



FOR IMMEDIATE RELEASE

Exosome Diagnostics and the Addario Lung Cancer Medical Institute (ALCMI) Announce Collaboration to Accelerate Development of Plasma-Based Lung Cancer Diagnostics

Clinical testing underway utilizing matched samples from ALCMI's Collaborative Advanced Stage Tissue Lung Cancer (CASTLE) Trial

Collaboration will support validation for Exosome Diagnostics' ALK and T790M plasma-based diagnostics planned to launch in 2015

Novel biofluid-based diagnostics offer the potential to provide precise, real-time molecular insights to help inform individualized treatment decisions for lung cancer patients

CAMBRIDGE, Mass. and LOS ANGELES, Calif., Jan. 9, 2015 – Exosome Diagnostics, Inc., a developer of revolutionary, biofluid-based molecular diagnostics, today announced a strategic collaboration with the Addario Lung Cancer Medical Institute (ALCMI) to accelerate the development of its lead plasma-based diagnostics in development for mutation detection and monitoring in patients with lung cancer. The collaboration will support validation of Exosome Diagnostics' ALK and T790M lab developed tests (LDTs) planned to launch in 2015 and help advance future development of the company's ALK and T790M in vitro diagnostic (IVD) kits.

Exosome Diagnostics' ALK and T790M tests have the potential to provide clinicians with real-time, precise molecular insights to help inform individualized treatment decisions for patients with lung cancer upon initial diagnosis and throughout the course of treatment. As liquid biopsy tests, these diagnostics analyze biomarkers in blood plasma, providing molecular information about cancer cells in the body without needing direct access to the actual cells. They are designed to complement tissue biopsy and provide an important alternative to monitor for emerging mutations when repeat biopsies are not practical or feasible.

Exosome Diagnostics' novel technology platform enables the development of tests that can analyze stable, high-quality exosomal RNA (exoRNA), representing a potentially important advance given that many known cancer mutations, such as gene arrangements and splice variants, are difficult or impossible to detect utilizing circulating DNA analysis. For certain mutation targets where the addition of the circulating DNA fraction would enhance the sensitivity of detection, such as with low abundance resistance mutations like T790M, Exosome Diagnostics' platform offers the unique versatility to create tests that can simultaneously capture and analyze exoRNA and cell-free DNA (cfDNA).

ALCMI, a patient-founded international research consortium, in partnership with the Bonnie J. Addario Lung Cancer Foundation, has assembled a consortium of leading clinical centers into a cooperative network to drive the molecular understanding of lung cancer in several clinical trials, including the Collaborative Advanced Stage Tissue Lung Cancer (CASTLE) trial, from which the samples for this collaboration are derived. Through shared infrastructures and centrally coordinated scientific planning, ALCMI's researchers are pooling their knowledge, specimens and data to understand the molecular

basis of lung cancer and accelerate the development and delivery of effective, targeted diagnostics and treatments tailored for individual patients. Exosome Diagnostics has already received matched samples from the CASTLE trial and clinical testing is underway.

“Our collaboration with Exosome Diagnostics represents our first corporate partnership using the collected specimens and data for the CASTLE trial, which was designed to provide opportunities to study innovative molecular tests that hold the promise of empowering physicians to make more informed decisions about the best, most targeted treatment decisions for patients,” said Steven Young, ALCMI president & COO. “Testing that can be performed via a blood draw and yield precise molecular insights would represent a significant advance in the overall treatment of lung cancer. We look forward to the outcome of Exosome Diagnostics’ clinical testing and to the availability of the company’s ALK and T790M tests later this year.”

“This clinical collaboration marks an important milestone as we continue to progress our diagnostics toward commercialization and realizing our goal of providing clinicians with precise, real-time molecular insights via plasma-based tests,” said Vincent J. O’Neill, M.D., Chief Medical Officer of Exosome Diagnostics. “We believe the clinical testing underway will enable us to launch our ALK and T790M lab developed tests in 2015 and provide important data to support future regulatory approval of our ALK and T790M in vitro diagnostic kits. Additionally, we believe these data will help educate clinicians and payers about the potential of our diagnostics to detect, with high sensitivity, rare mutations in order to drive both adoption and reimbursement.”

Exosome Diagnostics plans to present data from the ALCMI collaboration at the 2015 American Society of Clinical Oncology (ASCO) Annual Meeting later this year. In addition to launching the ALK and T790M plasma-based tests in 2015, the company also plans to launch a plasma-based solid tumor panel diagnostic and a urine-based prostate cancer diagnostic in 2015.

About Exosome Diagnostics’ Technology Platform

Exosomes are messengers released by all cells into biofluids, such as plasma/serum, urine, cerebrospinal fluid and saliva. Exosomes contain RNA, including mRNA, microRNA, lncRNA and other RNA species, as well as DNA and proteins, from their cell of origin. Exosome Diagnostics’ exosome-based technology platform can achieve real-time access to comprehensive molecular information about cells in the body without direct access to the actual cells. The company offers the only biofluid-based platform that can simultaneously isolate and analyze both exosomal RNA (exoRNA) and cell-free DNA (cfDNA), two cell-free sources of nucleic acids, to offer highly sensitive mutation detection.

Biofluid exosomes are particularly useful for differential molecular profiling because they are present not only in primary and metastatic cancer but also in inflammatory, metabolic, cardiovascular, neurodegenerative and other disease processes. Exosome Diagnostics is collaborating with leading academic institutions, research-focused advocacy organizations and government to explore the broad promise and clinical application of its technology.

About Exosome Diagnostics

Exosome Diagnostics is a privately held company focused on developing and commercializing revolutionary, biofluid-based diagnostics to deliver personalized precision healthcare that improves lives. The company’s novel exosome-based technology platform can yield comprehensive and dynamic molecular insights to transform how cancer and other serious diseases are detected, diagnosed, treated and monitored. Exosome Diagnostics is developing and plans to launch diagnostics in lung, solid tumor and prostate cancer in 2015. Visit www.exosomedx.com to learn more.

About the Addario Lung Cancer Medical Institute

The Addario Lung Cancer Medical Institute (ALCMI), founded in 2008 as a 501c(3) non-profit organization, is a patient-centric, international research consortium driving research otherwise not possible, evidenced by ALCMI's current clinical studies CASTLE, INHERIT EGFR T790M, Genomics of Young Lung Cancer and others. ALCMI overcomes barriers to collaboration via a world-class team of investigators from 21+ institutions in the U.S., France, Italy, Spain and U.K., supported by dedicated research infrastructures such as centralized project management, tissue banks and data systems. ALCMI directly facilitates research by combining scientific expertise found at leading academic institutions with patient access through our network of community cancer centers – accelerating novel research advancements to lung cancer patients. To learn more, please visit www.alcmi.net.

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