November 30, 2023

CMS Posts Final Payment Determination for bioAffinity Technologies' CyPath® Lung Effective January 2024

SAN ANTONIO,--(BUSINESS WIRE)-- **bioAffinity Technologies, Inc. (Nasdaq: BIAF; BIAFW),** a biotechnology company addressing the need for noninvasive detection of early-stage lung cancer and other lung diseases, today announced that the Centers for Medicare and Medicaid Services (CMS) has made a final determination for payment for CyPath® Lung, a noninvasive test for early-stage lung cancer, for the 2024 calendar year.

"CyPath® Lung, our noninvasive test for the detection of early-stage lung cancer, is now on CMS' 2024 clinical laboratory fee schedule, a major milestone that facilitates reimbursement by both Medicare and private payers, which in turn should make our test even more attractive to both physicians and their patients at high risk for lung cancer," bioAffinity Technologies President and CEO Maria Zannes said. "The CMS payment determination is an important achievement in our strategic plan to ramp up the commercialization of CyPath® Lung."

Based on the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests recommendation, CMS previously released a preliminary payment decision for the Current Procedural Terminology (CPT) code specific to CyPath® Lung. For the calendar year 2024 Medicare Clinical Lab Fee Schedule, CMS finalized the panel's recommendation for CyPath® Lung for purposes of payment by Medicare. This payment information also serves as a reference for private payers and other public health insurance programs.

In June 2023, the American Medical Association (AMA) issued the CPT Proprietary Laboratory Analyses (PLA) code 0406U for CyPath® Lung with the descriptor "Oncology (lung), flow cytometry, sputum, 5 markers (meso-tetra [4- carboxyphenyl] porphyrin [TCPP], CD206, CD66b, CD3, CD19), algorithm reported as likelihood of lung cancer." CMS released a preliminary payment decision in September 2023, agreeing with the Medicare Advisory Panel's recommendation. In November 2023, CMS finalized the 2024 payment determination for CPT 0406U, effective January 1, 2024.

Physicians can order CyPath® Lung from Precision Pathology Laboratory Services, a subsidiary of bioAffinity Technologies. CyPath® Lung, a laboratory developed test (LDT), uses flow cytometry to identify cell populations in patient sputum that indicate malignancy. Automated data analysis developed using proprietary artificial intelligence can help determine if cancer is present or if the patient is cancer-free. CyPath® Lung incorporates a fluorescent porphyrin, TCPP, that is preferentially taken up by cancer and cancer-related cells. In a clinical trial, CyPath® Lung showed 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. Half of all patients in the trial who had cancer were diagnosed in early Stages I or II.

The discovery of small pulmonary nodules as part of annual lung cancer screening using low dose computed tomography (LDCT) can be problematic to diagnose. Patients may be asked to “wait and see” if the next scan reveals the nodule has grown or proceed immediately with invasive procedures, including biopsy, that may turn out to be unnecessary. “Actionable results from CyPath® Lung may help doctors and their patients determine appropriate next steps for suspected cases of lung cancer,” Ms. Zannes said.

About bioAffinity Technologies, Inc.
bioAffinity Technologies, Inc. addresses the need for noninvasive diagnosis of early-stage cancer and 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. Research and optimization of the Company’s platform technologies are conducted in its laboratories at Precision Pathology and The University of Texas at San Antonio. For more information, visit www.bioaffinitytech.com and follow us on LinkedIn, Facebook and X.

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 CMS’ 2024 clinical laboratory fee schedule making the Company’s test even more attractive to both physicians and their patients at high risk for lung cancer and CyPath® Lung helping 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 to benefit from the 2024 payment determination for CPT 0406U, 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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