Exosome Diagnostics’ Second Prospective Validation Study of EPI to be Highlighted at American Urological Association (AUA) Annual Meeting Press Briefing in San Francisco, CA

WALTHAM MA, May 17th 2018 - Exosome Diagnostics’ novel urine-based prostate cancer liquid biopsy biomarker test, ExoDx™ Prostate(IntelliScore) or EPI, was selected out of 3000 abstracts for presentation at the Press Sessions during the AUA meeting. This elite group of abstracts undergoes a rigorous review and selection process to ensure the abstract is not only newsworthy, but also scientifically sound and ready for presentation to the general public. The study findings in over 500 men will be presented by the study’s Lead Investigator, James McKiernan, M.D., John K. Lattimer Professor and Chair, Department of Urology at New York-Presbyterian Hospital/Columbia University, during the Press Session on Friday May 18th, 2018.

EPI is designed to reduce unnecessary initial prostate biopsies in men 50 years of age or older, with a PSA (Prostate Specific Antigen) value between 2-10ng/ml. The PSA blood test lacks specificity as a screening test for prostate cancer and does not discriminate between high- and low-grade cancer. The EPI urine liquid biopsy genomic test has been previously validated (JAMA Oncology 2016) as a “follow-on” test after PSA that identifies men at high risk of high-grade aggressive prostate cancer on prostate biopsy. This second prospective Validation Study, two years later, confirms the diagnostic value of the test in a contemporary population.

Up to 2 million prostate biopsies are performed annually in the United States and Europe, and it is estimated that more than 75 percent of these biopsies are unnecessary because the patient has benign or low-grade/indolent prostate cancer. Use of the EPI test reduces the number of these unnecessary biopsies. In contrast to other non-tissue based prostate biomarker tests, EPI is a non-PSA based, completely non-invasive liquid biopsy genomic test that requires a simple first-catch urine sample without the need for a prostate massage or digital rectal examination (DRE).

“This test is based on the ground-breaking science of exosomes, small vesicles released from tumor cells into biofluids such as urine. These exosomes contain the molecular information of the tumor that we can use to see what is going on inside the tumor in real-time”, said Dr Johan Skog, Chief Scientific Officer and founding scientist of Exosome Diagnostics.

“This second prospective, real-world validation study of the EPI test confirms the findings of the first validation study reported in JAMA Oncology in 2016 and establishes the role of EPI as a follow-on prostate biomarker test in men with prostate specific antigen levels in the grey zone (2-10ng/ml). The EPI score offers clear risk stratification of aggressive, high grade cancer in men considering prostate biopsy and will reduce over-diagnosis and overtreatment of indolent/low risk prostate cancer” said Grannum R Sant, MD, Head of Medical Affairs at Exosome Diagnostics.

“This second large validation study, an undertaking not employed by molecular diagnostic companies in the prostate cancer space, highlights not only the sensitivity and reproducibility of EPI, but also is a testament to the company’s adherence to rigorous quality testing for its diagnostics,” stated John Boyce, President and CEO of Exosome Diagnostics. “The management team at Exosome Diagnostics is driven by a commitment to the highest quality of patient care, above all else,” Boyce concluded.
Exosome Diagnostics will be exhibiting and presenting at the AUA Annual Meeting in San Francisco on May 18th - 21st. If you are interested in learning more about Exosome Diagnostics’ unparalleled technology and EPI’s supreme data, please visit booth 6452 or the poster sessions on Saturday May 19th.

Poster session 1: 1:00 – 3:00 PM

Extended validation results from a prospective adaptive utility trial confirm performance of a novel urine exosome gene expression assay to predict high-grade prostate cancer at initial biopsy.

Poster session 2: 3:30 – 5:30 PM

Development of a clinical implementation plan (CarePath) for a novel urine exosome gene expression assay as part of a two-cohort, adaptive decision impact utility trial)

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™, and point of care instrument for protein capture and analysis, Shahky™, can yield comprehensive and dynamic molecular insights to transform how cancer and other serious diseases are diagnosed, treated and monitored.

Visit [www.exosomedx.com](http://www.exosomedx.com) to learn more.

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