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Exosome Diagnostics Announces Positive Results from Initial Clinical Study of Novel Prostate Cancer Liquid Biopsy

Data Demonstrate Non-Invasive, Urine-Based Test's Ability to Predict High-Grade Prostate Cancer By Analyzing Biomarkers on Exosomal RNA (exoRNA)

Orlando, Fla., and Cambridge, Mass., February 26, 2015 – Exosome Diagnostics, Inc., a developer of revolutionary, biofluid-based molecular diagnostics, today announced positive data from an initial clinical study of the company's novel prostate cancer liquid biopsy. The non-invasive, RNA-based test demonstrated the potential to accurately predict high-grade prostate cancer by analyzing biomarkers on exosomal RNA (exoRNA) via a simple urine sample.

"We believe this liquid biopsy test has the potential to transform the diagnostic treatment paradigm for prostate cancer and are very encouraged by these initial data," said Vince O'Neill, M.D., Chief Medical Officer of Exosome Diagnostics. "The real-time genetic information derived from this test is designed to complement PSA and other prognostic factors to help better inform current decision models with the goal of reducing unnecessary biopsies. We look forward to the results of our large prospective clinical validation study, which is expected to be completed mid-2015, and anticipate bringing this important test to physicians and patients later this year."

The data were presented today at a poster session titled, "A first catch, non-DRE urine exosome gene signature to predict Gleason 7 prostate cancer on an initial prostate biopsy," at the 2015 Genitourinary Cancers Symposium taking place February 26 – 28, 2015 in Orlando, Florida. [Abstract #45/Poster #C12]

Exosome Diagnostics' prostate cancer liquid biopsy is being developed to non-invasively assess the risk for high-grade prostate cancer in men with an elevated gray zone PSA (2 – 10 ng/mL). The test analyzes the expression of three biomarkers utilizing exoRNA and, using a proprietary algorithm, assigns a predictive risk score (EXO106 Score) for patients. The test involves patients submitting a simple urine sample; other predictive urine-based tests on the market and in development require patients to undergo a digital (finger) rectal exam (DRE).

Study Findings

In the study, first-catch non-DRE urine samples from 170 men who were scheduled for an initial prostate needle biopsy and had "gray zone" serum PSA levels (2 – 10 ng/mL) were analyzed and assigned an EXO106 Score.

The results demonstrated that the EXO106 Score is predictive of biopsy results for high-grade prostate cancer. The test performed better overall than the standard of care based on an area under the curve (AUC) comparison, a commonly quoted assessment of a test's sensitivity and specificity. EXO106 also demonstrated a 98.6 percent negative predictive value (NPV), a commonly used measure of a test's predictive accuracy. Fewer than 2 percent of patients were misclassified on the EXO106 Score for the presence of high-grade prostate cancer (Gleason score ≥ 7), establishing the test's optimized NPV performance. Additionally, the EXO106 Score was able to predict high-grade prostate cancer biopsy results with 97.2 percent sensitivity. "Sensitivity" (also called the true positive rate) measures the percentage of high-grade prostate cancer that the EXO106 Score correctly identified.

"A significant percentage of men undergo biopsies today only to determine that their cancer is low-risk and doesn't require immediate treatment," said Gordon A. Brown, DO, FACOS, Delaware Valley Urology, Voorhees Township, New Jersey, and an investigator in the study. "A test that could better enable physicians to identify patients at greater risk for high-grade prostate cancer with high predictive accuracy via a simple, non-DRE urine catch would represent a significant advancement for patient care and potentially allow us to avoid countless unnecessary biopsies."

Exosome Diagnostics has completed enrollment in a large clinical validation study to confirm these data and plans to present the results at a medical meeting mid-2015. Pending the validation study findings, the company plans to commercialize the prostate cancer liquid biopsy test in the second half of 2015.

About the Technology

Exosome Diagnostics' prostate cancer liquid biopsy test utilizes its proprietary, patented exosome-based technology to isolate and analyze biomarkers on exoRNA. 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. The company's platform is uniquely versatile, enabling the development of tests that can analyze either exoRNA alone or, when appropriate, simultaneously isolate and analyze exoRNA and cell-free DNA (cfDNA). In addition to the prostate cancer liquid biopsy, Exosome Diagnostics also plans to launch liquid biopsy tests for lung and other solid tumor cancers in 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 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.

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