**FOR IMMEDIATE RELEASE**

**Exosome Diagnostics Announces Publication of ExoIntelliScore™ *Prostate* Initial Clinical Study Positive Results**

*Exosomal RNA-Based Urine Liquid Biopsy Test Detects High-Grade Prostate Cancer With 97.5 Percent Accuracy Prior to Initial Biopsy*

*Simple, First-Catch Urine Test Provides Risk Score Based on Three-Gene Exosomal RNA Signature, Does Not Require Patients to Undergo Digital Rectal Exam*

*Test Poised to Drive New Prognostic Paradigm, Enabling Significant Number of Men to Avoid Unnecessary Initial Prostate Tissue Biopsies*

**Cambridge, MASS., September 21, 2015** – Exosome Diagnostics, Inc., a developer of revolutionary, biofluid-based molecular diagnostics, today announced the publication of positive data from its initial clinical study of ExoIntelliScore™ *Prostate* (previously referred to as EXO 106). The first-catch urine-based, three-gene signature liquid biopsy test that does not require a digital rectal exam or prostate massage before sample collection predicted high-grade prostate cancer (Gleason score ≥ 7) with 97.5 percent accuracy prior to initial biopsy. The paper titled, "*A molecular signature of PCA3 and ERG exosomal RNA from non-DRE urine is predictive of initial prostate biopsy result*," appears in the current online edition of *Prostate Cancer and Prostatic Diseases,* a peer-reviewed journal of Nature Publishing Group.

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 their patients molecular insights about prostate cancer using exosomal RNA (exoRNA). The test involves patients giving a simple, first-catch urine sample without having to first undergo a digital rectal exam (DRE). ExoIntelliScore™ *Prostate* is poised to drive a new prognostic paradigm in which the aggressiveness of prostate cancer can be predicted completely non-invasively from genetic-based information ahead of initial prostate biopsy. For men demonstrating a low-risk for aggressive disease using the assay, urologists may determine that an initial prostate biopsy is not warranted. As a result, ExoIntelliScore *Prostate* has the potential to help stem the tide of unnecessary biopsies that occur today given the current void of accurate pre-initial biopsy prognostic information.

"There currently are a lack of diagnostic tools to discriminate between high-grade and low-grade prostate cancer. As a result, most men with elevated PSA levels are moved immediately to tissue biopsy, even though many have low-grade or no prostate cancer," said Vince O'Neill, M.D., Chief Medical Officer

at Exosome Diagnostics. “These data demonstrate that ExoIntelliScore *Prostate* offers a new tool to accurately predict the aggressiveness of prostate cancer prior to initial biopsy based on real-time, comprehensive genetic information derived from exosomal RNA. By enhancing the current decision model upstream, our goal is to enable a significant number of men who are low-risk or benign to avoid unnecessary biopsies. Overall, we believe ExoIntelliScore *Prostate* will advance a more sophisticated, genetic-based and patient-centric prognostic paradigm for this disease.”

ExoIntelliScore *Prostate* assesses the risk for high-grade prostate cancer in men with an elevated gray zone prostate specific antigen (PSA) (2 – 10 ng/mL) prior to initial biopsy. The test analyzes the expression of three biomarkers utilizing exoRNA and, using a proprietary algorithm, assigns a predictive risk score for 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 exosomes, researchers 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 deep, 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).

“We are seeing molecular insights enhance decision-making and lead to more informed, individualized treatment options across a spectrum of cancers and other diseases. It’s very exciting and gratifying to see this progress now make its way into the prostate cancer space, where we are in dire need of better prognostic tools,” said Gordon A. Brown, DO, FACOS, Delaware Valley Urology, Voorhees Township, New Jersey, and a co-author of the publication. “The validation data for ExoIntelliScore *Prostate* are extremely compelling and demonstrate the high predictive accuracy of this test as well as its potential to allow us to avoid unnecessary biopsies for many patients.”

**About the Data**

First-catch non-DRE urine samples from 195 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 a score with the ExoIntelliScore™ *Prostate* test.

ExoIntelliScore *Prostate*, when added to standard of care (defined as PSA, age, race, and family history), resulted in a statistically significant improvement in the ability to predict high-grade prostate cancer versus standard of care alone based on an area under the curve comparison (0.803 versus 0.6723; p-value < 0.00009).

ExoIntelliScore *Prostate* demonstrated a 97.5 percent negative predictive value (NPV), a commonly used measure of a test’s predictive accuracy. Fewer than 3 percent of patients were misclassified for the presence of high-grade prostate cancer (Gleason score ≥ 7), showing the test’s optimized NPV performance. Additionally, ExoIntelliScore *Prostate* was able to predict high-grade prostate cancer biopsy results with 95 percent sensitivity. “Sensitivity” (also called the true positive rate) measures the percentage of high-grade prostate cancer that ExoIntelliScore *Prostate* correctly identified.

The findings from a subsequent large clinical validation study of ExoIntelliScore *Prostate* confirming these data were presented in a late-breaking plenary session at the American Urological Association (AUA) Annual Meeting in New Orleans, La., in May 2015.

**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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