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bioAffinity Technologies Opens Test Validation Trial of CyPath® Lung

SAN ANTONIO, July 17, 2018 (GLOBE NEWSWIRE) -- bioAffinity Technologies, a privately held cancer diagnostics company, today announced it has commenced its test validation trial for CyPath® Lung, an advanced flow cytometry test for the early detection of lung cancer.

Recruitment is ongoing for patients diagnosed with lung cancer and individuals at high risk for the disease who have undergone screening.

The validation trial follows earlier clinical studies that resulted in final design of the non-invasive test that will help physicians determine whether biopsy or other invasive diagnostic testing is warranted after screening a patient for lung cancer with low-dose computer tomography (LDCT).

“Lung cancer is the leading cancer killer worldwide, claiming nearly 1.6 million lives annually. If detected and treated early at Stage 1, the dismal five-year survival rate of 18 percent leaps to a 10-year survival rate of 88 percent,” said Maria Zannes, President and Chief Executive Officer of bioAffinity Technologies.

Screening with LDCT is recommended for people 55-years or older who have smoked the equivalent of 30 years or more and have not quit within the last 15 years. “Screening can save lives, but LDCT currently has a 96 percent false-positive rate, and there is currently no consistently reliable, non-invasive method that can detect lung cancer at an early stage,” Zannes said.

“We expect CyPath® Lung to be commercially available by year end and available to physicians who need to determine whether surgical biopsy or monitoring is the best option for their patients,” Zannes said. “CyPath® Lung is designed to be the most accurate and affordable non-invasive, early-stage lung cancer diagnostic on the market.”

The CyPath® test requires study participants to provide sputum samples over a three-day period with the help of an airway assist device that helps open and clear the lungs. Four clinical sites – Summit Medical Group in New Jersey, Radiology Association of Albuquerque in New Mexico, Waterbury Pulmonary Associates in Connecticut and Atlantic Health Systems in New Jersey – are enrolling volunteers for the study. Four additional collection sites are currently undergoing review and approval by Institutional Review Boards (IRBs) and will participate in the clinical trial.

CyPath® Lung will enter the U.S. market as a Laboratory Developed Test (LDT) for use by patients who receive a positive diagnosis by LDCT imaging, the current “gold standard” for lung cancer screening. Medicare reimbursement codes are available for CyPath® Lung.

Nearly 14 million Americans are estimated to be at high risk for lung cancer because they are current or former heavy smokers over 55 years of age. High-risk individuals are eligible for insurance reimbursement for annual LDCT screening. Based on its very high false-positive rate, LDCT imaging could identify nearly four million of the 14 million high-risk individuals as positive for lung cancer. The expectation is that only about 160,000, or 4 percent, of those high-risk individuals diagnosed as positive by LDCT actually will have lung cancer. The CyPath® Lung diagnostic can dramatically increase overall accuracy leading to increased survival, fewer unnecessary invasive procedures and lower medical costs.

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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