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Exosome Diagnostics Announces Positive Results from Large Clinical Validation Study of Prostate Cancer Liquid Biopsy

Novel urine-based test demonstrates ability to accurately predict high-grade prostate cancer; holds potential to advance new prognostic paradigm, reduce unnecessary tissue biopsies

Outcomes and Economic Studies Planned in 2015, Commercial Launch Planned in 2016

NEW ORLEANS, La., and CAMBRIDGE, Mass., May 17, 2015 – Exosome Diagnostics, Inc., a developer of revolutionary, biofluid-based molecular diagnostics, today announced positive data from a large clinical validation study of its novel prostate cancer liquid biopsy test. The study met its primary endpoint demonstrating that the urine-based liquid biopsy test when added to the current prognostic standard of care (SOC) significantly improved the ability to accurately predict high-grade prostate cancer in men presenting for an initial biopsy. James McKiernan, M.D., John K. Lattimer Professor and Chair, Department of Urology at New York-Presbyterian Hospital/Columbia University Medical Center and principal investigator of the study, presented the data today in a late-breaking plenary session at the American Urological Association (AUA) Annual Meeting in New Orleans, La.

The prospective study was conducted at 22 clinical sites across the United States and involved some of the country's leading urologists and prostate cancer researchers from both academic and community-based settings. The study enrolled men 50 years or older who were scheduled for initial biopsy with a prostate-specific antigen (PSA) 2-10 ng/mL. According to the study findings, the test when added to SOC (defined as, PSA, age, race, and family history) resulted in a statistically significant improvement in the ability to predict high-grade prostate cancer versus SOC alone based on an area under the curve comparison (0.73 versus 0.63; p-value < 0.00004). In addition, the test demonstrated a 91.3 percent negative predictive value (NPV), a commonly used measure of a diagnostic's predictive accuracy. The test was able to predict high-grade prostate cancer biopsy results with 91.9 percent sensitivity. "Sensitivity" (also called the true positive rate) measures the percentage of high-grade prostate cancer that the test correctly identified.

The current screening paradigm for prostate cancer has certain challenges that lead to unnecessary biopsies and, ultimately, overtreatment. PSA has a high false positive rate and high false negative rate, and does not discriminate between high-grade and low-grade prostate cancer. Low-grade disease could remain indolent for a long period of time and typically does not require aggressive treatment. There is a need for pre-biopsy diagnostic tools that can accurately identify high-grade prostate cancer that needs immediate intervention.

Exosome Diagnostics is developing a non-invasive urine-based liquid biopsy test to predict the aggressiveness of prostate cancer prior to initial tissue biopsy. The test is being designed to enable physicians, along with PSA and other SOC factors, to more accurately predict whether a patient presenting for an initial biopsy does not have high-grade prostate cancer and, thus, could potentially avoid an initial biopsy and, instead, continue to be monitored.

“We are extremely encouraged by these results and the potential significance this liquid biopsy test may have for men with prostate cancer,” said co-author Gerald L. Andriole, Jr., M.D., Professor and Chief of Urology at Washington University School of Medicine in St. Louis. “The current diagnostic standard of care for this disease is notoriously imprecise, leading to a significant number of unnecessary tissue biopsies and often unwarranted aggressive treatment. These data demonstrate the clinical utility of exosomes to reveal critical molecular information about the aggressiveness of prostate cancer. They also signal the potential to leverage the benefits of precision medicine prior to initial biopsy, possibly forging a completely new paradigm for prostate cancer screening and treatment.”

Liquid biopsies are an emerging class of diagnostics that are designed to reveal molecular information about cancer non-invasively from biofluids such as urine or blood plasma, without the need for direct access to the cancerous tissue. Exosome Diagnostics’ non-invasive urine-based liquid biopsy test in development analyzes exosomal RNA for three biomarkers known to be expressed in men with high-grade prostate cancer. Using a proprietary algorithm that integrates this three-gene signature, the test assigns an individualized risk score for patients that predicts the presence of high-grade (Gleason Score ≥ 7) prostate cancer. The test, which is intended for use in men 50 years or older with a PSA 2-10ng/mL presenting for an initial biopsy, involves patients submitting a simple urine sample, without having to first undergo a digital rectal exam (DRE). Other predictive urine-based tests on the market and in development require patients to undergo a DRE.

“The impact of unnecessary biopsies and overtreatment in prostate cancer is a paramount health and economic concern,” said Howard R. Soule, Ph.D., executive vice president and chief science officer, Prostate Cancer Foundation (PCF). “These data, and the involvement of such a prestigious group of urology leaders in the study, suggest that we might be on the threshold of a long-needed new approach to this disease that could reduce costs to the health care system and, importantly, improve numerous men’s lives.”

