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AMA Issues CPT Code for bioAffinity Technologies' CyPath® Lung Test for Early-Stage Lung Cancer

SAN ANTONIO, Texas--(BUSINESS WIRE)-- [bioAffinity Technologies, Inc. \(Nasdaq: BIAF; BIAFW\)](#), a biotechnology company addressing the need for noninvasive detection of early-stage lung cancer, today announced that the American Medical Association (AMA) has released a Current Procedural Terminology (CPT) code specifically for use with CyPath® Lung, a noninvasive test for early-stage lung cancer.

Created and maintained by the AMA's independent CPT Editorial Panel, CPT codes provide a uniform system to identify medical services and procedures and seek reimbursement from private payers and public health insurance programs, including Medicare and Medicaid. The [reimbursement code for CyPath® Lung](#) will be effective Oct. 1, 2023.

"Our mission is to detect cancer at an early stage to improve long-term survival. The AMA's approval of a CPT code specific to CyPath® Lung is an important milestone along that path," bioAffinity Technologies President and CEO Maria Zannes said. "We believe the CPT code is recognition by clinical and industry experts that our noninvasive test is an innovative addition to current clinical practice for patients at high risk for developing lung cancer."

Marketed by [Precision Pathology Services](#) as a laboratory developed test (LDT), CyPath® Lung uses flow cytometry and automated analysis to profile patient sputum samples to reliably predict the presence of lung cancer. CyPath® Lung incorporates a fluorescent porphyrin, TCPP, that is preferentially taken up by cancer and cancer-related cells. In a recent [clinical trial](#), CyPath® Lung showed 92% sensitivity and 87% specificity in high-risk patients who had lung nodules smaller than 20 millimeters.

When a low dose computed tomography (LDCT) scan reveals nodules smaller than 20 millimeters, doctors and patients may not have a clear path forward. The common choices are to "wait and see" what the next scan reveals or proceed with an invasive procedure, including biopsy, that may turn out to be unnecessary.

"The AMA's recognition of CyPath® Lung reflects the need for noninvasive and accurate follow-up in patient care after lung cancer screening," Ms. Zannes said. "Actionable results from our test will help doctors and their patients determine appropriate next steps for suspected cases of lung cancer."

The CyPath® Lung CPT code was approved as a Proprietary Laboratory Analyses (PLA) code, which can be provided by a single laboratory or licensed or marketed to multiple

providing laboratories. CyPath[®] Lung is currently available through [Precision Pathology Services](#), an accredited CAP/CLIA laboratory in San Antonio, Texas.

About bioAffinity Technologies, Inc.

bioAffinity Technologies, Inc. addresses the need for noninvasive diagnosis of early-stage cancer and diseases of the lung, and targeted cancer treatment. The Company's first product, [CyPath[®] Lung](#), is a noninvasive test that has shown high sensitivity and specificity for the detection of early-stage lung cancer. CyPath[®] Lung is marketed as a laboratory developed test (LDT) by [Precision Pathology Services](#). OncoSelect[®] Therapeutics, LLC, a subsidiary of bioAffinity Technologies, is advancing its discoveries shown in vitro to kill cancer cells without harm to normal cells. Research and optimization of the Company's platform technologies are conducted in its laboratories at The University of Texas at San Antonio. 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 detecting cancer at an early stage in order to improve long-term survival, the AMA's approval of a CPT code specific to CyPath[®] Lung being recognition by clinical and industry experts that the Company's test is an innovative addition to current clinical practice for patients at high risk for developing lung cancer, and actionable results from the Company's test will help doctors and their patients determine appropriate next steps for suspected cases of lung cancer. 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 the Company's test to produce actionable results to help doctors and their patients determine appropriate next steps for suspected cases of lung cancer and the other factors discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, 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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