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Precision Pathology Services and bioAffinity Technologies Announce Initiation of CLIA Validation for Non-Invasive Early Lung Cancer Test

Precision Completes Development of CyPath® Lung and Starts CLIA Validation of Cancer Assay for Sale as a Laboratory Developed Test (LDT)

SAN ANTONIO--(BUSINESS WIRE)-- bioAffinity Technologies, a privately held biotech company advancing cutting-edge cancer diagnostics, and Precision Pathology Services, a CAP/CLIA-certified anatomic and clinical pathology laboratory, announced initiation of CLIA validation for CyPath® Lung, a non-invasive flow cytometric test for early-stage lung cancer. Precision Pathology has licensed bioAffinity's intellectual property for development of CyPath® Lung as a laboratory developed test (LDT).

"With our development phase complete, we are very pleased to start the validation studies for certification of the CyPath® Lung flow cytometry test as an LDT," said Roby Joyce, MD, President of Precision Pathology. "This is a very exciting time for us. Lung cancer is the leading cancer killer. Our test for early detection of this dreaded disease can help many people live longer and healthier lives."

The validation study is conducted in accordance with College of American Pathologists (CAP) guidelines and Clinical Laboratory Improvement Amendments (CLIA) regulations. The CAP/CLIA validation study is designed to establish and validate performance characteristics of CyPath® Lung, including accuracy, precision, reproducibility and analytical sensitivity, that are necessary for commercialization. Following CyPath® Lung certification as an LDT, physicians can order the test for their patients at high risk for lung cancer who receive a positive screening result or are otherwise suspected of having the disease.

"Precision Pathology rightfully enjoys an excellent reputation for quick turnaround times while providing accurate pathology diagnoses. The company is known for its exceptionally responsive and helpful service to the physicians and patients it serves," bioAffinity President Maria Zannes said. "Dr. Joyce and his team will bring the same very high quality to CAP/CLIA validation of CyPath® Lung and its eventual sale later this year. CyPath® Lung is in excellent hands."

CyPath® Lung is a flow cytometric test to aid in the diagnosis of lung cancer. Patients collect sputum samples non-invasively at home, a particular benefit during the COVID-19 pandemic. The sample is shipped overnight to the laboratory for processing. Sample data is acquired by flow cytometry, a technique that can count, sort and profile individual cells with

remarkable speed. Using an automated analysis with pre-set parameters, CyPath® Lung profiles the lung environment including the presence of cancer-associated cells. Data acquisition and physician reports can be generated in minutes.

In a recent CyPath® Lung test validation trial of 150 individuals at high risk for lung cancer including 28 people with diagnosed cancer, the test showed 88% specificity and 82% sensitivity, a positive predictive value of 62% and a negative predictive value of 95%. The test was 87% specific and 92% sensitive in detecting cancer in participants who had nodules of less than 20 mm in diameter, indicating CyPath® Lung is highly accurate in finding lung cancer in its earliest stages.

The U.S. Preventive Services Task Force recommends that smokers and former smokers at high risk for lung cancer undergo annual screening by low dose computed tomography (LDCT). Screening by LDCT has been proven to detect lung cancer at earlier stages when it can be more successfully treated. The National Lung Cancer Screening Trial (NLCST) of more than 53,000 participants resulted in a 20% decrease in lung cancer-specific mortality when LDCT screening was performed in high-risk patients. However, screening by LDCT had a low 3.8% positive predictive value (PPV) which raises the risk of unnecessary, invasive and costly procedures for those who test positive. In the NLCST, for every 100 people who received a positive LDCT, less than four of those individuals actually had lung cancer.

“CyPath® Lung can assist physicians in determining next steps after a patient presents with a positive LDCT result, particularly in many cases where the lung nodule is considered indeterminate. In our test validation trial, bioAffinity successfully tested the automated analysis program used by CyPath® Lung and found it to be fast and very robust in predicting who has cancer and who was at high risk but did not have lung cancer,” Zannes said. “Physician reports can be generated immediately after flow cytometry acquires sample data in approximately 20 minutes per sample. Looking beyond lung cancer, we believe our automated platform can be successfully applied to cancer diagnostic tests for several other cancers, which will improve overall survival rates for patients through early diagnosis and treatment. We look forward to working with Precision Pathology in the development of additional life-saving diagnostic tests.”

About Precision Pathology Services

The board-certified pathologists practicing at Precision Pathology Services and Village Oaks Pathology Services, PA, have provided anatomic and clinical pathology services for patients and their physicians since 1986. The Company is committed to bringing a spirit of excellence to all its services, remembering that every specimen has come from someone’s loved one and requires precise diagnosis every time and as quickly as possible. Precision Pathology Services is known for exceptionally responsive and helpful service to the physicians and patients.

About bioAffinity Technologies, Inc.

bioAffinity Technologies, Inc. is a privately held company addressing the significant unmet need for non-invasive, early-stage cancer diagnosis and treatment. The Company develops proprietary *in vitro* diagnostic tests and targeted cancer therapeutics using breakthrough technology that preferentially targets cancer cells. Research and optimization of its platform

technology are conducted in bioAffinity Technologies' laboratories at the University of Texas San Antonio (UTSA). The Company's platform technology is being developed to diagnose, monitor and treat many cancers.

FAQ: Answers to Questions about CyPath® Lung

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