CardioDx Blood-Based Gene Expression Test Demonstrates Superior Performance to Myocardial Perfusion Imaging to Rule Out Obstructive Coronary Artery Disease

Results of COMPASS Multi-Center Validation Study of Genomic Test Presented at AHA 2011

PALO ALTO, Calif. – November 15, 2011 – CardioDx, a pioneer in the field of cardiovascular genomic diagnostics, announced results of its COMPASS (Coronary Obstruction Detection by Molecular Personalized Gene Expression) trial, which were presented today at the American Heart Association Scientific Sessions 2011 conference in Orlando, Fla. This prospective, blinded multi-center study was designed to provide a third independent validation of the Corus® CAD blood-based gene expression test for ruling out obstructive coronary artery disease in lower-risk patients with typical and atypical presentations of stable chest pain, and to compare the diagnostic performance of Corus CAD to myocardial perfusion imaging (MPI), a common test that uses a radioactive agent to evaluate the blood flow and function of the heart.

"COMPASS builds on previous results of the PREDICT trial. In this real-world patient population, the Corus CAD test demonstrates very high sensitivity and negative predictive value, enabling clinicians to rule out patients who do not have obstructive coronary artery disease with high accuracy," said Gregory S. Thomas, M.D., M.P.H., clinical professor of medicine and director of nuclear cardiology education at the University of California-Irvine School of Medicine, who presented the findings. "The use of this gene expression test, followed by MPI for higher scores, may optimize diagnostic performance and utilization of health care resources."

COMPASS enrolled 537 stable patients with symptoms suggestive of coronary artery disease who had been referred to MPI at 19 U.S. sites. A blood sample was obtained in all patients prior to MPI, and Corus CAD gene expression testing was then performed, with study investigators blinded to Corus CAD test results. Following MPI, patients were referred either to invasive angiography or to CT angiography (CTA), gold-standard measurements of blood vessel lumen anatomy for diagnosis of coronary artery disease. A total of 431 patients were eligible for analysis, having completed gene expression testing, MPI and either invasive angiography or CTA.

In the COMPASS study, Corus CAD was superior to MPI in diagnostic accuracy, sensitivity (89 percent vs. 27 percent, $p<0.001$) and negative predictive value (96 percent vs. 88 percent, $p<0.001$) and demonstrated excellent performance for ruling out obstructive coronary artery disease relative to both invasive angiography and CTA.[1]

"Chest pain symptoms account for two percent of all visits to the doctor's office each year," said Mark Monane, M.D., chief medical officer of CardioDx. "Corus CAD has now been validated in more than 1,100 patients in three separate studies. For physicians, methods to improve the diagnosis of symptoms suggestive of coronary artery disease represent a huge unmet need, and the Corus CAD test may help clinicians make better decisions. For patients, the test may lead to better diagnostic accuracy as well as avoidance of unnecessary procedures. For payers, we believe that Corus CAD can address a major expense category."

A study published in the March 11, 2010 issue of *The New England Journal of Medicine* found that in nearly 400,000 patients who underwent elective invasive angiographic procedures, 62 percent were

found to have no obstructive coronary artery blockage. The study authors concluded that current modalities for identifying which patients should undergo elective invasive coronary angiography to diagnose coronary artery disease have limitations, and that better methods are needed for patient risk stratification.

About Corus CAD

Corus CAD is the first and only clinically validated blood-based test for obstructive coronary artery disease. The test involves a routine blood draw conveniently administered in the clinician's office and does not expose patients to risks of radiation or imaging agent intolerance. Corus CAD is a decision-making tool that can help primary care clinicians and cardiologists rule out obstructive coronary artery disease as the cause of a nondiabetic patient's symptoms. It is the only sex-specific test for obstructive coronary artery disease, accounting for critical biological differences between men and women.

Findings from the PREDICT validation study of the Corus CAD gene expression test were published in 2010 in the *Annals of Internal Medicine*, the journal of the American College of Physicians. The test has been honored as a winner of *The Wall Street Journal*'s prestigious Technology Innovation Awards and one of *TIME*'s Top Ten Medical Breakthroughs.

The Corus CAD test measures the RNA levels of 23 genes from a whole blood sample. Because these RNA levels are increased or decreased when obstructive coronary artery disease is present, the Corus CAD score indicates the likelihood that an individual patient does not have obstructive coronary artery disease.

Corus CAD is commercially available through an innovative patient sample kit that includes everything needed for blood collection and express delivery to the company's CLIA-certified Palo Alto, Calif. laboratory. Test results are delivered promptly to the clinician's office. Corus CAD is currently available in the United States.

For more information please visit http://www.cardiodx.com/media-kit/.

About Gene Expression Testing

Gene expression testing provides valuable tissue and cell-specific information about the molecular mechanisms involved in disease processes, enabling evaluation of an individual patient's disease state, activity, and/or progression at a given point in time. Unlike genetic tests, which measure genetic variations, mutations, traits and predispositions—factors that are constant over a person's lifetime—gene expression testing assesses a dynamic process, integrating both genetic predisposition and additional behavioral and environmental influences on current disease state.

About CardioDx

CardioDx, Inc., a pioneer in the field of cardiovascular genomic diagnostics, is committed to developing clinically validated tests that empower clinicians to better tailor care to each individual patient. Strategically focused on coronary artery disease, cardiac arrhythmia and heart failure, CardioDx is poised to expand patient access and improve healthcare quality and efficiency through the commercialization of genomic technologies. For more information, please visit www.cardiodx.com.

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Media Contact: Nicole Osmer
650.454.0504
nicole@nicoleosmer.com

[1] By ROC analysis.