

**Predictive Biosciences Presents Novel Multi-Analyte Approach to Diagnostic Assay Development at Annual Meeting of the Society of Urologic Oncology (SUO)**

*- Predictive Assay First to Combine Both Protein and DNA Urinary Biomarkers to Optimize Assay Performance -*

**Lexington, MA - December 02, 2009** - Predictive Biosciences today announced that Company scientists will be presenting a novel multi-analyte approach to the development of a non-invasive, urine-biomarker based diagnostic assay during the 10<sup>th</sup> Annual Meeting of the Society of Urologic Oncology (SUO). The research was done under collaboration agreements with Lahey Clinic Medical Center and Mayo Clinic. This pioneering scientific research represents the first example of protein and DNA biomarkers being combined into one assay to optimize performance. The SUO meeting is being held December 2-4, 2009 at the Natcher Conference Center of the National Institutes of Health (NIH) in Bethesda, Maryland.

Predictive's unique approach to diagnosing and monitoring bladder cancer will be highlighted in a poster presentation titled "*Multi-Analyte Diagnostic Readout (MADR): Combining Protein and DNA Markers to Maximize Clinical Performance*," during Poster Session I, which takes place on Thursday, December 3, from 4:00 p.m. to 6:00 p.m. E.T. Cecilia A. Fernández, Ph.D., senior scientist at Predictive Biosciences and first author, will present the poster, which demonstrates how the performance of Predictive's bladder cancer assay was improved by utilizing both Matrix Metalloproteinase (MMP) biomarkers and Fibroblast Growth Factor Receptor 3 (FGFR3) biomarkers, leveraging the sensitivity and specificity achieved by each. Predictive's proprietary MADR method is an extension of its Clinical Intervention Determining Diagnostic approach – termed CIDD – to the non-invasive management of bladder and other cancers.

The poster first illustrates how Predictive's assay, by utilizing MMPs detected in urine as monitors of disease-free status, was able to identify with high confidence – as measured by negative predictive value (NPV) – the bladder cancer participants who did *not* have cancer recurrence at the time of evaluation. The poster goes on to demonstrate that by adding a Real Time PCR (polymerase chain reaction) based assay to detect FGFR3 mutations as monitors of disease recurrence, Predictive was able to further increase the assay's NPV, with no reduction in specificity.

"To our knowledge, we are the first and only company to combine both protein and DNA biomarkers into one assay to deliver both high negative and high positive predictive values for the absence or presence of cancer, respectively," commented Anthony P. Shuber, co-founder and chief technology officer for Predictive Biosciences.

FGFR3 gene mutations, detectable in the urine of bladder cancer patients, have been shown to be associated with early stage/early grade bladder cancer with up to 70 percent of low grade tumors

showing mutation. Predictive believes that the inclusion of this binary DNA biomarker in its bladder cancer assay will also help to detect lower stage/grade bladder cancers which have been difficult to detect with other biomarkers.

Mr. Shuber continued, “Carried forward into the clinical setting, we are aiming to provide urologists with a non-invasive diagnostic tool that we anticipate will initially be used in tandem with current standard-of-care approaches such as cystoscopy, cytology and upper urinary tract imaging. Ultimately, our goal would be for physicians to use the test as an actionable tool prior to cystoscopy. We believe it will allow them to confidently triage patients by those who are highest risk and require accelerated intervention, those who are average risk and should receive standard-of-care, and importantly, those who are at very low risk and can forgo cystoscopy.”

Mr. Shuber will accompany Dr. Fernández at the SUO poster presentation.

### **About Predictive Biosciences**

Leveraging its portfolio of patented biomarkers and clinical algorithms, Predictive Biosciences is pioneering intervention diagnostic assays for informed cancer management™. Predictive Biosciences’ tests will enable physicians to reliably determine the presence or absence of cancer. This information, incorporated into current standard clinical practice, should lead to more effective utilization of existing diagnostic tools and ultimately better outcomes for patients. Predictive Biosciences’ first assays are designed to detect urinary biomarkers fundamentally associated with the physiological changes resulting from cancer development and progression. The initial focus for these tests will be the growing cancer survivor population and the large number of individuals undergoing clinical workups for cancer. Predictive Biosciences was launched in 2006 and is privately funded by Flybridge Capital Partners, Highland Capital Partners, Kaiser Permanente Ventures and New Enterprise Associates. For more information and partnership inquiries, visit Predictive Biosciences’ website at [www.predictivebiosci.com](http://www.predictivebiosci.com).

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