CardioDx Announces Publication of COMPASS Study Demonstrating the Corus® CAD Test Outperforms Myocardial Perfusion Imaging in Overall Diagnostic Accuracy for Obstructive Coronary Artery Disease

- Study Highlights the Validity of Corus CAD as a First-Line Test to Help Clinicians Exclude Obstructive CAD as a Cause of the Patient's Symptoms -

PALO ALTO, Calif. – [February 19, 2013] – CardioDx, Inc., a pioneer in the field of cardiovascular genomic diagnostics, today announced the publication of the COMPASS (Coronary Obstruction Detection by Molecular Personalized Gene Expression) study in *Circulation: Cardiovascular Genetics,* a journal of the American Heart Association. Results of the prospective, multi-center U.S. study showed that Corus® CAD, a blood-based gene expression test, demonstrated high accuracy with both a high negative predictive value (96 percent) and high sensitivity (89 percent) for assessing obstructive coronary artery disease (CAD) in a population of patients referred for stress testing with myocardial perfusion imaging (MPI). The study's authors conclude that using Corus CAD earlier in the diagnostic algorithm could reduce the number of invasive cardiac tests by more accurately evaluating the presence of obstructive coronary artery disease compared to the traditional algorithm of stress myocardial perfusion imaging (MPI) in these patients.

COMPASS enrolled stable patients with symptoms suggestive of CAD who had been referred for MPI at 19 U.S. sites. A blood sample was obtained in all 431 patients prior to MPI and Corus CAD gene expression testing was performed with study investigators blinded to Corus CAD test results. Following MPI, patients underwent either invasive coronary angiography or coronary CT angiography, gold-standard anatomical tests for the diagnosis of coronary artery disease.

The study was designed to provide additional independent validation of the Corus CAD test in a real-world intended use patient population of patients presenting for MPI, a common noninvasive test for CAD, and builds on the results of the previous PREDICT validation study. Corus CAD requires only a simple blood draw for testing, making it safe, convenient, and easy to administer. The study evaluated results in stable non-diabetic patients with typical or atypical symptoms suggestive of CAD and found that Corus CAD surpassed the accuracy of MPI, a test that was administered more 10 million times in the U.S. in 2010.[1]

"The evaluation of stable patients with chest pain and other symptoms suggestive of CAD is a common challenge for clinicians, accounting for as many as 10,000 outpatient visits each day," said the publication's lead author, Gregory S. Thomas, M.D., M.P.H., Medical Director of the MemorialCare Heart & Vascular Institute at Long Beach Memorial Medical Center and Clinical Professor of Medicine and Director of Nuclear Cardiology Education at the University of California-Irvine School of Medicine. "In the U.S., MPI testing is often performed in these patients and is followed by referral to invasive coronary angiography. Based on the results of this study of the Corus CAD gene expression test, we now have a reliable diagnostic approach for evaluating patients with symptoms of obstructive CAD. With its high sensitivity and negative predictive value, Corus CAD may help clinicians accurately and efficiently exclude the diagnosis of obstructive CAD early in the diagnostic pathway, so they can assess for other causes of their patients' symptoms."

The pre-specified primary endpoint of the COMPASS study was the receiver-operator characteristics (ROC) analysis to evaluate the ability of Corus CAD to identify coronary arterial blockages of 50 percent or greater by

quantitative coronary angiography. Corus CAD outperformed MPI in overall diagnostic accuracy for assessing obstructive CAD, with an area under the curve (AUC) of 0.79 for the Corus CAD test compared to MPI site and core-lab read AUCs of 0.59 and 0.63 respectively (p<0.001). In addition, Corus CAD performed better than MPI in sensitivity (89 percent vs. 27 percent, p<0.001) and negative predictive value (96 percent vs. 88 percent, p<0.001) parameters, thus demonstrating excellent performance for excluding obstructive CAD as the cause of a patient's symptoms. The COMPASS results corroborated earlier findings from the PREDICT multicenter U.S. validation study[2] demonstrating that the Corus CAD score is proportional to coronary artery stenosis severity.

"Corus CAD can help solve an enormous unmet need in healthcare by providing clinicians with a safe, convenient and reliable tool to help evaluate common patient symptoms and triage them more appropriately for subsequent therapy or additional testing," said David Levison, President and CEO of CardioDx. "In addition to its higher diagnostic accuracy, Corus CAD holds potential to reduce a major healthcare expense category – unnecessary noninvasive imaging and/or invasive coronary angiography procedures and their associated risks and side effects. We have worked closely with leading clinicians to build a solid clinical and economic foundation for Corus CAD, leading to its growing acceptance in the medical and payer communities as evidenced by the more than 35,000 tests performed to date and Medicare's decision to cover the test."

About Obstructive Coronary Artery Disease

Coronary artery disease is a very common heart condition in the United States. One in five deaths among Americans is caused by CAD.[3] CAD can cause a narrowing or blockage of the coronary arteries (vessels to the heart that supply the heart with blood, oxygen, and nutrients), reducing blood flow to the heart muscle. This narrowing or blockage in the coronary arteries is often referred to as obstructive CAD, characterized by the presence of atherosclerosis, or plaque.

About Corus CAD

With a simple blood draw, Corus CAD can safely, accurately and conveniently help primary care clinicians and cardiologists assess whether or not a stable nondiabetic patient's symptoms are due to obstructive coronary artery disease, enabling many patients to avoid unnecessary invasive procedures and exposure to imaging-related radiation risks or imaging agent intolerance. The test has been clinically validated in multiple independent patient cohorts, including two prospective, multicenter U.S. studies, PREDICT and COMPASS. Additionally, a retrospective, multicenter chart review study and the prospective IMPACT trial at Vanderbilt University demonstrated that Corus CAD use yields statistically significant and clinically relevant changes in patient management decisions in both primary care and cardiology settings. Corus CAD has been used commercially by clinicians in more than 35,000 patients and is a covered benefit for more than 40 million Medicare enrollees in the U.S.

Corus CAD has also been recognized by *The Wall Street Journal*'s Technology Innovation Awards, honored as a Gold Edison Award recipient, and named one of *TIME*'s Top Ten Medical Breakthroughs. CardioDx was recently honored as one of *FierceMedicalDevices*' "Fierce 15" most promising privately held medical device and diagnostic companies.

The Corus CAD test is intended for use in nondiabetic stable patients who present with typical or atypical symptoms suggestive of CAD, with no known history of CAD, no prior myocardial infarction (MI) or revascularization procedure, and who are not currently taking steroids, immunosuppressive agents or chemotherapeutic agents.

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.

###

For media inquiries, please contact Susan Rood of Lazar Partners, +1-212-843-0210, srood@lazarpartners.com.

---

[1] IMV 2011. Nuclear Medicine Market Outlook Report.

[2] Rosenberg S, Elashoff MR, Beineke P, et al. Multicenter Validation of the Diagnostic Accuracy of a Blood-Based Gene Expression Test for Assessing Obstructive Coronary Artery Disease in Nondiabetic Patients. *Ann Intern Med*. 2010;153:425-434.

[3] Lloyd-Jones D, Adams R, Carnethon M, et al. Heart Disease and Stroke Statistics--2009 Update: A Report From The American Heart Association Statistics Committee and Stroke Statistics Subcommittee. *Circulation*. 2009;119:480–486.