Exosome Diagnostics Presents Data Demonstrating Utility of Urine Exosome Technology to Predict Prostate Biopsy Outcome at American Urological Association Annual Meeting

NEW YORK – May 8, 2013 – Exosome Diagnostics, a leading developer of biofluid-based molecular diagnostic products for use in personalized medicine research and clinical diagnostics, today announced the presentation of data at the American Urological Association Annual Meeting in San Diego demonstrating the performance of urine exosome technology in accurately predicting the outcome of a prostate biopsy. James McKiernan, M.D., professor of urology and the director of urologic oncology at NewYork-Presbyterian Hospital/Columbia University Medical Center in New York City presents the data today at 8 a.m. PDT.

In this study, a urine sample was collected from patients scheduled to undergo prostate biopsy or radical prostatectomy. Exosomes containing ribonucleic acids (RNA) shed into the urine from the prostate were analyzed using Exosome Diagnostics's proprietary EXO70 Urine RNA Isolation Kit in conjunction with real-time PCR. Notably, patients did not undergo a digital rectal exam or a prostate massage prior to the urine collection.

"There is clearly an unmet need in the field of prostate cancer detection and prognosis today," said Dr. McKiernan. "A noninvasive method to improve upon PSA and its potential to predict who does or does not have cancer would immediately benefit patients and help address the controversy surrounding prostate cancer detection. A potential future application—the ability to use exosome technology to determine who has significant prostate cancer prior to performing a biopsy—would be revolutionary. In these preliminary studies exosome technology has shown promise to deliver on both of these challenges."

James McCullough, chief executive officer of Exosome added, "These results are part of a multi-center clinical study program for EXO106, the first *in vitro* diagnostic in our exosome genitourinary (GU) oncology program. EXO106 is being developed to provide patients and clinicians with a non-invasive diagnostic that can deliver real-time information following the finding of an elevated PSA. We have now completed testing on over 1,000 urine samples from patient to characterize diagnostic performance."

In the study presented by Dr. McKiernan, biopsy patients were divided into two cohorts. The first cohort was tested using a known prostate cancer biomarker, while a novel four-gene prostate cancer signature was tested in the second cohort. Both groups were stratified based on whether their biopsies were positive or negative. Besides predicting positive biopsy outcome, exosome testing was able to distinguish histologically less aggressive, lower Gleason scores (≤7) cancers from those with higher, more aggressive Gleason scores (≥8). The results demonstrate that urinary exosome-derived RNA can be used to non-invasively evaluate gene expression in the prostate and accurately predict the likelihood of a positive or negative needle biopsy in addition to distinguishing more aggressive cancers.

This study was funded by the Prostate Cancer Foundation.

Exosome Diagnostics and its collaborators will also be presenting data on two other studies.

Abstract #13-7010, 3:30 to 5:30 p.m. PDT, May 6: Urinary Exosomal RNA Provides a Non-Invasive Way to Accurately Detect PCA3 Expression in Men Undergoing Evaluation for Prostate Cancer, Shapiro, E., Ahn, J.J., Zampella, B., Motamedinia, P., Scott, A., Salazar, G., Bate, K., Seaman, M., Badani, K., McKiernan, J.M., Russo L.
Exosome-derived PCA3 expression correlated well with the prostatic massage technique with a similar true positive rate. Urinary exosome sampling captured all patients found to have positive prostate massage PCA3 scores while eliminating patient discomfort and variability associated with prostate massage.

Abstract #13-7188, 1 to 3 p.m. PDT, May 6: Evaluation of urinary Exosomes in Bladder Cancer Patients Ahn, J.J., Salazar, G., Seaman, M., Scott, A., Motamedinia, P., Castaneda, C., Comper, W., McKiernan, J.M., Russo, L.
Exosome-derived RNA was successfully isolated from the urine of patients with bladder cancer as well as individuals with no evidence of disease. Significant up-regulation of ICAM1 was seen in patients with high-grade bladder cancer.

About Exosome Diagnostics
Exosome Diagnostics is a leading developer of biofluid-based molecular diagnostic tests for use in personalized medicine. Exosomes are packaged and shed into all biofluids, including blood, urine and CSF, providing a stable source for intact, cell-specific nucleic acids. The Company's proprietary exosome diagnostic technology makes use of the presence and natural stability of RNA in exosomes to detect and measure levels of genes responsible for cancer and other diseases. The Company is developing *in vitro* diagnostic products for use in companion diagnostic applications, detection, and real-time monitoring of disease. The Company maintains facilities in New York, St. Paul, MN and Munich, Germany. For more information, please visit www.exosomedx.com.

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