



Contact:

Robert Gottlieb
RMG Associates, LLC
857-891-9091
Robertmg52@gmail.com

Cellanyx Diagnostics' Novel Live Cell Phenotypic Test for Prostate Cancer Risk Stratification Recognized as Best Prostate Cancer Biomarker Poster Presentation at 2016 American Urological Association Annual Meeting

Beverly, MA, June 1, 2016 – Cellanyx Diagnostics' data on its novel, live tumor cell phenotypic test for risk stratifying prostate cancer patients was awarded the best prostate cancer biomarker poster presentation at the 2016 American Urological Association annual meeting in San Diego, CA (May 6-10). The poster described the interim results of the company's clinical validation study in patients undergoing radical prostatectomy and demonstrated that the Cellanyx test accurately predicted adverse pathologic findings in the surgical specimens. Furthermore, the Cellanyx test predicted the adverse pathology from the tissue samples taken away from the tumor (referred to as a 'field' tissue sample) with high degree of sensitivity and specificity. Cellanyx is currently developing phenotypic tests to address an important unmet clinical need in prostate cancer risk stratification by providing quantitative assessment of tumor aggressiveness and metastatic potential that complements the standard-of-care Gleason pathology scores.

"Cellanyx is pioneering in the development live cell phenotypic tests to aid in prostate cancer risk stratification," said Grannum R. Sant, MD, FRCS, FACS, Former Chair of Urology, Tufts University School of Medicine, co-author of the poster and Chairman, Cellanyx Scientific Advisory Board. "The AUA award recognizes the innovativeness of this phenotypic approach and the strength of the data developed to date." Dr. Sant noted that the clinical validation study provides a foundation for conducting a prospective trial in prostate needle biopsy samples to confirm the test's predictive metrics.

The poster reported on blinded multicenter clinical validation study results from 250 patient fresh tumor samples from prostate cancer patients undergoing radical prostatectomy. The fresh tissue samples evaluated by the Cellanyx phenotypic test included samples from [suspected] tumor tissue as well as samples away from the suspicious core (referred to as 'field' samples). The live tumor (and 'field') cells were

assayed in the Cellanyx platform, which uses a microfluidic device, machine vision and machine learning technologies to analyze multiple morphological, biophysical, and cellular dynamic biomarkers to generate quantitative analyses to predict adverse pathology at the time of radical prostatectomy - extension into the prostate capsule or seminal vesicle (sensitivity = 0.796; specificity = 0.789; AUC = 0.848) and vascular invasion and lymph node involvement (sensitivity = 0.769; specificity = 0.897; AUC = 0.886). The novel Cellanyx phenotypic test accurately predicted adverse pathology in the 'field' samples (n=67) for adverse pathology (extension into the prostate capsule or seminal vesicle (sensitivity = 0.878; specificity = 0.882; AUC = 0.905) and lymphovascular invasion (sensitivity = 0.886; specificity = 1.00; AUC = 0.994).

The poster is entitled, "[Clinical validation of a live cell, phenotypic biomarker-based diagnostic assay for the prediction of adverse pathology in Prostate Cancer.](#)"

About Cellanyx Diagnostics

Cellanyx Diagnostics is developing a proprietary living cell phenotypic cancer diagnostic platform to aid clinical decision making. The company's unique 'biopsy-on-a-chip' methodology provides quantitative, actionable assessment of individual cancer cells in biopsy samples using multiple phenotypic biochemical and biophysical markers of tumor aggressiveness and metastatic potential. Cellanyx has demonstrated clinical proof-of-concept with its lead product in development, a diagnostic to improve risk stratification in men with prostate cancer. Learn more at www.cellanyx.com.

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