Predictive
BIOSCIENCES

# NEWS RELEASE

**CONTACT:** Sondra Newman
Pure Communications, Inc.
(617)877-5687

## Predictive Biosciences' Breast Cancer Biomarker Findings Highlighted in Proceedings of the National Academy of Sciences

*Predictive's Portfolio of Biomarkers from Children's Hospital Boston Poised for Application in Non-Invasive Diagnostic Assays*

**LEXINGTON, MA and SAN DIEGO, CA. – March 5, 2009 –** Predictive Biosciences, an emerging molecular diagnostics company developing non-invasive diagnostic products for *informed cancer management*™, today announced the publication of research conducted at Children's Hospital Boston on February 23, 2009 in the online, early edition of the *Proceedings of the National Academy of Sciences* (PNAS). This research demonstrates that the protein lipocalin 2, or Lcn2, promotes breast cancer progression by inducing the epithelial to mesenchymal transition (EMT), one of the key processes involved in tumor progression and metastasis. Further, the studies show that Lcn2 levels can be measured in urine samples, and high levels are correlated with cancer cell migration and invasiveness in women with advanced or metastatic estrogen-receptor (ER)-negative breast cancer. These findings suggest the potential for Lcn2 as a non-invasive biomarker for advanced breast cancer. Lcn2, along with other urine biomarkers for various cancers discovered at Children's Hospital Boston, is exclusively licensed to Predictive for diagnostic assay development.

"Estrogen-receptor negative breast tumors are among the most difficult to treat," said Marsha A. Moses, Ph.D., Professor of Surgery at Harvard Medical School and interim Director of the Vascular Biology Program at Children's Hospital Boston, and co-author of the PNAS publication. Dr. Moses, a co-founder of Predictive Biosciences, added, "We are excited by this research showing a strong correlation between high levels of Lcn2 and the aggressiveness of breast cancer. These studies suggest the potential for a simple, urine-based assay to measure Lcn2 as a way of monitoring cancer development and progression on an individual basis, and to determine if more aggressive treatment is needed. This would be an important step towards more accurate and personal cancer management for these patients."

Utilizing its portfolio of patented biomarkers and proprietary clinical approaches (such as Clinical Intervention Determining Diagnostic™ or CIDD); Predictive is developing novel diagnostic assays that have exceptionally high negative predictive value (NPV) and positive predictive value (PPV) for cancer development and progression. This information, incorporated into current standard clinical practice, should lead to more effective utilization of existing tools and ultimately better outcomes for patients. Predictive aims to deliver highly accurate, convenient diagnostics to provide physicians with actionable information for personalized diagnostic follow-up and treatment plans – avoiding expensive, invasive procedures and increasing patient compliance and comfort.

“We are very pleased to be collaborating with Professor Marsha Moses and Children’s Hospital Boston on developing a number of urine-based cancer diagnostic assays,” said Peter Klemm, Ph.D., President and Chief Executive Officer of Predictive. “Already, Predictive is advancing novel bladder cancer assays, with plans to commercialize these tests via our CLIA lab. In addition, we have a rich pipeline of biomarkers poised for diagnostic assay development, including this very compelling breast cancer biomarker, Lcn2. Leveraging our deep clinical development and scientific capabilities, we are building a robust portfolio of innovative cancer assays, in collaboration with others who share our interest in delivering highly accurate and convenient cancer diagnostics for *informed cancer management*™.”

**About Predictive Biosciences**

Leveraging its portfolio of patented biomarkers and clinical approaches, 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

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