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Cellanyx Diagnostics Announces Expanded Clinical Data with a Novel Live Tumor Cell, Phenotypic Biomarker Test in Prostate Cancer

Quantitative Test for Risk Stratification in Low and Intermediate Grade Prostate Cancer Patients Presented at American Urological Association Annual Meeting

Beverly, MA, May 15, 2015 – Cellanyx Diagnostics announced today expanded clinical results from an ongoing clinical proof-of-concept study of its novel live tumor cell phenotypic diagnostic biomarker test for risk stratification in men with prostate cancer. The data, which support the test's potential as a new tool to aid clinical decision making in low- and intermediate-risk Gleason grade patients, was presented at a poster session during the American Urological Association's (AUA) 2015 Annual Meeting in New Orleans.

"Distinguishing clinically significant from indolent disease in men with low or intermediate Gleason grade prostate cancer, Gleason 6 or 7 (4+3 or 3+4), is a critical challenge in prostate cancer management," said Grannum R Sant MD, Chairman of Cellanyx's Scientific Advisory Board and an author on the poster. "The absence of strong predictive tools leads to significant over-diagnosis and over-treatment of prostate cancer."

The Cellanyx test is based on a biopsy-on-a-chip platform designed to assess tumor cell behavior by analyzing a suite of phenotypic biomarkers from individual live cells cultured from fresh tumor tissue. These biomarkers represent multiple biological pathways and morphological, metabolic and biophysical cellular characteristics of tumor cells including cell motility and adhesion. They are evaluated by culturing the biopsied cells in a proprietary extracellular matrix and analyzing tumor and normal cells with machine vision learning and Cellanyx's proprietary algorithms. The test distinguishes tumor cells from normal cells and generates quantitative, actionable measure of cell behavior that predict local tumor invasion and growth (oncogenic potential or OP) and metastatic spread (metastatic potential or MP).

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"These results suggest that this test, which quantifies cell behavior and maps it directly to disease, has strong potential to buttress Gleason scores and other established measures in stratifying risk in this patient group," commented David Albala MD, Chief of Urology at Crouse Hospital (Syracuse, NY), an investigator in the study, and member of Cellanyx Scientific Advisory Board. "The test has shown an impressive capability to generate quantitative metrics that predict adverse pathologies, including seminal vesicle invasion and/or lymph node involvement, which are important for making shared treatment decisions. The data strongly support continued risk stratification validation studies in prostate cancer."

Study Details

The objective of this blinded study was to demonstrate clinical proof-of-concept in prostate cancer and provide analytical validation of this proprietary diagnostic test. In the study, fresh tissue samples were obtained from 104 radical prostatectomy procedures across six centers in the U.S. Results based on a smaller sample set were previously presented at the ASCO Genitourinary Cancers Symposium (February 2015) and the American Association of Cancer Research (April 2015) .

The Cellanyx platform measures phenotypic biomarkers in tumor cells and generates predictive metrics of adverse pathology in radical prostatectomy (RP) surgical specimens related to local tumor invasion (positive surgical margins, seminal vesicle invasion, and extra-prostatic extension) and potential for distant spread (perineural and lympho-vascular invasion, and pelvic lymph node involvement). The predictive metrics of oncogenic potential (OP) and metastatic potential (MP), allow for improved patient risk stratification, and predicted adverse pathology in RP specimens in this multicenter blinded study.

The results demonstrate that the Cellanyx predictive metrics of oncogenic (OP) and metastatic (MP), complement Gleason scores and can improve tumor risk stratification in low- and intermediate-risk prostate cancer. True positives and true negatives for early pathology and Gleason scores were predicted accurately at >80 percent.

The Cellanyx platform distinguishes normal from tumor cells and specifically Gleason Grade 6 vs 7 (sensitivity = 0.88 and specificity = 0.81) and Gleason 7 (4+3) vs Gleason 7 (3+4) (sensitivity=0.85 and specificity=0.80).

The poster, "A novel live cell microfluidic diagnostic using phenotypic biomarkers with objective algorithmic analysis for prostate cancer risk stratification" will be presented May 15, 2015 at 10:30 AM CT/11:30AM ET. In addition to Drs. Albala and Sant, authors on the poster include Kimberly M. Rieger-Christ, PhD, Travis Sullivan, MS, Naveen Kella, MD, Ray Hernandez, MD, Hani Rashid MD and Vladimir Mouraviev, MD/PhD, who served as clinical investigators. In addition, Kevin Knopf, MD, member of Cellanyx's SAB also participated in the design and analytics of the clinical study.

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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 low and intermediate grade prostate cancer and thereby reduce overtreatment. Learn more at www.cellanyx.com.

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