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bioAffinity Technologies Announces Notification of Allowance for U.S. Patent Application for Its Diagnostic Algorithm and Test Method for Lung Cancer

U.S. award protects AI-built platform and adds to growing international patent portfolio

SAN ANTONIO, Texas--(BUSINESS WIRE)-- **bioAffinity Technologies, Inc. (Nasdaq: BIAF; BIAFW),** a biotechnology company advancing early-stage cancer diagnostics including CyPath® Lung, the Company's commercially available test for early-stage lung cancer, today announced it has received a notification of allowance from the United States Patent and Trademark Office (USPTO) for a new patent covering the AI-built algorithm and flow cytometry platform that analyzes cell populations in sputum leading to detection of lung cancer.

"Artificial intelligence was integral to the development of our CyPath® Lung test and has resulted in the detection of lung cancer at its earliest Stage 1A, a potentially curative stage," said Maria Zannes, President and CEO of bioAffinity Technologies. "A quarter of a million Americans are expected to receive a lung cancer diagnosis in 2025, representing the leading cause of cancer death. Harnessing AI with our novel flow cytometry platform has resulted in a diagnostic that produces high-precision, standardized, data-driven results."

The patent, titled "*Detection of Early-Stage Lung Cancer in Sputum using Automated Flow Cytometry and Machine Learning,*" covers a system and method for predicting the likelihood of lung cancer by analyzing patient sputum samples. CyPath® Lung's advanced flow cytometry process detects changes in the lung linked to cancer, including populations of immune cells, apoptotic cells and cancer and cancer-related cells labeled by the Company's proprietary TCPP porphyrin. CyPath® Lung's AI-driven analysis combines these variables with patient age to predict cancer in the lung.

CyPath® Lung can be utilized by physicians to determine next steps for patients with pulmonary nodules requiring follow-up. The noninvasive test is designed to perform with high sensitivity and specificity and seeks to deliver valuable diagnostic insight while alleviating patient anxiety, preventing unnecessary invasive procedures and reducing costs to the healthcare system.

This newly allowed U.S. patent complements bioAffinity's expanding global patent estate, which now includes 18 awarded and 33 pending patents. bioAffinity Technologies holds patents in the U.S., Canada, China, France, Germany, Hong Kong, Italy, Japan, Mexico,

Spain, Sweden, and the United Kingdom.

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 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 benefits to be derived from the patent, the Company's ability to safeguard its intellectual property, the effectiveness of its AI-based technology, the ability of CyPath® Lung to identify lung cancer, 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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