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Exosome Diagnostics Presents Data on Plasma-Based Solid Tumor Mutation Panel Liquid Biopsy Test, Demonstrates Excellent Analytical Performance for Detection of Actionable Mutations across Multiple Cancers

Data provide further validation of company's proprietary exosomal RNA (exoRNA) platform for biofluid-based molecular profiling

Combined capture of exoRNA and cell-free DNA (cfDNA) yields superior detection of rare mutations, enables longitudinal monitoring of BRAF mutant melanoma and early detection of disease progression

Company plans to launch liquid biopsy tests in lung, prostate and other solid tumor cancers in 2015

Chicago, Ill. and Cambridge, Mass., June 2, 2015 – Exosome Diagnostics, Inc., a developer of revolutionary, biofluid-based molecular diagnostics, today announced data demonstrating the ability of its plasma-based liquid biopsy panel for solid tumors, which co-isolates and analyzes exosomal RNA (exoRNA) and cell-free DNA (cfDNA), to provide robust, highly sensitive detection of actionable mutations in plasma across multiple cancers. The company announced additional data showing that its proprietary exoRNA plus cfDNA platform also enabled plasma-based longitudinal monitoring of BRAF mutant melanoma, and demonstrated the ability to detect early disease progression multiple months prior to clinical evidence of the changes. Exosome Diagnostics is developing innovative plasma- and urine-based liquid biopsies that analyze exoRNA for biomarkers and can simultaneously isolate and analyze cfDNA to enhance detection of rare mutations.

The solid tumor liquid biopsy panel and BRAF data were presented in poster sessions at the 2015 American Society of Clinical Oncology (ASCO) Annual Meeting, taking place May 29 – June 2 in Chicago, Ill. Based on these and earlier data, Exosome Diagnostics plans to commercialize its solid tumor panel liquid biopsy as a laboratory developed test in the company's certified CLIA laboratory in 2015. The test, which is performed on simple blood samples, and covers 26 genes and 1000 associated mutations in the most significant cancer pathways, including EGFR/MAPK and PI3K, will initially be made available to pharmaceutical companies as a clinical development tool.

"These findings further validate our unique, exoRNA-based liquid biopsy approach, and the potential clinical significance of analyzing exoRNA to reveal molecular insights about cancer," said Vince O'Neill, M.D., Chief Medical Officer of Exosome Diagnostics. "These data also demonstrate the performance of our exoRNA plus cfDNA platform to enhance gene copy numbers, and to detect low-abundance, rare

somatic mutations, which can be missed analyzing cfDNA only. Combined with other features, including a novel process for yielding high-quality RNA, proprietary downstream analytics, rapid results reporting, and our ability to capture exoRNA in any biofluid, we believe that our approach offers distinct advantages over competitive tissue- and plasma-based mutation panels, and that we are well positioned to be a partner-of-choice for the pharmaceutical industry.”

Exosomes are messengers released by all living cells into biofluids, such as plasma/serum, urine, cerebrospinal fluid and saliva. Exosomes contain RNA, DNA and proteins from their cell of origin. Exosome Diagnostics’ technology platform can achieve real-time access to comprehensive molecular information about cells in the body without direct access to the actual cells.

In addition to the solid tumor panel, in 2015 Exosome Diagnostics plans to launch plasma-based liquid biopsy tests for the EML4-ALK and EGFR T790M mutations in non-small cell lung cancer (NSCLC), as well as a urine-based liquid biopsy test for prostate cancer. The liquid biopsies will launch as laboratory developed tests in the company’s certified CLIA laboratory in 2015.

About the ASCO Data

The solid tumor mutation panel liquid biopsy presented at ASCO demonstrated the ability to utilize the combined capture of exoRNA and cfDNA from plasma to detect actionable mutations, including KRAS, BRAF and EGFR, in various cancers such as melanoma, colorectal cancer and lung cancer. Combining exoRNA and cfDNA, Exosome Diagnostics’ technology substantially increased the number of gene copies available for low abundant somatic mutation detection versus cfDNA alone, helping ensure that the mutation would not be missed or overlooked. In the BRAF-specific data, the technology platform enabled longitudinal monitoring of BRAF mutant melanoma and demonstrated the ability to detect early disease progression prior to clinical evidence or radiographic changes. One example includes increase of detectable BRAF mutations in the plasma of a malignant melanoma patient four months before clinical progression was seen by standard practices.

“In patients with an aggressive cancer, such as melanoma, insights about treatment response and disease progression are immensely time-critical in order to help guide and adjust treatment strategy,” said Keith T. Flaherty, M.D., Director, Henri and Belinda Termeer Center for Targeted Therapies at the Massachusetts General Hospital (MGH) Cancer Center. “We’re very encouraged by these data as they validate the utility of the combined capture of exoRNA and cfDNA to detect BRAF. Moreover, they demonstrate the ability of this plasma-based approach to detect disease progression much sooner than clinical or radiographic evidence, which would represent a potentially landmark advance in the diagnostic paradigm for melanoma and a host of other cancers.”

The company also presented clinical validation data for its non-invasive, non-digital rectal exam (DRE) urine-based prostate cancer liquid biopsy test, confirming the test’s three-gene signature on exoRNA demonstrated independent, negative predictive value for the diagnosis of Gleason Score > 7 from first biopsy patients with ‘gray zone’ prostate-specific antigen (PSA) levels (>4 and <10 ng/ml). The study population consisted of 499 men aged ≥ 40 years scheduled for an initial or repeat prostate needle

biopsy, due to a suspicious digital rectal exam (DRE) and/or PSA levels. Exosome Diagnostics successfully completed a large clinical validation study of the test, which enrolled more than 1,000 patients. The [results](#) were presented in a late-breaking plenary session at the American Urological Association Annual Meeting in May 2015.

2015 ASCO Annual Meeting Poster Sessions

Exosome Diagnostics poster sessions at the 2015 ASCO meeting included:

- [“Plasma-based Monitoring of BRAF Mutations During Therapy for Malignant Melanoma Using Combined Exosomal RNA and Cell-Free DNA Analysis,”](#) which was held Monday, June 1. [Abstract #9017/Poster Board #260]
- [“Highly sensitive detection of low abundant somatic mutations in circulating exosomal RNA and cfDNA with next-generation sequencing,”](#) which was held Sunday, May 31. [Abstract #11061/Poster Board #274]
- [“Interim performance of a non-DRE urine exosome gene signature to predict Gleason \$\geq 7\$ prostate cancer on initial prostate needle biopsy from patients enrolled in a prospective observational trial,”](#) which was held Saturday, May 30. [Abstract #5064/Poster Board #58]

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 plans to launch diagnostics in lung, solid tumor and prostate cancer as laboratory developed tests in the company's certified CLIA laboratory in 2015. Visit www.exosomedx.com or follow us on Twitter [@ExosomeDx](https://twitter.com/ExosomeDx) to learn more.

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