



New Data Presented at the AHA Scientific Sessions Highlight the Clinical Utility of the Corus CAD Gene Expression Test in Women and Demonstrate that the Corus CAD Score Correlates with Cardiovascular Outcomes

- Data Presented Demonstrate the Advantages of Corus[®] CAD in Improving Clinical Decision-Making and Reducing Diagnostic Test Overutilization in Women with Symptoms Suggestive of Obstructive Coronary Artery Disease -

PALO ALTO, Calif. – [November 18, 2013] – CardioDx, Inc., a molecular diagnostics company specializing in [cardiovascular genomics](#), today announced results from two studies reinforcing the value of [Corus[®] CAD](#) as an initial diagnostic test for the evaluation of patients with symptoms suggestive of obstructive coronary artery disease (CAD). The studies were presented at the American Heart Association (AHA) Annual Scientific Sessions, taking place November 16-20, 2013 in Dallas, Texas.

Corus CAD is the first and only commercially available blood-based gene expression test that provides a current-state assessment of obstructive CAD in non-diabetic patients presenting with typical or atypical symptoms. Corus CAD helps clinicians accurately rule out obstructive CAD as the cause of these symptoms.

A Peripheral Blood Gene Expression Score for Obstructive Coronary Artery Disease is Significantly Associated with Major Adverse Cardiovascular Events and Revascularizations in the PREDICT Trial (Abstract 16271), led by John A. McPherson, M.D., Vice Chair for Education, Department of Medicine at Vanderbilt University Medical Center in Nashville, Tennessee, found that after one year of monitoring, patients referred for invasive angiography in the PREDICT trial with low Corus CAD scores (≤ 15) were less likely to experience major adverse cardiovascular events (MACE) greater than 30 days after the initial catheterization and less likely to undergo additional cardiovascular procedures compared to patients with elevated scores (> 15). A MACE event is defined as cardiac death, nonfatal myocardial infarction, or target lesion revascularization. The Corus CAD score was significantly associated with all events and procedures ($p < 0.001$), extending the test's utility from diagnosing obstructive CAD to predicting cardiovascular outcomes. The odds ratio for MACE likelihood for low Corus CAD scores versus high Corus CAD scores (≥ 28) was 0.32 (95% CI 0.12--0.82, $p = 0.018$).

"These results from the PREDICT trial demonstrate that the Corus CAD score significantly correlates with cardiovascular outcomes, where low scores are associated with low MACE event rates," said Dr. McPherson. "Findings from this study further validate, and confirm, the test's ability to safely and reliably rule-out obstructive CAD in patients. Our growing understanding of the test's clinical utility will provide critical insights for clinicians and healthcare decision-makers working to integrate gene expression testing into routine practice."

The Use of a Personalized Gene Expression Score in Women Presenting to Primary Care with Symptoms of Suspected Obstructive Coronary Artery Disease Improves Clinical Decision-Making Around Non-Invasive Diagnostic Testing: Gender-Specific Results from the IMPACT-PCP

(Investigation of a Molecular Personalized Coronary Gene Expression Test on Primary Care Practice Pattern) Trial (Abstract 18490), led by Lee Herman, M.D., Johns Creek Primary Care, Suwanee, Georgia, concluded that Corus CAD showed clinical utility in the evaluation of suspected obstructive CAD in women by impacting clinical decision-making among primary care practitioners. The test was associated with a relevant reduction in further diagnostic test utilization among women with low Corus CAD scores (≤ 15). In this subgroup analysis of the IMPACT-PCP trial, among female patients who had their diagnostic plans changed following a Corus CAD test, 96% (66/69) with decreased testing had a low Corus CAD score and 93% (13/14) of women with increased testing had an elevated Corus CAD score (>15).

“These subgroup findings on the clinical utility of Corus CAD in women from the IMPACT-PCP trial are clinically meaningful,” said Dr. Herman. “Because women are more likely to present with atypical symptoms of obstructive CAD, it is often difficult for the primary care practitioner to make a confident diagnosis. This scenario results in additional testing and referrals to cardiologists for patients who are then later found to have conditions that are due to non-cardiac sources, such as acid reflux, which cause similar symptoms that are often confused with obstructive CAD. Corus CAD fulfills the need for a new diagnostic strategy that both improves decision-making early in the care pathway for obstructive CAD and addresses a critical unmet need by accounting for the sex-differences between how women and men present with obstructive CAD so that care can be tailored to each patient.”

“2013 has been a robust year for validating the clinical utility of Corus CAD, and the two studies presented at this year’s AHA Scientific Sessions add important new clinical evidence that will help define the test’s value in the diagnostic pathway for obstructive CAD,” said David Levison, President and Chief Executive Officer of CardioDx. “It is encouraging to see that the findings from these clinical utility studies closely align with the clinical validity studies and describe the potential role of Corus CAD to influence clinical decision-making. When used in routine clinical practice, Corus CAD can have a broad impact at both the patient level and the practice level by improving the quality 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 as a test to exclude obstructive CAD, demonstrating a significantly higher sensitivity (89% vs. 27%, $p < 0.001$) and a significantly higher negative predictive value (96% vs. 88%, $p < 0.001$) than MPI for assessing the presence of obstructive CAD. Over 47,000 Corus CAD test results have been commercially delivered to clinicians. Corus CAD is a covered benefit for the estimated 48 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, California.

About Gene Expression

Corus CAD is a gene expression test, not a genetic test. Whereas genetic testing may inform on lifetime disease risk, the Corus CAD gene expression test provides a current-state assessment of obstructive CAD by looking at the gene expression changes associated with atherosclerosis. Gene expression levels change depending on a person's disease status resulting from genetic and environmental factors.

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 www.cardiodx.com.

Forward-Looking Statements

This press release may contain forward-looking statements, including statements regarding the safety, efficacy and the adoption rate of and the 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 Genet*. 2013;6:154-162.