FOR IMMEDIATE RELEASE

Exosome Diagnostics' Exosomal RNA (exoRNA) Plus Cell-Free DNA (cfDNA) Liquid Biopsy Panel Demonstrates Superior Detection of EGFR Activating and Resistance Mutations in NSCLC Versus cfDNA-Only Approach

Results provide further validation that Exosome Diagnostics' ability to co-isolate and analyze exoRNA and cfDNA provides leading liquid biopsy approach, potential key alternative to tissue biopsy

Company poised to help advance promise of liquid biopsies to yield real-time, non-invasive molecular insights, better informing treatment decisions for patients

Data presented in a poster session at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics

Cambridge, Mass., Nov. 9, 2015 – Exosome Diagnostics, Inc., a developer of revolutionary, biofluid-based molecular diagnostics, today announced new data demonstrating the ability of its plasma-based liquid biopsy panel for solid tumors to detect EGFR mutations in patients with non-small cell lung cancer (NSCLC) with acquired resistance to first-generation EGFR tyrosine kinase inhibitors (TKIs). Additionally, utilizing Exosome Diagnostics' proprietary technology platform that co-isolates and analyzes exosomal RNA (exoRNA) and cell-free DNA (cfDNA), the panel was able to detect mutations in NSCLC patients previously characterized as negative by an external high-sensitivity PCR-based method relying on cfDNA alone. Notably, in patients with intrathoracic disease, the panel exhibited superior sensitivity for activating EGFR mutations enabling high-sensitivity detection.

The study evaluated tumor tissue and plasma collected from patients enrolled in TIGER-X, a Phase 1/2 study of rociletinib in previously treated mutant EGFR patients with advanced NSCLC. Rociletinib (CO-1686) is a novel, oral, targeted covalent (irreversible) inhibitor of EGFR being developed by Clovis Oncology for the treatment of NSCLC.

The data were presented on Saturday, November 7, 2015 in a poster session entitled, "Plasma EGFR mutation detection using a combined exosomal RNA and circulating tumor DNA approach in patients with acquired resistance to first-generation EGFR-TKIs," at the 26th AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics in Boston, Mass.

"As the development of targeted therapies for cancer continues to advance and mature, diagnostics are playing an increasingly critical role in ensuring that we can match patients to treatments that are best suited for them and the real-time drivers of their disease," stated Jean-Charles Soria, M.D., Ph.D., Professor of Medicine and Medical Oncology, South-Paris University and Chair of Drug Development Department at Gustave Roussy Cancer Center in Paris, and a co-author on the poster. "The field of liquid

biopsies is of enormous interest, as it offers opportunities for the serial and longitudinal monitoring that is so critical in cancer, given its dynamic and evolutionary nature. I'm extremely interested in these results and the demonstrated potential of Exosome Diagnostics' technology to yield heightened, plasma-based mutation detection in patients with NSCLC."

About the Data

The study evaluated pretreatment tumor tissue and plasma collected from 84 patients enrolled in TIGER-X, a Phase 1/2 study of rociletinib in previously treated mutant EGFR patients with advanced NSCLC. Among the 84 patients, 56 cases were randomly chosen from the clinical patient population and an additional 28 cases were previously determined to have low T790M levels in plasma using cfDNA-based approaches. Of the 56 cases randomly chosen from the clinical patient population, 54 had valid tumor tissue results.

In the randomly chosen cohort, the positive percent agreement (PPA) between plasma and tumor tissue was 96 percent (52/54) for EGFR activating mutations and 88 percent (43/49) for EGFR T790M resistance mutations with tumor tissue as the reference method. For most cases analyzed, the combined mutation signal from exoRNA and cfDNA was greater than the signal from cfDNA alone. Furthermore, mutations were detected in some patients who were previously thought to be negative by analysis of cfDNA alone, suggesting improved sensitivity from the addition of exoRNA. In the subset of patients with low or undetectable levels of cfDNA and valid tumor tissue results (N=50), the difference was more pronounced. EGFR activating mutations were detected in 39 of 48 cases using exoRNA and cfDNA (PPA 81%) compared to 28 of 48 (PPA 58%) by cfDNA alone.

"The liquid biopsy arena has exploded in recent months as the industry and the medical community continue to realize the tremendous promise of liquid biopsies to provide real-time molecular insights about cancer and overcome many of the challenges associated with tissue biopsy," said Vince O'Neill, M.D., Chief Medical Officer at Exosome Diagnostics. "These data help further validate that Exosome Diagnostics' ability to combine exosomal RNA and cell-free DNA positions us an emerging leader in the liquid biopsy space. We believe that by offering sensitive mutation detection we are well positioned to advance the promise of liquid biopsies to dramatically shift the diagnostic paradigm for lung and other types of cancer, better informing treatment approaches and improving patients' lives."

About EGFR Activating and Acquired Resistance Mutations

Patients with EGFR activating mutations often initially respond to treatment with first- and second-generation tyrosine kinase inhibitors (TKIs). However, many patients' lung cancer continues to progress because they develop new, so-called "acquired resistance" mutations, including T790M, the most common resistance mutation. Rociletinib was designed to selectively target both the initial activating EGFR mutations and the dominant acquired T790M resistance mutation, while sparing wild-type, or normal EGFR at anticipated therapeutic doses, with an improved toxicity profile.

Exosome Diagnostics also presented a poster in a late-breaking session on Sunday, November 8, 2015 at the AACR-NCI-EORTC entitled, "Early exosome mRNA changes are associated with improved progression free survival of metastatic melanoma patents on ipilimumab: Identification of a novel exosome mRNA signature of ipilimumab response."

About the Technology

Exosome Diagnostics' plasma-based liquid biopsy panel for solid tumors covers 26 of the most important genes and 1000 associated mutations in the most significant pathways of cancer, including EGFR/MAPK and PI3K. The panel utilizes the company's unique exosome-based technology platform to simultaneously isolate and analyze exosomal RNA (exoRNA) and cell-free DNA (cfDNA), two biologically distinct sources of circulating nucleic acids. Combining exoRNA and cfDNA in a single step enables the panel to achieve ultra-sensitive detection of rare cancer mutations.

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. Visit www.exosomedx.com to learn more.

Media Contact:
Liz Melone
Feinstein Kean Healthcare
617-256-6622
liz.melone@fkhealth.com

###