More than 1 million prostate biopsies are performed annually in the United States. While the number of positive biopsies is increasing, only about 25 percent of men who have a prostate biopsy due to an elevated PSA level have high-grade prostate cancer. The remaining 75 percent have low-grade disease that may remain indolent, or are found to not have cancer at all. Serious complications associated with the prostate biopsy, including infection and hospitalization, are increasing. In addition, the cost of unnecessary biopsies in the United States is approximately \$1.3 billion. Despite the high prevalence of low-risk disease, approximately 50 percent of men are still treated with surgery or radiation at diagnosis. Aggressive treatment is often associated with significant, often long-term complications including impotence and incontinence.

“We fully appreciate that clinicians need to have the utmost confidence when relying on a new modality to inform critical treatment decisions. As such, we’ve implemented a rigorous design for this large prospective clinical validation study, and are extremely pleased with the test’s performance on key accuracy and sensitivity measures,” said Vincent J. O’Neill, M.D., M.R.C.P, Chief Medical Officer at Exosome Diagnostics. “We are approaching our planned introduction of the test to the market with equal rigor, and look forward to working in partnership with the urology community to advance the care of men impacted by this disease.”

In 2015 Exosome Diagnostics plans to conduct additional studies, including outcomes and economic studies, for the prostate cancer liquid biopsy test. Exosome Diagnostics plans to proceed with a commercial launch of a laboratory developed test in the United States in 2016. The company also plans future submissions in Europe for a CE Mark, as well as for approval of an in vitro diagnostic version of the test with the U.S. Food and Drug Administration.

Exosome Diagnostics has developed a sophisticated economic model that calculates the expected cost savings health plans would realize by incorporating the test into the current prognostic standard of care pre-initial biopsy. The company estimates that national health plans (defined as 15 million members) could save approximately \$166 million per year with full adoption, and regional health plans (defined as 2.5 million members) could save approximately \$29 million per year with full adoption.

About the Study Design

The prospective study, which was conducted at 22 urology centers across the country, enrolled 1,064 patients, with 519 patients in the intended use population: 50 years or older scheduled for initial biopsy with a PSA 2-10 ng/mL. The study objective was to determine whether Exosome Diagnostics' prostate cancer liquid biopsy test when added to prognostic standard of care (SOC) improved discrimination of high-grade cancer versus SOC alone. First-catch, non-digital rectal exam (DRE), random urine was collected at all sites and shipped to a central lab; samples were analyzed and assigned a risk score. The risk score was then compared to the final biopsy results to assess the test's ability to predict high-grade prostate cancer.

Abstract Authors

James McKiernan, M.D., John K. Lattimer Professor and Chair, Department of Urology at New York-Presbyterian Hospital/Columbia University Medical Center, served as principal investigator of the study and lead author for the AUA abstract. Other study investigators who served as abstract co-authors included Alan W. Partin, M.D., Ph.D., Chairman of the James Buchanan Brady Urological Institute, Jakurski Family Professor and Director, Urologist-in-Chief, Chairman, Department of Urology, Professor, Department of Oncology, Pathology, Johns Hopkins Medicine; Gerald L. Andriole, Jr., M.D., Robert Killian Royce Distinguished Professor, Professor, Surgery, Chief, Division of Urologic Surgery, Director, Men's Health Center, Washington University School of Medicine in St. Louis; Gordon A. Brown, D.O., F.A.C.O.S., Chair of Urology, Residency Program Director, Clinical Associate Professor, Rowan University School of Osteopathic Medicine; James S. Cochran, M.D., D.A.B.U., F.A.C.S., Urology Clinics of North Texas, Diplomate, American Board of Urology, Fellow, American College of Surgeons; John T. Wei, M.D., Professor and Associate Chair for Research, Department of Urology, University of Michigan; Ian Thompson, M.D., CTSC Director, Professor, Glenda and Gary Woods Distinguished Chair in GU Oncology, Henry B. and Edna Smith Dielman Memorial Chair in Urologic Science, University of Texas Health Science Center School of Medicine; Peter Carroll, M.D., M.P.H., Professor and Chair, Department of Urology, University of California, San Francisco.

About the Technology

Exosome Diagnostics' prostate cancer liquid biopsy test utilizes its [proprietary, patented exosome-based technology](#) to isolate and analyze biomarkers on exosomal RNA (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). Exosome Diagnostics also plans to launch blood plasma-based 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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