

Michigan Institute of Urology, P. C. to Perform Clinical Trial Using Cella, Inc's Same Day OligoFISH® Probes for Prostate Cancer



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November 09, 2011 - St. Clair Shores, Michigan and Cambridge, Massachusetts – Michigan Institute of Urology, P. C. (MIU) and Cella, Inc. today announced that MIU will exclusively perform a clinical trial for prostate cancer using Cella's Same Day OligoFISH® probe panel. Data from this trial will be included in Cella's premarket approval (PMA) application for submission to the U.S. Food and Drug Administration. This novel, non-invasive screening test is designed to detect chromosomal abnormalities in prostate cells obtained in a urine sample after a digital rectal exam. This investigational use test uses fluorescence in situ hybridization (FISH) technology to detect chromosome gains and losses which have been associated with prostate cancer.

Prostate cancer is the most common cancer in males in the United States, and there are approximately 200,000 new cases diagnosed annually and 38,000 deaths per year. However, due to inaccuracies of the current screening method, the PSA blood test, more than 600,000 invasive biopsies are performed annually. The ability to differentiate non-aggressive from aggressive, metastatic prostate cancers has been a continuous clinical and diagnostic challenge. Cella expects that

the clinical trial will demonstrate that its rapid non-invasive, Same Day OligoFISH® panels will improve diagnosis, prognosis, and treatment using a cost effective, patient friendly assay.

Alphonse M. Santino, M.D., CEO and a Founder of MIU, noted, "MIU is pleased to be the exclusive clinical trial site for Cella's Same Day OligoFISH® probe panels for prostate cancer for its PMA submittal. Our relationship with Cella reinforces our commitment to the people of Michigan to provide the most effective diagnosis and treatment for urological disorders and disease. This is an important relationship for us and our community, since African-Americans are 3.5 times more likely to develop prostate cancer than the rest of the male population. Moreover, this group presents with the aggressive type of prostate cancer at an earlier age with higher rates of mortality."

"Cella appreciates that MIU has committed to serve as exclusive site for the clinical trial of our Same Day OligoFISH® probe panels for prostate cancer. MIU's physicians' group is recognized as one of the nation's premier urology practices and sets the standard for diagnosis and treatment of urologic disorders. Cella welcomes MIU's support and participation in this novel clinical trial," said Ed O'Lear, President & CEO of Cella.

About Michigan Institute of Urology

As one of the oldest and largest sub-specialty Urology practices in Michigan, MIU is dedicated to providing its patients the most up to date, state of the art urologic care. Its specialists have joined MIU from the most respected research universities and hospitals in the United States.

About Cella

Cella is a privately held, manufacturer of Same Day OligoFISH® probes for high complexity, physician owned laboratories, which contract with Cella to manufacture and supply individual probes or multiple probes of the laboratories' choice pursuant to FDA and Clinical Laboratory Improvement Amendments (CLIA) regulations. Cella is registered with the FDA.

About FISH

FISH is an established [cytogenetic](#) technique that is used to detect and localize the presence or absence of specific [DNA sequences](#) on [chromosomes](#). FISH uses [fluorescent probes](#) that bind to only those parts of the chromosome with which they show a high degree of sequence complementarity. Same Day

OligoFISH® probes were introduced in 2007 and hybridize extremely fast with much higher analytical sensitivity and penetrability in cells and tissues than traditional probes.

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