

Review Published in *PLOS Currents* Highlights Overall Evidence for the Use of Corus[®] CAD to Evaluate Obstructive Coronary Artery Disease

- Sex-Specific Blood-based Genomic Test Helps Exclude the Diagnosis of Obstructive CAD in Symptomatic Patients -

PALO ALTO, Calif. – **[August 26, 2013]** – CardioDx, Inc., a molecular diagnostics company specializing in <u>cardiovascular genomics</u>, today announced the publication of a comprehensive review of the evidence demonstrating that <u>Corus[®] CAD</u>, a blood-based gene expression test, can help clinicians accurately and safely exclude obstructive coronary artery disease (CAD) as the cause of a patient's symptoms and lead to improved patient management. The paper, available online in *PLOS Currents*, assessed existing peer-reviewed and published Corus CAD analytical and clinical validity as well as clinical utility data. The paper found that the extensive research supports the benefits of Corus CAD as a promising test to evaluate patients with typical and atypical symptoms suggestive of obstructive CAD.

Corus CAD is the only commercially available blood test that provides clinicians with a current-state assessment of obstructive CAD. The convenient blood test helps clinicians enhance patient care and management by optimizing the diagnostic strategy and reducing unnecessary referrals for further cardiac work-up in patients whose symptoms may not be due to a cardiac cause. Over 40,000 Corus CAD test results have been commercially delivered to clinicians. Corus CAD is a covered benefit for the nearly 50 million Medicare enrollees in the U.S. CardioDx processes all Corus CAD test samples at its CLIA-certified and CAP-accredited clinical laboratory in Palo Alto, CA.

"Inconclusive results from current noninvasive testing modalities for the diagnosis of obstructive CAD are common and may lead to unnecessary referral to invasive procedures such as coronary angiography," said Pamela S. Douglas, M.D., M.A.C.C., Ursula Geller Professor of Research in Cardiovascular Diseases, Duke University. "Only about 40 percent of patients referred for invasive angiography, the gold standard for diagnosing obstructive CAD, are estimated to have the disease, despite extensive noninvasive testing prior to the invasive angiography procedure."

Patients with suspected obstructive CAD may present with typical symptoms such as chest pain, pressure or heaviness that may radiate to the neck, shoulder, jaw, back or arm, or atypical symptoms such as sudden onset of weakness, nausea, vomiting or body aches. These atypical symptoms may occur more frequently in women, can be more difficult to diagnose and may resemble many other conditions. Corus CAD is the only test for the assessment of obstructive CAD that accounts for the key biological differences between men and women.

"Corus CAD offers healthcare practitioners a safe, convenient, and quick method to assess a patient's likelihood of obstructive CAD," said Mark Monane, M.D., Chief Medical Officer, CardioDx. "By accurately helping exclude obstructive CAD in symptomatic patients early in the diagnostic pathway, clinicians can reduce the amount of test overutilization in the healthcare system and help patients avoid the risks and

expenses associated with cardiac testing. Corus CAD has the potential to improve a patient's overall quality and efficiency of care."

About Obstructive Coronary Artery Disease

Coronary artery disease is a very common heart condition in the United States. One in six deaths among Americans is caused by CAD.¹ 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

Corus CAD is a blood test that can safely, accurately and conveniently help primary care clinicians and cardiologists assess whether or not a stable non-diabetic patient's symptoms are due to obstructive CAD, enabling many patients to avoid unnecessary noninvasive and invasive cardiac procedures and exposure to imaging-related radiation risks, imaging agent intolerance, or complications with cardiac catheterization. The test involves a routine blood draw that is conveniently administered in the clinician's office. The test is simple, convenient, and as a sex-specific test for the diagnosis of obstructive CAD, accounts for critical biological differences between men and women.

The test has been clinically validated in independent patient cohorts, including two prospective, multicenter U.S. studies, PREDICT and COMPASS.^{2,3} In the COMPASS study, Corus CAD outperformed MPI in diagnostic accuracy, demonstrating a significantly higher sensitivity (89 percent vs. 27 percent, p<0.001) and a significantly higher negative predictive value (96 percent vs. 88 percent, p<0.001) than MPI for assessing the presence of obstructive CAD. Over 40,000 Corus CAD test results have been commercially delivered to clinicians. Corus CAD is a covered benefit for the nearly 50 million Medicare beneficiaries in the U.S. CardioDx processes all Corus CAD test samples at its CLIA-certified and CAP-accredited clinical laboratory in Palo Alto, CA.

About CardioDx

CardioDx, Inc., a molecular diagnostics company specializing in cardiovascular genomics, 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 committed to expanding patient access and improving healthcare quality and efficiency through the commercialization of genomic technologies. For more information, please visit <u>www.cardiodx.com</u>.

Forward-Looking Statements

This press release may contain forward-looking statements, including statements regarding the safety and efficacy, adoption rate and size of the market for Corus CAD, and beliefs regarding the need for and value of gene expression diagnostics. These statements relate to future events and involve known and unknown risks, uncertainties and other factors that could cause actual levels of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements. These statements reflect the views of CardioDx as of the date of this press release with respect to future events and, except as required by law, it undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the

date of this press release.

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 ¹ Go AS, Mozaffarian D, Roger VL, et al. Heart Disease and Stroke Statistics--2013 Update: A Report From the American Heart Association. *Circulation*. 2013; 127:e6-e245.
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 Thomas GS, Voros S, McPherson JA, et al. A Blood-Based Gene Expression Test for Obstructive Coronary Artery Disease Tested in Symptomatic Nondiabetic Patients Referred for Myocardial Perfusion Imaging: The COMPASS Study. *Circ Cardiovasc* Corner 4:04016/14/1402 Genet. 2013;6:154-162.