Evaluation of the MiCheck® MIA test performance in differentiating aggressive from non-aggressive prostate cancer – the MiCheck-01 prospective trial

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INTRODUCTION AND OBJECTIVES: A diagnostic test which can better inform both clinicians and patients regarding a decision to proceed with a prostate biopsy, while still utilizing traditional parameters of Prostate Specific Antigen (PSA) kinetics and/or the digital rectal examination (DRE) is still an unmet need. The MiCheck® test is designed as a triage test to assist clinicians in the decision to proceed to prostate biopsy. The MiCheck® test is a simple blood test that measures the levels of the Glypican-1 protein and related signalling molecules.

The MiCheck®-01 prospective trial builds on a previous pilot trial that examined the ability of the MiCheck® test to distinguish between normal subjects, patients with benign disease or Gleason 7 and above prostate cancer. The MiCheck® test showed sensitivity of 60% and specificity of 96% in distinguishing between subjects with Gleason ≥7 and normal or BPH patients. In a separate study, the MiCheck® test could differentiate aggressive (GS ≥3+4) from non-aggressive (GS 3+3) prostate cancer with a sensitivity of 85% and specificity of 90%.

METHODS:
The trial consists of two arms: Arm 1 (normal patients, n=50) and Arm 2 (prostate biopsy patients, n = 300). **Inclusion criteria**: **Arm 1**: Age ≥50, Low PSA (performed at most 12 months prior, defined as PSA < 1.5 ng/mL between ages 50 and 60 and PSA < 3 ng/mL above age 60). **Arm2:** Age ≥40, all subjects who are referred for or have undergone either a de novo or a repeat prostate biopsy for high PSA (defined as PSA ≥ 1 ng/ml between ages 40 and 49, PSA ≥2 ng/mL between ages 50 and 60 and PSA ≥ 3 ng/mL for age 60 and above age 60). **Key exclusion criteria**: prior history of cancer, patients taking ADT, DRE or other prostate manipulation within 72 hrs, subjects taking 5 ARIs.

RESULTS:
The trial has recruited 30 Arm 2 patients to date. Interim analyses will be performed following accrual of 100 and 200 Arm 2 patients. Full accrual is expected by mid Q4 2017.

CONCLUSIONS: Interim analysis data will be presented showing test performance.

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