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Exosome Diagnostics Presents Data at American Urology Association Demonstrating Potential Utility of Urine Exosomes to Non-invasively Detect and Manage Prostate Cancer

Data shows strong correlation between validated prostate cancer gene biomarkers in prostate cancer tissue and urinary exosomes

NEW YORK – May 23, 2012 – Exosome Diagnostics, a leading developer of biofluid-based molecular diagnostic tests for use in personalized and non-invasive cancer diagnostics today, presented two clinical studies demonstrating the potential utility of non-invasive sampling of patients' urine to detect and manage prostate cancer.

In the first study, the presence of a prostate cancer-specific biomarker in exosomes collected from random patients' urine samples demonstrated a strong correlation to the presence of that marker in prostate tissue removed via radical prostatectomy (RP). The study also correlated the expression level of the marker in urine with the likelihood of a positive cancer biopsy.

In a second study, urinary exosomes demonstrated elevated levels of survivin messenger RNA (mRNA) from patients with castration-resistant prostate cancer (CRPC) following primary therapy. Survivin expression has been implicated in hormone-independent prostate cancer growth.

"These studies, led by our director of research, Dr. Leileata Russo and conducted by our clinical collaborators, are part of our prostate cancer *in vitro* molecular diagnostics program," said James McCullough, chief executive officer of Exosome Diagnostics. "The urinary exosome provides us with a

stable source of RNA that we can interrogate using qPCR to non-invasively analyze different stages of prostate cancer."

Motamedinia et al. (abst. # 2108) obtained random samples of urine from men and measured the concordance of prostate cancer with detection of the biomarker, TMPRSS2:ERG (T:E). The investigators found that TMPRSS2:ERG expression occurred in 17 of 21 post-RP tissue samples. They also found that T:E expression in urinary exosomes from non-digital rectal exam (DRE) patients was nine-fold higher in the prostate biopsy positive patients versus biopsy negative patients. The study also demonstrated a high level of concordance between exosome-biomarker signature and the marker's presence in cancerous prostate tissue.

"The diagnosis and management of prostate cancer and patients with elevated PSA remains challenging for both patients and their physicians," said James McKiernan, M.D., the John and Irene Given professor of Urology and director of Urologic Oncology, Columbia University Medical Center and co-author of the study. "Patients with high PSA results must decide whether to undergo a biopsy procedure, which in itself may not be definitive as further suggested from the results of the study. A reliable, non-invasive diagnostic test that can determine the presence and nature of a prostate malignancy as well as its response to treatment would be of great value. The biofluid-based technology highlighted in this study is a very promising approach to reaching this goal."

Lin et al. (abst. # 2232), investigated the relationship of Survivin expression measured in exosomes and the disease status of patients diagnosed with CRPC. The presence of Survivin, an inhibitor of apoptosis, has been implicated as a factor in hormone-independent tumor growth. Survivin expression was higher in patients with measurable disease than in patients without disease and this was correlated with castration resistance.

"Monitoring patient response to treatment is largely limited to PSA testing and new tools are needed," said Daniel Petrylak, M.D., associate professor of medicine, Columbia University Medical Center and co-author of the study. "The non-invasive biofluid test we employed in this study directly measures one component of the genetic profile of malignant prostate cells. This approach should enable us to better understand a patient's response to treatment and, if an alternative therapy is required, an analysis of exosome RNA and DNA content could better direct a treatment decisions."

Exosomes are one of many different sub-populations of microvesicles that can be isolated from biofluids such as blood, urine and cerebrospinal fluid (CSF). Exosomes are shed by cells under both normal and pathological conditions. These vesicles contain high quality RNA and DNA that can be extracted and purified for analysis.

About Exosome Diagnostics

Exosome Diagnostics is a leading developer of biofluid-based molecular diagnostic tests for use in personalized medicine. Exosomes are shed into all biofluids, including blood, urine and CSF, forming a stable source of intact, disease-specific nucleic acids. The Company's proprietary exosome technology makes use of this natural stability to achieve high sensitivity for rare gene transcripts and the expression of genes responsible for cancers and other diseases. The Company is commercializing *in vitro* diagnostic tests for use in companion diagnostic applications and real-time monitoring of disease. Exosome

Diagnostics' development program is focused on blood, urine and cerebrospinal fluid with programs in collaboration with the Prostate Cancer Foundation in prostate cancer and Accelerate Brain Cancer Cures in brain cancer. The Company maintains facilities in New York, St. Paul, MN and Munich, Germany. For more information, please visit www.exosomedx.com.