



FOR IMMEDIATE RELEASE

Clinical Data for World's First Truly Non-Invasive Prostate Cancer Test Published in *JAMA Oncology*

ExoDx™ Prostate(IntelliScore) Could Eliminate Hundreds of Thousands of Unnecessary Tissue Biopsies Annually

Data Supports Value of Developing Tests Using Exosomal RNA for Diagnostic and Patient Screening Applications

Commercial Launch planned in Q2 2016

CAMBRIDGE MA, April 12, 2016 - Exosome Diagnostics, Inc., a developer of revolutionary biofluid-based molecular diagnostics, announced the recent [*JAMA Oncology*](#) publication of a prospective clinical evaluation study for the company's novel urine-based prostate cancer liquid biopsy test, ExoDx™ *Prostate(IntelliScore)*. Topline results from the study were first presented in a late-breaking plenary session at the American Urological Association (AUA) Annual Meeting in May, 2015. Exosome Diagnostics plans to launch this first-of-its-kind RNA-based test in its CLIA lab in the second quarter of 2016.

The current screening paradigm for prostate cancer faces challenges that lead to unnecessary biopsies and, ultimately, overtreatment. The disadvantage of Prostate-Specific Antigen (PSA) testing is lack of specificity for prostate cancer resulting in both false positive and false negative results. Further, PSA does not discriminate between high- and low-grade prostate cancers. 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 requires more immediate intervention. In terms of overall statistics, there are more than 2 million prostate biopsies performed in the United States and Europe each year. It is estimated that more than 75 percent of these biopsies are unnecessary because the patient has benign or low-grade disease.

"ExoDx *Prostate(IntelliScore)* was designed based on input from a panel of leading urologists in the United States to help address these challenges," said Tom McLain, Chief Operating Officer of Exosome Diagnostics. "When our test result is considered in combination with accepted standard of care factors such as age, race, PSA, and family history, it can help physicians more accurately assess whether a patient presenting for an initial biopsy is more likely to have high-grade prostate cancer." Men at lower risk for high-grade prostate cancer could potentially avoid an initial biopsy. Based on the study results published in *JAMA Oncology* more than a third of these patients could continue to be monitored, hence avoiding the cost, discomfort and complications of an unnecessary prostate biopsy and associated overtreatment. The complications that have been associated with unnecessary biopsy and overtreatment range from erectile dysfunction and incontinence, to infections, sepsis and serious cardiovascular events.

"The current diagnostic landscape for prostate cancer is imprecise, setting off a cascade of events that starts with unnecessary and inaccurate biopsies, and leads to over-diagnosis and over-treatment of the

disease with radical treatment choices including prostatectomies,” said James A. Eastham, M.D., Chief of Urology at Memorial Sloan Kettering Cancer Center. “This assay’s ability to give urologists a more precise, genetically informed understanding of a man’s risk for aggressive disease via a simple urine sample, without the need for an invasive prostate tissue biopsy could help prevent that cascade. In the coming years, I believe we’re going to see the continual and much-needed transformation of the diagnostic and treatment pathway of prostate cancer.”

As opposed to any other prostate cancer test, ExoDx *Prostate(IntelliScore)* is completely non-invasive. The test requires a simple first- catch urine from a patient, meaning it does not require a prostate massage or digital rectal exam. This provides flexibility for sample collection in the physician’s office, at home or in a clinic, options that are not available with other tests. Integrating ExoDx *Prostate(IntelliScore)* into the practice workflow will be much more convenient for the clinician and patient.

The publication of the clinical study data also demonstrates the importance of exosomal RNA from urine in the speciation of prostate cancer. With further clinical studies, RNA signatures can be developed to address other important clinical needs in screening for and treating prostate cancer. In describing the potential for developing a screening test using exosomal RNA, Jonathan Simons, MD, President and Chief Executive Officer and David H. Koch Chair of the Prostate Cancer Foundation commented, “Interrogating urinary exosomes’ RNA is a fascinating new area of biotechnology. For over 50 years, we have been looking for a new platform for earlier detection of curable, lethal prostate cancer. These results, while they will need to be validated prospectively in thousands of patients in several new ways, are very provocative. The urine exosome gene expression assay appears to be superior in this pilot study compared to serum PSA alone.”

Lead author, 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 stated, “The possibility of a ‘liquid biopsy’ that does not involve an invasive procedure and may be as simple as a urine test, has the potential to change the way we approach the most common cancer in men. If the predictive accuracy of the assay can be validated in further studies, it has the potential to replace the PSA test once and for all.”

John Boyce, President and Chief Executive Officer of Exosome Diagnostics, said, “Earlier this year, Exosome Diagnostics launched the world’s first and only RNA based liquid biopsy test, ExoDx™ *Lung(ALK)* enabling detection of ALK from a simple blood draw for the many lung cancer patients for whom tissue samples are unavailable or who are unwilling or unable to undergo repeat biopsy. All tests developed with our proprietary platform provide the ability to determine the proliferation of variants within a living tumor, as opposed to analyzing DNA, in isolation, from dead cells, thus potentially providing vital information to oncologists to develop a patient personalized treatment approach.” Commenting on the results of the study published in *JAMA Oncology* Boyce added, “Leveraging the sensitivity of the Exosome Diagnostics development platform while working with the prominent thought leaders in urology, ExoDx *Prostate(IntelliScore)* has been carefully developed, and validated, over many years, and has the potential to obviate hundreds of thousands unnecessary prostate biopsies.”

About the Urine-Based Liquid Biopsy Prostate Test

ExoDx *Prostate(IntelliScore)* is a clinically validated, non-digital rectal exam (DRE) urine-based liquid biopsy test that predicts the presence of high-grade (Gleason score ≥ 7) prostate cancer for men 50 years of age and older with a PSA 2 – 10 mg/mL presenting for an initial biopsy. A “rule out” test, it is designed 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. The test is a Laboratory Developed Test offered in Exosome Diagnostics’ CLIA laboratory.

Patients submit a simple, non-DRE, first-catch urine sample. ExoDx *Prostate(IntelliScore)* then analyzes the urine for three biomarkers on exosomal RNA (exoRNA) that are expressed in men with high-grade prostate cancer. Using a proprietary algorithm that combines the relative weighted expression of the three-gene signature, the test assigns an individual risk score for patients ranging from 0 to 100. A score >15.6 is associated with an increased likelihood of high-grade prostate cancer on a subsequent biopsy. Physicians can utilize the score in conjunction with other standard of care prognostic information to determine whether to proceed with a tissue biopsy.

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™, 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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