



## **PREDICTIVE BIOSCIENCES ANNOUNCES PUBLICATION IN JOURNAL OF UROLOGY OF RESULTS FROM A PILOT STUDY OF ITS NON-INVASIVE ASSAY TO MONITOR PATIENTS FOR BLADDER CANCER**

### **CONFIRMATORY CLINICAL TRIALS OF DIAGNOSTIC TEST NOW UNDERWAY**

**November 3, 2009**

Predictive Biosciences Inc. today announced the publication of pilot study results in the November issue of the *Journal of Urology*, highlighting the Company's novel urinary biomarker approach to bladder cancer detection that achieves exceptionally high Negative and Positive Predictive Values (NPV and PPV). The study demonstrates that Predictive's unique non-invasive clinical approach, known as Clinical Intervention Determining Diagnostic™ or CIDD, can identify with extremely high confidence those patients who do *not* have bladder cancer. Based on the strength of these initial study results, Predictive has commenced two prospective clinical trials to evaluate its bladder cancer assay; each is to enroll approximately 1,000 subjects at 10 or more clinical trial sites.

As described in the *Journal of Urology*, Predictive's novel CIDD approach was applied to optimize assay cutoffs for a non-invasive bladder cancer assay, using urinary matrix metalloproteinases (MMPs) as biomarkers. Researchers analyzed urine samples from 530 patients, including 84 with bladder cancer, for levels of urinary MMPs, the expression of which has been shown to highly correlate with disease status in bladder and other cancers. The pilot study results could lead to new, non-invasive and highly reliable tests that individualize diagnostic follow-up in patients undergoing surveillance for bladder cancer recurrence and in patients with hematuria (blood in the urine) undergoing evaluation for bladder cancer.

"We are very encouraged by the results of this study and their publication in the prestigious *Journal of Urology*. While cystoscopy, cytology, and upper urinary tract imaging remain the standard-of-care for bladder cancer patients, our manuscript details a novel approach focusing a new diagnostic assay on delivering high negative and positive predictive value, which we feel is more consistent with the way physicians practice diagnostics," said Anthony P. Shuber, chief technology officer of Predictive Biosciences. "We believe that the application of our non-invasive assay will enable clinicians to focus their attention on those patients with a high likelihood of bladder cancer, while continuing to monitor those who are cancer-free in a relatively simple and efficient manner."

Predictive has commenced both multi-site clinical trials to further evaluate its bladder cancer assay. One trial is focused on the performance of the assay relative to cystoscopy for patients undergoing surveillance for urothelial bladder cancer recurrence. The other trial will compare the performance of the assay to cystoscopy for patients undergoing evaluation for the referral diagnosis of gross or microscopic hematuria.

"There remains a significant unmet need for a non-invasive test that could unambiguously identify patients who do not have disease and would allow clinicians to determine which patients may forgo cystoscopy. While bladder cancer has a high survival rate, its high rate of recurrence means that currently, survivors must undergo cystoscopies at regular intervals over their lifetime. A reliable test that can reduce the burden and associated costs of this invasive procedure would be an important improvement for both patients and physicians," said co-author John A. Libertino, M.D., professor and chairman, Department of Urology, Lahey Clinic Medical Center.

The *Journal of Urology* is the official journal of the American Urological Association (AUA), the premier professional association for the advancement of urologic patient care. It is the most widely read and highly cited journal in the field. Access to the abstract and full manuscript cited in this release can be obtained at <http://tinyurl.com/Journal-Urol-Nov-09>.



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