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For Immediate Release

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

Quantitative Test for Risk Stratification in Prostate Cancer Patients to be Presented at ASCO Genitourinary Cancers Symposium

Beverly, MA, February 24, 2015 – Cellanyx Diagnostics announced today that it will present at the ASCO Genitourinary Cancers Symposium, in Orlando, Florida, their first clinical data in prostate cancer with a novel live tumor cell phenotypic diagnostic test. Data will be presented at a poster session which demonstrate the test's potential to stratify the risk of tumor advancement and metastasis in patients diagnosed with low and intermediate Gleason scores in prostate cancer. The test is designed to provide a new tool to aid clinical decision making for patient care.

The poster (No. 211) is entitled, Novel Live Tumor Cell Diagnostic Test Utilizing Biophysical and Molecular Biomarkers to Assess Local, Advanced, and Metastatic Prostate Cancer," and will be presented Feb. 27 at 12:15PM-1:45PM ET and 6:00PM-7:00PM ET.

"The results of this initial proof-of-concept study suggest this phenotypic, live tumor cell test has great potential to complement Gleason scores and other established measures such as PSA testing and to stratify the local invasive and metastatic risk of patients with low and intermediate grade cancer," said Kevin B. Knopf, MD, MPH, Hematologist & Oncologist at California Pacific Medical Center, Sutter Health, the first author and member of Cellanyx Scientific Advisory Board. "The assay's ability to predict adverse pathologies such as seminal vesicle invasion and/or lymph node involvement by analyzing phenotypic markers from individual cells is striking. These encouraging results warrant further development of this novel diagnostic test."

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"There is an enormous need for better predictive biomarkers to differentiate indolent vs. aggressive disease in men with low or intermediate grade prostate cancer – Gleason 6 or Gleason 7 (4+3 and 3+4) – and to aid shared decision making in men with newly diagnosed prostate cancer," 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 lack of risk stratification tools is a major reason why 144,000 patients in the U.S. annually are over-treated with surgery or radiation."

The Cellanyx test is based on a biopsy-on-a-chip platform that is designed to assess tumor cell behavior by analyzing a set of phenotypic markers of individual live cells cultured from fresh biopsy samples. The markers represent multiple biological pathways and morphological, metabolic and biophysical cellular characteristics such as cell motility and adhesion. These biomarkers are accessible through a proprietary method of cell culture and analysis of living tumor cells. Analysis of living tumor cells is enabled by the platform's proprietary extracellular matrix and microfluidic chip that mimic the cells' microenvironment, coupled with machine vision and learning algorithms.

These algorithms are designed to distinguish tumor cells from normal cells, and further, generate quantitative, actionable metrics that predict local tumor growth (i.e. oncogenic potential -OP) and distant spread (i.e. metastatic potential - MP).

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 70 radical prostatectomy procedures across 6 centers in the US. The assay measured the phenotypic biomarkers in single cells and generated predictive metrics of adverse pathology related to local tumor growth (surgical margins, seminal vesicle invasion, and extra-prostatic extension) and capacity for distant spread (perineural and vascular invasion and lymph node involvement). The predictive metrics, OP and MP, allow for patient risk stratification, and predicted pathologic findings in the radical prostatectomy specimens.

The results demonstrate that the Cellanyx biomarker test strongly predicts Gleason score in radical prostatectomy specimens and that the oncogenic (OP) and metastatic (MP) scores can stratify men with low and intermediate risk prostate cancer. True positives and true negatives for early pathology and Gleason scores were predicted accurately at >80 percent.

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The results also demonstrated the Cellanyx test's potential to distinguish between normal and tumor cells and specifically among Gleason Grade 6 vs. 7 (sensitivity = 0.90 and specificity = 0.91) and Gleason 7 (4+3) vs. Gleason 7 (3+4) (sensitivity=0.91 and specificity=0.81).

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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