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bioAffinity Licenses CyPath® Lung to Precision Pathology Services

SAN ANTONIO, Oct. 10, 2018 (GLOBE NEWSWIRE) -- bioAffinity Technologies, a privately held biotech company, today announced a licensing agreement with Precision Pathology Services for the continued development and commercial sale of CyPath® Lung as a Laboratory Developed Test (LDT) for the diagnosis of early stage lung cancer.

bioAffinity currently is conducting a test validation trial of CyPath® Lung to confirm the differential characteristics between sputum samples collected from three participant cohorts, including patients with lung cancer, high-risk participants without lung cancer and healthy individuals with no or minimal smoking history who are cancer-free. The study will be completed and results presented prior to commercialization expected in early 2019.

“CyPath® Lung will provide clinicians and patients with an accurate, affordable and non-invasive assay to confirm a lung cancer diagnosis in the early stages of the disease when it is most treatable,” said Dr. Roby Joyce, President and Medical Director of Precision Pathology. “We are looking forward to partnering with bioAffinity to bring this valuable tool to market to save lives, ease patient anxiety and reduce health care costs in a meaningful way.”

Accredited by the College of American Pathologists (CAP) and certified under the Clinical Laboratory Improvement Amendments (CLIA), San Antonio-based Precision Pathology operates under the highest standards of quality, accuracy and consistency under a team of board-certified pathologists.

Precision Pathology will offer CyPath® Lung to clinicians and their patients to assist with diagnosis after a positive result from low dose computed tomography (LDCT) screening. LDCT has a high false-positive rate of 96.4 percent that can lead to invasive and expensive follow-up, including PET scans, bronchoscopy and lung biopsy to confirm a lung cancer diagnosis. CyPath® Lung can lower the number of unnecessary invasive procedures.

The National Comprehensive Cancer Network, American Lung Association, American Association for Thoracic Surgery, American Society of Clinical Oncologists, American College of Chest Physicians, American Thoracic Society and the American Cancer Society all now recommend LDCT lung cancer screening for individuals at high risk for developing lung cancer. Medicare and many private insurers will cover the cost of screening.

An estimated 14 million Americans are at high risk for lung cancer. If all those at high risk are screened annually by LDCT, an estimated four million people would receive a positive result. Only four out of 100 people who receive a positive result will have lung cancer, according to the results of the National Lung Screening Trial. This means that of the four

million people who would receive a positive LDCT diagnosis, only 160,000 ultimately would be diagnosed with lung cancer.

“We are very pleased that Precision Pathology Services will license our technology and develop the CyPath® Lung test as a LDT for commercial sale by first-quarter 2019,” bioAffinity President and Chief Executive Officer Maria Zannes said. “We believe physicians will see the benefit of surer diagnosis, earlier disease detection and fewer unnecessary procedures for patients.”

CyPath® Lung’s proprietary technology that preferentially binds to cancer cells collected in sputum samples and causes them to fluoresce in contrast to non-cancer cells will improve the positive predictive value of lung cancer screening and diagnosis. The test uses flow cytometry to evaluate a person’s sputum sample for the presence of cancer and cancer-related cells that can indicate the presence of a malignant tumor.

Precision Pathology will market CyPath® Lung nationwide to major hospitals and large pulmonary and internal medicine practices, as well as rural and smaller medical centers and practices. Insurance reimbursement codes are available for use with CyPath® Lung at a national CPT allowance of $380. According to bioAffinity’s analysis, CyPath® Lung can save nearly $1 billion in health care costs for every 1 million people who undergo LDCT screening for lung cancer assuming those with a positive result use CyPath® Lung to confirm diagnosis.

About bioAffinity Technologies, Inc.

bioAffinity Technologies, Inc. (www.bioaffinitytech.com) is a privately held company that develops proprietary in-vitro diagnostic tests and targeted cancer therapeutics using breakthrough technology that preferentially targets cancer cells. Research, optimization and commercialization of its platform technology are conducted in bioAffinity Technologies’ laboratories at the University of Texas San Antonio. The Company’s initial product is CyPath® Lung, a diagnostic assay for the non-invasive detection of early-stage lung cancer.

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Source: bioAffinity Technologies, Inc.