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bioAffinity Technologies Launches New Study To Expand Use of CyPath® Lung Technology for Asthma and COPD Diagnosis and Treatment

Collaboration with nation's largest military medical center focuses on bioAffinity Technologies' pipeline of solutions to address debilitating respiratory diseases

Study to explore the potential for proprietary flow cytometry+AI diagnostic tests targeting the asthma and COPD treatment market estimated at $92 billion[1]

SAN ANTONIO--(BUSINESS WIRE)-- **bioAffinity Technologies, Inc. (Nasdaq: BIAF; BIAFW)**, a biotechnology company advancing noninvasive diagnostics for lung cancer and other lung diseases, today announced a pilot study with Brooke Army Medical Center (BAMC) to evaluate the Company's proprietary tests under development to identify specific inflammatory biomarkers for asthma and chronic obstructive pulmonary disease (COPD). The study could lead to the development of diagnostic tests designed to help align patients with the most effective treatments and help monitor the drugs' effectiveness over time.

The research collaboration with BAMC builds on bioAffinity Technologies' research pipeline, leveraging its proprietary flow cytometry+AI technology to develop precision diagnostics and treatments for common airway diseases by assessing the extent and type of lung inflammation.

"We have made tremendous strides over the last decade in our understanding of the pathophysiology of asthma and COPD," said John J. Oppenheimer, MD, a leading authority on the diagnosis and treatment of asthma and COPD and professor at the University of Medicine and Dentistry of New Jersey-Rutgers. Dr. Oppenheimer also sits on the bioAffinity Technologies Board of Directors. "Emerging tools – such as bioAffinity's cytometry+AI platform – will likely accelerate this progress by enabling direct assessment of a patient's inflammatory milieu within the lung. With this level of resolution, we can better stratify the risk of disease progression and more accurately match the right medicine to the right patient."

The study will enroll approximately 40 participants in three cohorts: patients with asthma, patients with COPD and a healthy control group. The objective of the study is to use automated analysis of sputum samples collected from patients with asthma and COPD to identify and measure select immune cell populations and cytokines in sputum that can direct treatment and monitor the effectiveness of therapies.

Asthma is not a single disease. It includes multiple inflammatory subtypes. In military personnel, asthma is generally not the classic allergic form seen in civilian populations, making diagnosis and treatment more challenging. Service members are exposed to a wide range of environmental, occupational and deployment-related hazards that can fundamentally alter how asthma presents and progresses.

“Our flow cytometry platform provides a novel, noninvasive way to assess lung inflammation at the cellular level,” said Gordon Downie, MD, PhD, bioAffinity Technologies’ Chief Medical Officer. “By identifying a broader panel of inflammatory biomarkers, we hope to help shift asthma and COPD management toward a precision medicine model, where treatment is guided by each patient’s unique inflammatory signature rather than a one-size-fits-all approach. Our technology also has the potential to help physicians monitor treatment response over time, improving patient outcomes.”

The goal of the BAMC study is to determine whether the Company’s lung inflammation tests, including flow cytometry and enzyme-linked immunosorbent assay (ELISA) analysis, can help physicians tailor more effective treatment strategies for asthma and COPD. In the military context, a safe, reliable noninvasive way to assess lung inflammation could positively impact readiness and deployment decisions as well as long-term respiratory health outcomes for service members and veterans.

About CyPath® Lung

CyPath® Lung by bioAffinity Technologies 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. In a clinical trial of high-risk patients, CyPath® Lung demonstrated 92% sensitivity, 87% specificity, 88% accuracy and 99% negative predictive value (NPV) in detecting lung cancer in patients at high risk for the disease who had small indeterminate lung nodules less than 20 millimeters. The high NPV gives physicians greater confidence that a negative result is truly negative, potentially sparing patients from unnecessary invasive and costly procedures. CyPath® Lung is marketed as a Laboratory Developed Test (LDT) and is not intended for use as a sole diagnostic tool and should be considered alongside other clinical findings.

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. LDTs are overseen under the Clinical Laboratory Improvement Amendments (CLIA), administered by the Centers for Medicare & Medicaid Services. 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 early stage of the Company's asthma and COPD study and the uncertainty of its results; the ability to develop and commercialize new diagnostic tests; the regulatory status of the Company's products, including the evolving regulatory framework for Laboratory Developed Tests and the potential for increased FDA oversight; the need to obtain regulatory clearances or approvals for future products, including any companion diagnostics; the Company's ability to enroll participants in clinical studies; the Company's reliance on third-party collaborators, including military medical institutions; the competitive landscape for respiratory diagnostics; the Company's ability to protect its intellectual property; and the other factors discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2025, 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.

[1] Grand View Research, COPD And Asthma Therapeutics Market (2025 - 2030)

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bioAffinity Technologies
Julie Anne Overton
Director of Communications
investors@bioaffinitytech.com

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