



## **FOR IMMEDIATE RELEASE**

### **DANA-FARBER ONCOLOGISTS PRESENT RESULTS OF SOURCE MDx'S RNA TRANSCRIPT-BASED SIX-GENE TEST TO PREDICT SURVIVAL OF CASTRATION-RESISTANT PROSTATE CANCER PATIENTS AT GU ASCO SYMPOSIUM**

*—Source MDx announces the initiation of a prospective multi-site validation clinical trial of six-gene CRPC Precision Profile™ with the Prostate Cancer Clinical Trials Consortium —*

**Orlando, Fla., February 27, 2009** — Dana-Farber Cancer Institute (DFCI) and Source MDx today announced that Source MDx's whole blood RNA transcript-based Precision Profiles™ diagnostic test predicted survival in men with castration-resistant prostate cancer (CRPC). In a study of 62 CRPC patients, the model separated patients into a high risk group (survival less than 2.2 years) and a low risk group (survival greater than 2.2 years) (log rank  $p=0.00083$ ). The six-gene CRPC Precision Profile™ was 96 percent accurate in predicting low risk CRPC patients alive at study end and 93 percent accurate in predicting high risk CRPC patients who died prior to study completion, suggesting that the model may be a powerful tool for stratifying CRPC patients in clinical trials. The Prostate Cancer Clinical Trials Consortium (PCCTC) will begin a prospective, multisite clinical trial to validate using Source MDx's six-gene CRPC Precision Profile™ to stratify aggressive vs. non-aggressive CRPC patients.

In the study, circulating tumor cell (CTC) counts were not predictive of survival. In fact, the highest CTC counts (931 and 263) were found in patients from the low risk group. The Halabi nomogram, a commonly used clinical prognostic factor that uses seven clinical measures, also predicted low and high risk groups of men with CRPC, based on evaluations in 56 patients, but was less discriminatory ( $p=0.012$ ) than the six-gene Precision Profile™.

William K. Oh, M.D., clinical director, Lank Center for Genitourinary Oncology, DFCI today presented the data from **abstract 176** in a general poster session at the American Society for Clinical Oncology's Genitourinary Cancers Symposium. The study was co-investigated with Robert W. Ross, M.D., attending physician, Lank Center for Genitourinary Oncology, DFCI.

The PCCTC, a national clinical research group comprised of top U.S. research institutions, including DFCI, will conduct a prospective multi-site validation clinical trial of CRPC patients under the leadership of Dr. Oh. Consortium studies focus on the evaluation of novel agents for the management of prostate cancer at all stages of the disease. Source MDx has filed provisional patents on the six-gene model, which also states diagnostic claims for protein markers corresponding to patented RNA transcripts.

“Survival for castration-resistant prostate cancer ranges greatly from several months to several years, however, there are no available tools that allow clinicians to easily identify patients with the most aggressive form of the disease,” commented Dr. Oh. “The ability to identify patients with more aggressive forms of castration-resistant prostate cancer using a simple blood assay may prove to be a powerful tool for stratifying patients in clinical trials, leading to more robust studies with more relevant survival endpoints. I look forward to further evaluating this biologically-based test in forthcoming larger, multi-site clinical trials with the Prostate Cancer Clinical Trials Consortium.”

These data also show that individual differences in gene transcripts associated with cell-mediated and humoral immunity are associated with survival in CRPC patients. These specific immune system changes

were indicative of a decrease in both cell-mediated and humoral immunity in CRPC patients with higher mortality.

“The six genes predictive of more lethal castration-resistant prostate cancer in this trial suggest a fundamental difference in a patient’s immune system’s ability to deal with malignant tumors when confronted with more aggressive forms of prostate cancer,” stated Karl Wassmann, Chief Executive Officer of Source MDx. “The Source MDx six-gene CRPC Precision Profile™ is now available for patient stratification in prostate cancer clinical trials.”

### **About the Study:**

From August 2006 through June 2008, Source MDx and Dana-Farber Cancer Institute conducted a study to discover whole blood-based RNA-transcript biomarkers predictive of primary end-points of CRPC progression (i.e., survival). The study enrolled a total of 62 CRPC patients, with or without bone metastases, who had previously undergone a variety of treatments, including hormone therapy, chemotherapy and radiation. Each patient consented to the collection of whole blood in PAXgene™ blood RNA tubes for gene expression and CellSave™ tubes for the enumeration of circulating tumor cells (CTCs).

Using Source MDx Precision Profiles™, a total of 168 inflammation and prostate cancer-related genes were evaluated using optimized Q-PCR technology to assess biomarkers predictive of survival. Hazard ratio survival analysis models were performed on a weekly basis, both from the time of CRPC diagnosis through June 20, 2008 and from the time of blood draw through June 20, 2008. The results were similar regardless of the survival time definition (the time of castration-resistant diagnosis vs. blood draw) or the survival model used for statistical analysis. Treatment type was not predictive of survival.

### **About Prostate Cancer:**

Prostate cancer is the most common cancer, other than skin cancers, in American men and is the second leading cause of cancer death in men behind only lung cancer. The American Cancer Society estimates that during 2008 about 186,320 new cases of prostate cancer will be diagnosed in the United States. Tumors that are no longer responsive to hormone therapy are referred to as castration-resistant. Mean survival for CRPC is approximately 4.5 years, ranging from several months to more than eight years. Treatment options include hormone therapy, chemotherapy, and radiation.

### **About Source MDx:**

Source MDx, the leader in RNA transcript-based molecular diagnostics, uses its patented technology to monitor an individual’s health, disease status and response to therapy at the molecular level. The company is demonstrating how the link between cancer and the immune response can be translated into whole blood RNA transcript-based prognostic, predictive and early detection oncology biomarkers. Source is currently collaborating with leading academic institutions such as Dana-Farber Cancer Institute, NYU Medical Center and Brigham and Women’s Hospital. Source MDx also has a translational molecular medicine collaboration with Pfizer, Inc. to develop and validate RNA-based pharmacodynamic and predictive biomarkers within Pfizer’s cancer and inflammation therapeutic development programs for commercialization as companion diagnostics. Source MDx has patented Precision Profile™ biomarkers in nine cancers including prostate, lung, and melanoma, and eight autoimmune diseases, including multiple sclerosis. The company has completed over 150 preclinical and clinical projects for more than 30 leading pharmaceutical, biotechnology and diagnostic companies. Source has offices in both Boulder, Colorado and Newton, Massachusetts. For more information, please visit [www.sourcemdx.com](http://www.sourcemdx.com).

Study: Precision Profiles™ diagnostic test predicts survival in men with castration-resistant prostate cancer

February 27, 2009

Page 3

**About The Prostate Cancer Clinical Trials Consortium:**

The Prostate Cancer Clinical Trials Consortium (PCCTC) offers simplified solutions for multicenter clinical studies by bringing together leading prostate cancer investigators from the top research institutions across the country for the rapid design, development, and implementation of early phase prostate cancer clinical trials. Capitalizing on the scientific expertise and unique institutional resources, PCCTC members work together to address barriers to the timely execution of clinical trials. Coordinated scientific priorities, standard protocol and contract language and centralized data management allows the PCCTC to evaluate needed therapies more efficiently. The infrastructure of the PCCTC is funded and supported by the Department of Defense Clinical Consortium Award. For more information, please visit [www.pcctc.org](http://www.pcctc.org).

###

**Media Contact:** Michelle Linn, Linnden Communications, [michelle@linndencom.com](mailto:michelle@linndencom.com), (508) 362-3087