CEO of bioAffinity Technologies. “We are most appreciative of him sharing his experience with CyPath® Lung by highlighting the impact on real people with very real feelings and fears around the subject of cancer.”

The full white paper is available on www.cypathlung.com.

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 physicians using CyPath® Lung to make more informed decisions about whether to continue to monitor lung nodules or proceed with further evaluation, including biopsy. 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 to continue to confirm the value of adding CyPath® Lung to the standard of care for physicians navigating the complexities of pulmonary nodules in high-risk

patients 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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