



## **Exosome Diagnostics and QIAGEN Partner to Launch Comprehensive Line of Biofluid Nucleic Acid Kits to Address Limitations of Tissue Biopsy in Clinical Research Market**

- **Molecular testing of biofluids promises unprecedented access to gene mutations, real-time gene expression signatures and expression levels without costly, invasive tissue biopsies**
- **Exosome Diagnostics' biofluid nucleic acid extraction technology capable of delivering high quality nucleic acid preparations from both fresh and frozen blood, urine and cerebrospinal fluid**
- **Standardized, easy-to-use exosome preparation workflows will offer superior testing solutions, from basic research to personalized healthcare on PCR, pyrosequencing and next-generation sequencing technologies**

**New York, July 23, 2013** — Exosome Diagnostics and QIAGEN N.V. (NASDAQ: QGEN; Frankfurt Prime Standard: QIA) today announced a partnership to develop and commercialize high-performance, co-branded kit products for the capture and processing of RNA and DNA from biofluid exosomes and other microvesicles. The partnership will accelerate global availability of Exosome Diagnostics' platform technology products enabling researchers and drug developers to obtain repeated, real-time genetic "snapshots" of disease from patients' blood, urine or cerebrospinal fluid without the need for tissue biopsy. The companies are targeting initial product launches in the first half of 2014. Financial terms were not disclosed.

"QIAGEN is the industry leader in clinical sample preparation and our partnership brings global development, manufacturing, distribution and marketing expertise to the Exosome technology platform," said James McCullough, chief executive officer of Exosome Diagnostics. "Data emerging from research use of Exosome/QIAGEN kits will provide additional validation of the exosome technology platform and lead to clinical *in vitro* diagnostic applications in multiple settings including oncology and neurodegenerative disease."

Keith Flaherty, M.D., director of the Termeer Center for Targeted Therapy at Massachusetts General Hospital and associate professor, Harvard Medical School said, "Monitoring patients response in exosomes isolated from blood, as opposed to tumor biopsies, offers the possibility of optimizing the use of targeted therapies in cancer patients. The ability to rapidly diagnose mutation status without need of a biopsy, monitor response to therapy without radiology, and detect emergence of resistance at the earliest possible point, will allow us to initiate therapy more rapidly and switch treatments before a patient's cancer worsens in a way that compromises their quality of life. Our clinical research focus is to define both response and resistance biomarkers to novel therapies, all of which can be enabled by exosomes."

James McKiernan, M.D., director of Urologic Oncology, Columbia University said, "The ability to achieve a stable, high quality RNA preparation directly from a simple urine sample has significant implications for interrogating the prostate, the bladder and the kidney on a molecular level, all non-invasively. Through over 1,500 patient samples measured in clinical studies, we have shown that Exosome Diagnostics technology enables reproducible, sensitive measure of cancer specific molecular biomarkers directly from a simple, untreated urine sample."

Subject to successful completion of the solutions' performances, QIAGEN's exclusive agreement with Exosome Diagnostics will cover co-development, manufacturing and commercialization of a full product line for the life science and translational medicine markets. The product portfolio is also expected to create the basis development and commercialization of clinical *in-vitro* diagnostic products for a range of non-invasive personalized medicine solutions.

Exosomes and other extracellular vesicles can be isolated from biofluids such as blood, urine and cerebrospinal fluid and from which high quality nucleic acids, such as mRNA, miRNA and DNA, can be extracted and purified for analysis. Exosomes are shed by all cells under both normal and pathological conditions. They are a key part of the body's complex communication system that transfers genetic instructions from cell to cell through all biofluids. Exosomes carry nucleic acids and proteins from their host cell, which are widely considered to be essential for biomarker discovery for personalized medicine diagnostics. Tumor cells, for instance, release exosomes which contain tumor-specific RNA that can be more easily isolated from biofluids than from tissue biopsies.

As part of an active biological packaging and distribution mechanism, exosomes and their nucleic acid contents are being investigated for their implications in and utility for a broad range of diseases including cancer, central nervous system disorders such as Alzheimer's and Parkinson's diseases, cardiovascular disease, maternal/fetal medicine, and chronic kidney disease. The natural stability of the exosome compartment allows collection of clinical samples without special tubes or preservatives. Using Exosome Diagnostics proprietary technology kits, researchers can perform analysis and biomarker discovery on high-quality RNA from both, fresh and frozen plasma, serum, urine and cerebrospinal fluid samples.

#### **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 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 commercializing in vitro diagnostic tests for use in companion diagnostic applications and real-time monitoring of disease. For more information, please visit [www.exosomedx.com](http://www.exosomedx.com).

#### **About QIAGEN**

QIAGEN N.V., a Netherlands holding company, is the leading global provider of Sample & Assay Technologies that are used to transform biological materials into valuable molecular information. Sample technologies are used to isolate and process [DNA](#), [RNA](#) and proteins from biological samples such as blood or tissue. Assay technologies are then used to make these isolated biomolecules visible and ready for interpretation. QIAGEN markets more than 500 products around the world, selling both consumable kits and automation systems to customers through four customer classes: [Molecular Diagnostics](#) (human healthcare), [Applied Testing](#) (forensics, veterinary testing and food safety), Pharma (pharmaceutical and biotechnology companies) and Academia (life sciences research). As of March 31, 2013, QIAGEN employed approximately 4,000 people in more than 35 locations worldwide. Further information can be found at [www.QIAGEN.com/](http://www.QIAGEN.com/).

#### **Exosome Contact:**

James McCullough  
Chief Executive Officer  
Exosome Diagnostics  
(646) 843-4949

#### **Exosome Media Contact:**

Robert Flamm, Ph.D.  
Russo Partners  
(212) 845-4226  
[robert.flamm@russopartnersllc.com](mailto:robert.flamm@russopartnersllc.com)

###