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Peer-Reviewed Study: bioAffinity Technologies' CyPath® Lung Test Shows Potential Significant Healthcare Savings by Reducing Unnecessary Follow-Up, Medical Complications and Overdiagnosis

Study by BAMC's Michael Morris, M.D., and VA's Sheila Habib, M.D., evaluated potential economic impact of CyPath® Lung for the early detection of lung cancer

SAN ANTONIO, Texas--(BUSINESS WIRE)-- A new economic study found that adding CyPath® Lung, bioAffinity Technologies' noninvasive test for detection of early-stage lung cancer, to the standard of care for **Medicare patients** with a positive lung cancer screening could have saved an average of $2,773 per patient for total cost savings of $379 million in 2022. The peer-reviewed study, "Economic Evaluation of a Novel Lung Cancer Diagnostic in a Population of Patients with a Positive Low-Dose Computed Tomography Result," attributes the savings to a reduction in follow-up diagnostic assessments, expensive follow-up procedures and procedure-related complications.

Michael J. Morris, M.D., Brooke Army Medical Center (BAMC) pulmonology and critical care physician and Assistant Dean of Research at San Antonio Uniformed Services Health Education Consortium (SAUSHEC), and Sheila A. Habib, M.D., Director of the Pulmonary Lung Nodule Clinic and the Lung Cancer Screening Program at the South Texas Veterans Health Care Systems' Audie L. Murphy Memorial Veterans Hospital and Assistant Professor at the University of Texas Health Science Center at San Antonio, were first and second authors on the study published in the Journal of Health Economics and Outcomes Research Economists John E. Schneider, Ph.D., and Maggie L. Do Valle, Master of Public Health, of Avalon Health Economics also contributed to the study.

The study found that adding CyPath® Lung to the standard of care for **private-payer patients** with a positive lung cancer screening result could have saved even more, an average of $6,460 per patient. A positive screening result was defined as finding a pulmonary nodule between 6 to 29 millimeters in size. The analysis estimated total healthcare savings of $895 million if all individuals screened in 2022 were covered by private insurance.

"Our study suggests the potential for a very positive economic impact on healthcare costs with the widespread use of CyPath® Lung in the early diagnosis of lung cancer," Dr. Morris said. "CyPath® Lung closes a widely recognized gap in the screening and diagnosis of lung cancer. From the patient perspective, it is noninvasive and easy to use. From the physician

perspective, CyPath® Lung's demonstrated high sensitivity, specificity and accuracy give us a clearer picture of how to proceed."

"Most important, integrating companion tests like CyPath® Lung into the standard of care for high-risk patients has the potential to help us diagnose lung cancer earlier when treatment is more effective, saving or extending lives," Dr. Habib said. "The study demonstrates CyPath® Lung's potential to improve outcomes by reducing delays in diagnosis and reducing both the number of unnecessary procedures and any medical complications they could cause."

Since the National Lung Cancer Screening Trial (NLCST) released initial findings in 2010, multiple studies similarly concluded that annual screening by low dose computed tomography (LDCT) for high-risk patients reduces lung cancer mortality. But LDCT also has a relatively low positive predictive value, and there is often not a clear diagnostic recommendation for smaller, indeterminate pulmonary nodules. 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 economic model used in the Morris, et al., study evaluated the impact of adding CyPath® Lung to the diagnostic pathway for individuals with a positive LDCT, including patients with a primary lung cancer diagnosis. Cost calculations included procedure expenses, the cost of complications and adverse events due to a procedure, and diagnostic assessment costs.

The study considers the likelihood of clinicians' use of five specific follow-up procedures based on published, peer-reviewed studies (CT, positron emission tomography (PET), CT-guided biopsy, bronchoscopy, and surgical biopsy), the documented rate of complications for each procedure, and the cost of post-procedure diagnostic assessments. The most common complications included pneumothorax, pneumothorax requiring a tube, and hemorrhage.

The economic model for the study assumed two cohorts: one in which all patients were covered by Medicare and one in which all patients were covered by commercial insurance. The total savings related to each cohort are not additive. An independent and validated source for the percentage of patients who had Medicare, private insurance or a combination of insurance coverage in 2022 was not available for the analysis.

Base prices for the Medicare analysis were based on Medicare 2023 national payment data by Current Procedural Terminology (CPT) codes, and costs for the private payer analysis were determined by using a 2.64 multiplier. The Medicare payment set by the Centers for Medicare and Medicaid Services (CMS) for the CPT code specific to CyPath® Lung was used in the study. The projected cost savings reported in the study are primarily due to reductions in follow-up diagnostic procedures after adding CyPath® Lung to the diagnostic pathway between screening and diagnostic follow-up procedures. bioAffinity Technologies funded the work of Avalon Health Economics. Dr. Morris and Dr. Habib were not compensated for their work on the study.

The views expressed in this press release do not necessarily reflect the official policy or position of the Defense Health Agency, the Department of Defense, the Veterans Health Administration, the Department of Veterans Affairs or any other government agencies.

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, meso-tetra (4-carboxyphenyl) porphyrin (TCPP), 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. (Nasdaq: BIAF) 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. 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 the potential economic impact of adding CyPath® Lung to the standard of care for patients with a positive lung cancer screening for an average of $2,773 per Medicare patient and an average of $6,460 per private-payer patient, total healthcare savings of $895 million if all individuals screened in 2022 were covered by private insurance, how integrating CyPath® Lung into the standard of care for high-risk patients has the potential to help diagnose lung cancer earlier when treatment is more effective, and CyPath® Lung's potential to improve outcomes by reducing delays in diagnosis and reducing both the number of unnecessary procedures and any medical complications they could cause. 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, CyPath® Lung's ability to generate cost savings and to help diagnose lung cancer earlier and the other factors discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, 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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