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Mount Sinai Joins Test Validation Trial of bioAffinity's CyPath® Lung

SAN ANTONIO, Sept. 18, 2018 (GLOBE NEWSWIRE) -- bioAffinity Technologies, a privately held biotech company, today announced that the Icahn School of Medicine at Mount Sinai (ISMMS) in New York, NY, will be a clinical collection site for the Company's test validation trial of CyPath® Lung, a non-invasive test for the early detection of lung cancer. The study will be performed under the direction of the Clinical Trials Office in the Department of Medicine.

As the medical school for the Mount Sinai Health System, ISMMS and its Clinical Trials Office are international leaders in medical and scientific training, biomedical research and patient care. Dr. Louis R. DePalo, clinical director of the Mount Sinai National Jewish Health Respiratory Institute and professor of pulmonary medicine at ISMMS, will supervise the study at Mount Sinai as the principal investigator.

"We are very pleased to be working with Mount Sinai and Dr. DePalo to advance the clinical test validation trial of CyPath® Lung," bioAffinity President and Chief Executive Officer Maria Zannes said. "Our ongoing validation study will benefit enormously from Mount Sinai's high standards for breakthrough research and biomedical advances."

ISMMS will recruit volunteers and collect sputum samples from two cohorts: individuals who are at high risk for lung cancer and do not have the disease, and patients who are confirmed by biopsy to have the disease after providing a sputum sample. The high-risk population will be screened by low-dose computed tomography (LDCT) to confirm they do not have lung cancer.

"Early diagnosis is the key to improving the survival rate for lung cancer, which until now has

been notoriously difficult to detect in the early stages when it is most curable," Dr. DePalo said. "Today, LDCT is the gold standard for early detection, but it has a problematic false-positive rate, which can result in unnecessary and invasive procedures to confirm the patient does not have cancer. Physicians and patients both will benefit from a test that improves the predictive value of LDCT. Clinicians would have a clearer path to determine the appropriate next steps, whether surgical biopsy or monitoring is the best option for the patient."

Sputum samples will be processed and labeled with CyPath® Lung, a flow cytometric test that uses a proprietary compound that binds to cancer cells and causes them to fluoresce in contrast to non-cancer cells. CyPath® Lung is designed to be the most accurate and affordable non-invasive diagnostic for early-stage lung cancer on the market. The validation study will 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.

bioAffinity expects CyPath® Lung to enter the U.S. commercial market as a Laboratory Developed Test (LDT) by first quarter 2019. Medicare reimbursement codes are available for CyPath® Lung.

ISMMS joins five other clinical sites – Summit Medical Group in New Jersey, Radiology Associates of Albuquerque in New Mexico, Waterbury Pulmonary Associates in Connecticut, Cookeville Regional Medical Center in Tennessee, and Atlantic Health Systems in New Jersey – currently enrolling volunteers for the study. One additional collection site is undergoing review and approval by Institutional Review Boards (IRBs) to participate in the clinical trial.

Nearly 14 million Americans are considered at high risk for developing lung cancer based on their smoking history. By significantly increasing diagnostic accuracy, CyPath® Lung is expected to lead to improved patient 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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