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Exosome Diagnostics Demonstrates Superior Mutation Detection Utilizing Combined Exosomal RNA (exoRNA) and Cell-Free DNA (cfDNA) Isolation and Analysis

Company's proprietary technology platform enables comprehensive molecular analysis of RNA and DNA using single isolation column, enhancing sensitivity of detection

Analysis of fresh or frozen biofluid samples overcomes limitations of tissue biopsy and permits real-time, longitudinal disease monitoring

Company plans to launch industry's first exosome-based diagnostics in 2015

Barcelona, Spain and Cambridge, Mass., Nov. 19, 2014 – Exosome Diagnostics, Inc., a developer of revolutionary, biofluid-based molecular diagnostics, today announced new data demonstrating the ability of its technology platform to simultaneously isolate and analyze both exosomal RNA (exoRNA) and cell-free DNA (cfDNA) from plasma. Data presented from several studies involving blood plasma samples from cancer patients showed that combined analysis using the company's single isolation column enabled more precise, biologically comprehensive molecular biofluid-based mutation detection in cancer, including the capability for longitudinal monitoring, and also delivered a superior detection rate versus cfDNA-only analysis. In addition, the data demonstrated that diagnostic applications developed using the company's patented and proprietary exosome-based technologies detected actionable mutations in various cancers.

The data were presented today in an oral session at the 26th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics taking place November 18 – 21 in Barcelona, Spain, and will be presented in more detail at two upcoming poster sessions at the meeting. Based on these and earlier findings, Exosome Diagnostics is actively developing and plans to launch the industry's first exosome-based diagnostics in 2015, with an initial focus on tests for lung and other solid tumor cancers, including prostate cancer.

"We are very excited about these data and the promise of our exosome-based technology platform to drive a paradigm shift in molecular diagnostics and patient care," said Vince O'Neill, M.D., Chief Medical Officer of Exosome Diagnostics. "With the ability to comprehensively analyze RNA, DNA and proteins in readily accessible biofluids, we are developing our diagnostics to enable more molecularly precise diagnosis and drive earlier disease detection. In addition, we believe our diagnostics will give clinicians the opportunity to monitor disease over time, taking repeated molecular snapshots to reveal changes and emerging mutations to help guide treatment decisions; enhance the opportunity for treatment success; and, ultimately, lead to more individualized patient care and better outcomes."

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' technology platform can achieve real-time access to comprehensive molecular information about cells in the body without direct access to the actual cells. 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.

"These data reinforce and validate the utility of exosomes as an important source of actionable biomarkers in solid tumors," said Keith T. Flaherty, M.D., Director, Henri and Belinda Termeer Center for Targeted Therapies at the Massachusetts General Hospital (MGH) Cancer Center in Boston, Mass. "Biofluid-based molecular analysis is truly a groundbreaking field. We are excited to have the capacity to isolate exosomes utilizing Exosome Diagnostics' technology platform in our laboratory, as we believe it will help accelerate our ability to identify underlying disease mechanisms and advance targeted therapies for patients impacted by cancer."

About the Data

Johan Skog, Ph.D., Chief Scientific Officer and Founding Scientist at Exosome Diagnostics, presented the findings during his talk today entitled, "Exosomes: Cancer Mutation and Transcriptome Analysis," which was part of the EORTC-NCI-AACR Symposium's "Liquid Biopsies in Solid Tumors" session.

Exosome Diagnostics' technology demonstrated the ability to use a single capture of both exoRNA and cfDNA from plasma to detect actionable mutations, including KRAS, BRAF and EGFR, in various cancers such as melanoma, colorectal and lung cancer. In addition, data from a Phase 3 clinical trial cohort in glioblastoma showed that exoRNA profiling from serum utilizing the company's technology was effective in tracking patients' treatment response.

"The data presented today build upon and confirm earlier published findings and clearly demonstrate the rich molecular information about cancer that is carried by exosomes in serum and other biofluids," said Dr. Skog. "We look forward to continuing to advance the understanding of exosome biology and to delivering truly novel molecular diagnostics in the near term for patients faced with cancer. Additionally, we are actively collaborating with a number of organizations to explore the future clinical application of our exosome-based technology across a broad range of other diseases."

Dr. Skog also presented data demonstrating the successful co-isolation of all exoRNA and cfDNA, two cell-free sources of nucleic acids contained within plasma. By combining high-quality exoRNA/DNA and cfDNA, Exosome Diagnostics' technology platform, which utilizes a novel, spin column-based isolation method, detected somatic (or acquired) mutations in malignant melanoma and colorectal cancer, maximizing the ability to capture tumor-derived mutations in circulation in the body. Moreover, the combined analysis yielded a superior mutation detection rate versus the use of cfDNA only. The platform is uniquely positioned to also enable detection of fusion transcripts, splice variants and other RNA-based biomarkers.

Additional data from an analysis of clinical samples with patients with malignant melanoma over the course of up to eight months of treatment showed that combined isolation of exoRNA and cfDNA in plasma allowed for the longitudinal monitoring and targeted molecular analysis of both biologically different sources for treatment response and presence of the BRAF mutation and other somatic mutations. The ability to repeatedly monitor for drug resistance and arising mutations at multiple time points over the course of treating melanoma and other cancers without the need for a tissue sample could yield critical information to guide targeted drug selection or clinical trial participation.

Poster Sessions

Exosome Diagnostics will present these comprehensive data at two upcoming poster presentations at the EORTC-NCI-AACR Symposium:

Development of a one-step isolation platform for exosomal RNA and circulating cell-free DNA from cancer plasma samples (Abstract #313/Poster #093)

Molecular Targeted Agents I Poster Session

Thursday, Nov. 20, 2014 at 1:30 p.m. local time

Monitoring therapy response and resistance mutations in circulating RNA and DNA of plasma from patients with malignant melanoma (Abstract #454/Poster #026)

Molecular Targeted Agents II Poster Session

Friday, Nov. 21, 2014 at 9:00 a.m. local time

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.

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