FOR IMMEDIATE RELEASE

Exosome Diagnostics Launches World's First Exosomal RNA-Based Liquid Biopsy, ExoDx™ *Lung(ALK)*

ExoDx *Lung(ALK)* is the World's First Non-invasive Test Allowing Identification of Specific ALK Fusions Using Exosomal RNA-Based Liquid Biopsy

ExoDx *Lung(ALK)* is the First in a Series of Exosomal RNA-based Liquid Biopsies across Multiple Bio-fluids and Solid Tumors Expected to be Launched by Exosome Diagnostics in 2016

Individual Fusion Detection using ExoRNA Informs Clinical Decision Making for Patients with Non-Small Cell Lung Cancer

Cambridge, MA – January 21, 2016 – Exosome Diagnostics, Inc., the developer of a revolutionary liquid biopsy platform that enables non-invasive detection of clinical biomarkers, potentially obviating the need for tissue biopsy, today announced the launch of ExoDx™ *Lung(ALK)*, the world's first liquid biopsy test designed to isolate and analyze exosomal RNA (exoRNA) from a blood sample. ExoDx *Lung(ALK)*, which has been validated in Exosome Diagnostics' CLIA certified laboratory, is a plasma-based diagnostic enabling sensitive, accurate and real-time detection of EML4-ALK mutations in patients with non-small cell lung cancer (NSCLC). Exosome Diagnostic's proprietary platform for the isolation of RNA from exosomes provides a more direct and sensitive method of detecting fusions such as EML4-ALK, compared to cell free DNA (cfDNA) alone.

ExoDx *Lung(ALK)* detects EML4-ALK fusion transcripts with the goal of informing individualized treatment decisions for patients. ExoDx *Lung(ALK)* is now commercially available in the United States and can be ordered by clinicians.

The test will assist oncologists in identifying patients who may benefit from ALK inhibitory therapy among the population of NSCLC patients whose tissue samples are unavailable or who are unwilling or unable to undergo repeat biopsy. "Capturing exosomal RNA for identifying ALK in a liquid biopsy is a huge advance in oncology," said Luis Raez, M.D., Medical Director, Memorial Cancer Institute, Fort Lauderdale, FL. "Understanding which fusion transcript is involved will be important as more targeted drugs become available."

Validation results of the test, comparing tissue ALK status with matched plasma samples in patients who had progressed on a prior ALK inhibitor and prior to receiving a second generation ALK inhibitor, showed sensitivity of 88% and specificity of 100%. Exosome Diagnostics has now presented these data at three large cancer conferences in 2015: The World Conference on Lung Cancer in Denver, the AACR-NCI-EORTC meeting in Boston, and the American Association for Cancer Research (AACR) meeting in Philadelphia.

"We're extremely pleased to be able to offer clinicians this test," said Dr. Vince O'Neill, Chief Medical Officer of Exosome Diagnostics. "The ability to detect specific fusion transcripts of the ALK gene represents a critical advance in the detection of this mutation. We believe this test will provide

physicians with the most complete molecular information they need in order to direct patients to the most targeted and appropriate available treatment or clinical trial."

ExoDx *Lung(ALK)* is the first in a series of 2016 planned diagnostic test launches for the company. ExoRNA isolation is uniquely suited to detection of fusions like EML4-ALK, splice variants and RNA transcriptional profiling. For rare mutation detection, the company has developed an innovative technology to isolate in a single step both exosomal RNA, which represents the living cellular process, and cfDNA, which comes exclusively from dying cells. ExoRNA analysis greatly enhances the diagnostic sensitivity over cfDNA isolation alone, and provides comprehensive insight into the biology of the tumor. The company intends to work with the appropriate regulatory agencies on its portfolio of validated diagnostic tests.

"The launch of the world's first exosomal liquid biopsy test is a key milestone for the diagnostic field, as it will enable a comprehensive molecular snapshot of a patient's disease," said John Boyce, President and Chief Executive Officer of Exosome Diagnostics. "The combined analysis of cfDNA and exoRNA will redefine what is possible for therapy selection, response monitoring, and ultimately early detection and screening. Our extensive pipeline is based on our proprietary suite of exosomal diagnostic tools that we have developed over the past eight years, using samples from over 30,000 patients across multiple disease states, and is poised to redefine clinical practice."

About ALK

EML4-ALK is a gene fusion found in a subset of patients with NSCLC, and predicts response to ALK inhibitor therapies. The current testing standard for EML4-ALK is FISH or IHC from a tissue biopsy. FISH has been shown to lack sensitivity and is generally acknowledged to miss the mutation in a significant number of patients (up to 60 percent) [*The Oncologist*, February 26, 2015].

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, ExoLution™, 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
617-761-6727
liz.melone@fkhealth.com

Company Contact:
Dan Baughman
Exosome Diagnostics
248-613-2247
dbaughman@exosomedx.com