Exosome Diagnostics Announces Publication of a Highly Sensitive Exosome Based Liquid Biopsy Test for EGFR T790M Mutations in Plasma from Non-Small Cell Lung Cancer Patients

Waltham, MA – March 20, 2018 – Exosome Diagnostics, Inc., a developer of revolutionary, biofluid-based molecular diagnostics, recently published a study on the detection of the Epidermal Growth Factor Receptor (EGFR) T790M mutation in plasma from patients with Non-Small Cell Lung Cancer (NSCLC). The study, demonstrated superior sensitivity and specificity utilizing the company's proprietary cGMP manufactured ExoLution™ Plus kit, which co-isolates exosomal RNA/DNA and cfDNA (exoNA) in a single step followed by a qPCR based mutation detection assay. The paper, "*Exosome-based Detection of EGFR T790M in Plasma from Non-Small Cell Lung Cancer Patients*", appears in the current online edition of Clinical Cancer Research, a journal of the American Association for Cancer Research.

About 60% of NSCLC patients develop resistance to EGFR inhibitor therapy due to the EGFR T790M mutation. Patients who fail therapy due to this mutation will benefit from treatment with osimertinib. However, performing a repeat lung biopsy to obtain the mutation status is challenging and cannot be done on all patients. Detection of EGFR T790M in a liquid biopsy would solve some of the issues, but it has proven difficult due to low abundance of T790M positive cell-free DNA in blood. This study identifies a non-invasive and highly sensitive alternative for the identification of this mutation, examining the combined plasma exoNA.

The study analyzed 210 patient plasma samples and achieved 92% sensitivity and 89% specificity for detection of EGFR T790M using tissue biopsy results as the gold-standard. A currently used liquid biopsy that utilizes cfDNA only (FDA approved cobas® *EGFR* Mutation Test v2) achieved a lower sensitivity of 58% and 80% specificity[1]. In employing the exoNA based assay presented in the study, the number of unnecessary follow-up biopsies could be reduced from 42% (using cfDNA only) to 8% using the combined exosome platform.

"One of the main issues with liquid biopsies has been the very low copy numbers of the mutations on cfDNA, especially in intrathoracic disease or early-stage cancer. Our ExoLution™ Plus platform efficiently captures both exosomes and cfDNA, and this publication is another example that the combined exoNA improves current liquid biopsy tests that look at cfDNA only. In a recent publication[2] we showed that mutated EGFR copy numbers in exoNA are up to 10-fold higher compared to analysis of cfDNA alone," says Johan Skog, Chief Scientific Officer and founding scientist of Exosome Diagnostics. "In addition, we are analyzing two biological processes since cfDNA is coming from the dying apoptotic/necrotic cells and exsomes from living cells," concluded Skog.

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[1] FDA: Summary of Safety and Effectiveness Data (SSED). Website: https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150044B.pdf. In: FDA, editor.

[2] A K Krug, et al. 2017, 'Improved *EGFR* mutation detection using combined exosomal RNA and circulating tumor DNA in NSCLC patient plasma', *Annals of Oncology*, https://doi.org/10.1093/annonc/mdx765.

"The sensitivity and specificity advantage of the Exosome Diagnostics platform provides a marked improvement for patient care within oncology," stated John Boyce, President and CEO of Exosome Diagnostics. "Providing a highly sensitive and specific liquid biopsy solution where repeat biopsies are problematic for the patient, as in intrathoracic disease, will allow more frequent testing and will significantly improve the quality of patient care," Boyce concluded.

About the Clinical Cancer Research, Journal of the American Association for Cancer Research

Clinical Cancer Research publishes innovative clinical and translational cancer research studies that bridge the laboratory and the clinic. The Journal is especially interested in clinical trials evaluating new treatments, accompanied by research on pharmacology, and molecular alterations or biomarkers that predict response or resistance to treatment. The Journal also prioritizes laboratory and animal studies of new drugs and molecule-targeted agents with the potential to lead to clinical trials, and studies of targetable mechanisms of oncogenesis, progression of the malignant phenotype, and metastatic disease.

Specific areas of interest include clinical and translational research in targeted therapies; mechanisms of drug sensitivity and resistance; pharmacogenetics and pharmacogenomics; personalized medicine; novel applications of bioinformatics and biostatistics; immunotherapy and clinical immunology; gene therapy; radiobiology and radiation oncology; large-scale molecular characterization of human tumors; diagnostic biomarkers; innovative imaging and other novel methods with potential applicability to clinical investigation; clinical genetics; and detection of minimal disease.

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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™, and point of care instrument for protein capture and analysis, Shahky™, can yield comprehensive and dynamic molecular insights to transform how cancer and other serious diseases are diagnosed, treated and monitored. Visit www.exosomedx.com to learn more.

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