Exosome Diagnostics Announces Bladder Cancer Surveillance Panel: The First Liquid Biopsy Designed Entirely By Artificial Intelligence (AI)

Waltham, MA – May 22, 2018 - Exosome Diagnostics, Inc. announced today completion of its pre-clinical validation of a urine-based, gene expression panel intended for use as a rule-out for bladder cancer *and* as a rule-in for bladder cancer recurrence in a surveillance population. Results show a 100% NPV (Negative Predictive Value) and 100% sensitivity for rule out of bladder cancer among two separate cohorts of 24 and 57 patients. The panel additionally shows 100% PPV (Positive Predictive Value) and 100% specificity for rule-in of bladder tumor recurrence. Exosome Diagnostics is now actively recruiting for further clinical validation.

Despite being the 6th most common cancer in the United Sates, bladder cancer is one of the most expensive to treat due to high rates of recurrence on non-muscle invasive bladder cancer (NMIBC). The standard of care for surveillance of NMIBC involves repeated surveillance cystoscopy and cytology as frequently as every three months.

“Urine cytology is standard of care for surveillance for recurrence/progression of non-muscle invasive bladder cancer. However, there is a need for a more accurate non-invasive urine test with high specificity and sensitivity. The urine exosome gene expression panel developed purely by artificial intelligence (AI) provides both the sensitivity and specificity required of an ideal urine biomarker of bladder cancer,” said Grannum R Sant, MD, Head of Medical Affairs at Exosome Diagnostics.

This marks the first application of “BIONIC”, Exosome Diagnostics’ AI platform for biomarker discovery. BIONIC automatically ranks tens of thousands of potential genomic biomarkers based on predicted power to discriminate between healthy and affected populations for any given disease or indication.

“BIONIC’s predictions have been proven to be highly accurate and rank-stable across dozens of experiments targeting several disease states,” said John Healy, Vice President of Informatics at Exosome. “This drastically reduces the initial search space from hundreds of manually selected markers of questionable relevance to a handful of markers that are highly enriched for their ability to discriminate healthy and affected populations. A process that used to require at least one full year of repeated cycles of semi-automated candidate marker selection, followed by prospective testing, can now be completed within a few weeks.”

BIONIC is uniquely capable of making predictions about the availability and specificity of markers with respect to any bio-fluid. This is a prerequisite to automatically choosing markers for a bladder cancer panel as candidate markers must be readily available in the urine, specific to bladder and robust to hematuria.

“The exquisite predictive capabilities of BIONIC are made possible by the breadth, depth and quality of the proprietary data that was used during training,” said Johan Skog, Chief Scientific Officer at Exosome Diagnostics. “We have built a vast, comprehensive data set that uniquely positions us to understand the subtle requirements of bio-fluid based diagnostics. Through our partnerships and internal development, we have amassed billions of data points capturing exosome derived gene expression levels, genetic variants and surface protein concentrations across thousands of clinically annotated bio-fluid samples including plasma, serum, urine, saliva and CSF.”

“BIONIC accelerates our learning process by maximally leveraging our current proprietary knowledge base. It enhances our lead in the liquid biopsy field with a uniquely powerful map to the next samples, targets and platform capabilities of highest value.” said John Boyce, President and CEO of Exosome Diagnostics. “The bladder cancer panel is the latest demonstration of our platform superiority for liquid biopsy and cements our standing as a leader in urology applications.”

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 to learn more.

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