Exosome Diagnostics Announces Data Demonstrating ExoIntelliScore™ *Prostate* **Accurately Predicted Gleason Score, Pathologic Stage and Tumor Volume in Patients with Prostate Cancer**

Exosomal RNA-Based Liquid Biopsy Test Significantly Correlated with Clinical Features Present in Radical Prostatectomy (RP) Specimens

Novel, Urine-Based Test Improved Discrimination of RP Gleason Score 4+3 Adverse Pathology, Suggesting Potential Role in Sequentially Monitoring Patients in Active Surveillance

Results of Clinical Study Show Promise of First-in-Class Predictive Test to Address Unnecessary Biopsies, Over-Diagnosis and Over-Treatment of Indolent Prostate Cancer

VIENNA, Austria, and CAMBRIDGE, Mass., October 1, 2015 – Exosome Diagnostics, Inc., a developer of revolutionary, biofluid-based molecular diagnostics, presented new positive data from a clinical study for the company's novel, urine-based prostate cancer liquid biopsy, ExoIntelliScore™ *Prostate* (formally referred to as Exo106)*.* The data demonstrated that ExoIntelliScore *Prostate* 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.

These results add to a growing body of clinical validation evidence that show ExoIntelliScore *Prostate's* unique ability to accurately and completely non-invasively identify high-grade prostate cancer. They also suggest the potential for the first-in-class genetic-based assay to be utilized throughout the diagnostic paradigm, including prior to initial biopsy, as well as for sequential monitoring of disease progression in patients enrolled in active surveillance.

The data were presented at a poster session entitled, "*A non-invasive urine exosome gene expression assay (ExoIntelliScore™* Prostate*) accurately predicts pathologic stage and grade in the prostatectomy specimen*," at the 18th European Cancer Congress (ECCO) – 40th European Society for Medical Oncology (ESMO) Annual Meeting in Vienna, Austria (September 25-29).

"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."

Distinct from all other predictive tests on the market or in clinical development for prostate cancer, ExoIntelliScore *Prostate* is the first assay to give urologists and patients molecular insights about prostate cancer using exosomal RNA (exoRNA). In this new study, pre-RP, first-catch, non-digital rectal exam (DRE) urine samples were collected from five urology practices (both academic medical institution and community urology practice settings) and analyzed at Exosome Diagnostics' certified CLIA laboratory. Samples from 430 patients were analyzed using ExoIntelliScore *Prostate*, and 359 complete and comparable RP, biopsy and ExoIntelliscore *Prostate* results were included in the analysis. According to the results, the test significantly correlated with the RP Gleason Score (p=0.025), RP tumor volume and stage of cancer (p=0.002). The test also improved discrimination of RP Gleason Score 4+3, which is often associated with more advanced disease and a greater risk of disease progression.

ExoIntelliScore *Prostate* analyzes the expression of three biomarkers utilizing exoRNA and, using a proprietary algorithm, assigns a predictive risk score to patients. A key source of nucleic acids, including RNA, exosomes are cell messengers found in all living cells and are carried throughout the body via biofluids, such as urine, plasma and cerebrospinal fluid. Using its proprietary exo-RNA technology, Exosome Diagnostics can achieve real-time access to comprehensive molecular information about cells in the body without needing direct access to the cells. ExoIntelliScore *Prostate* involves patients submitting a simple, first-catch urine sample to yield more accurate genetic insights. Other non-exosome-based predictive urine-based tests on the market and in development require patients to undergo a digital rectal exam (DRE) or prostate massage before sample collection.

"As urologists evaluate new diagnostic options for prostate cancer, they will need compelling data that clearly demonstrate an assay's predictive accuracy and clinical utility," said [Vincent J. O'Neill](), M.D., M.R.C.P., Chief Medical Officer at Exosome Diagnostics. "In coordination with leading urologists from around the country, we have designed and continue to pursue a highly robust clinical validation program for ExoIntelliScore *Prostate*. The data we have amassed to date show the ability of this exosomal RNA-based test to yield comprehensive, highly accurate genetic-based information about a patient's disease. Armed with information to more clearly distinguish between high and low grade prostate cancer, physicians will be able to use ExoIntelliScore *Prostate* to make treatment decisions that enhance patient outcomes."

About the ExoIntelliScore *Prostate* Test

ExoIntelliScore *Prostate* 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, ExoIntelliScore *Prostate* 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. ExoIntelliscore *Prostate* 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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