



FOR IMMEDIATE RELEASE

ExoDx™ *Prostate(IntelliScore)*: A More Precise, Genetically Informed Prostate Cancer Test from a Simple Urine Sample

New Clinical Data Supports Exosome Diagnostics' Plan to Develop Test for Monitoring At-Risk Patients

Test Accurately Predicted Gleason Score, Pathologic Stage, and Tumor Volume in Prostatectomy Specimens

San Francisco, Calif. and Cambridge, Mass.– January 26, 2016 – Exosome Diagnostics, Inc., the developer of a revolutionary liquid biopsy platform that enables non-invasive detection of clinical biomarkers, potentially obviating the need for tissue biopsy, today announced new positive data recently presented at the ASCO 2016 Genitourinary Cancers Symposium (January 7-9, San Francisco, California). These data from a prospective clinical study add to a growing body of clinical validation evidence demonstrating ExoDx™ *Prostate(IntelliScore)*, the company's completely non-invasive urine-based liquid biopsy for prostate cancer, has the unique ability to accurately identify high-grade prostate cancer (HGPCA) both at the time of biopsy and at surgery. These data demonstrate the potential for this first-in-class exosomal RNA (exoRNA)-based assay to be utilized throughout the care continuum, including prior to initial biopsy, as well as for sequential monitoring of disease progression in patients enrolled in active surveillance.

"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 co-author James A. Eastham, M.D., Chief of Urology, 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."

Data was presented at two poster sessions entitled, "Extended analysis of a validated urine-exosome signature to predict high grade prostate cancer on initial biopsy maintains performance across multiple sub-groups" and "A non-invasive urine exosome gene expression assay (ExoIntelliScore *Prostate*) accurately predicts pathologic stage and grade in the prostatectomy specimen."

The first poster showed prospective observational clinical data from 519 patients. The exoRNA-based assay accurately predicted high-grade prostate cancer (HGCPA, Gleason score ≥ 7) with a Negative Predictive Value (NPV) of greater than 90% for the intended use population, which is men 50 years of age or greater with an equivocal PSA of 2-10 ng/mL presenting for their first biopsy. Data also showed the assay also performed well within several sub-groups of the intended use population including those with or without prior negative biopsy and comparable results amongst African Americans.

The second poster was from a separate patient group and demonstrated that ExoDx *Prostate(IntelliScore)* accurately predicted in pre-radical prostatectomy (RP) urine samples of patients with prostate cancer, objective clinical features present in RP specimens and also provided initial improved discrimination of RP Gleason Score 4+3, a subset of patients at elevated risk for aggressive disease.

Exosome Diagnostics will be initiating a decision impact and economic outcome study that will start enrolling in Q1 2016. This study will further evaluate the clinical utility of the test for men with a moderately elevated PSA of 2-10 ng/ml presenting for consideration of their first biopsy.

"Having recently launched the world's first exosomal RNA based liquid biopsy, ExoDx™ *Lung(ALK)*, a plasma based test for detection of EML4-ALK for targeted lung cancer treatment, we are excited by these data, which validate the robustness of our platform technology in a second bio-fluid," said John Boyce, President and Chief Executive Officer of Exosome Diagnostics. "The pipeline of robust tests that we have validated over the years and will be launching, span multiple biofluids with a very high level of high sensitivity and specificity."

About ExoDx *Prostate(IntelliScore)*

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, ExoDx *Prostate(IntelliScore)* 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.

Patients submit a simple, non-DRE urine sample. ExoDx *Prostate(IntelliScore)* then analyzes the urine for three biomarkers on 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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