



New Data Highlight Value of Corus[®] CAD in Reducing Unnecessary Cardiac Testing and Costs for Women with Symptoms Suggestive of Obstructive Coronary Artery Disease

- Corus[®] CAD Has Potential to Reduce Cardiac Diagnostic Costs in Women by More Than \$500 per Patient -

PALO ALTO, Calif. – [October 10, 2013] – CardioDx, Inc., a molecular diagnostics company specializing in [cardiovascular genomics](#), today announced results of two studies indicating that [Corus[®] CAD](#), a blood-based gene expression test, may help reduce unnecessary cardiac testing and costs by aiding clinician decision-making in the evaluation of women with symptoms suggestive of obstructive coronary artery disease (CAD). The studies were presented at The North American Menopause Society (NAMS) 2013 Annual Meeting, taking place October 9-12, 2013 in Dallas, TX.

The first study, titled **“The Clinical Utility of a Novel Genomic-Based, Gene Expression Test in a Registry Study of Women Evaluated for Symptoms Suggestive of Obstructive Coronary Artery Disease in the Ambulatory Care Setting: Results from the REGISTRY I Study,”** included a total of 180 female patients presenting with non-acute symptoms suggestive of obstructive CAD at six community-based primary care practices. The primary outcome in this pre-specified, subgroup analysis was the association between the Corus CAD score, ranging from 1 to 40, and referrals to noninvasive and invasive cardiac testing among female patients based on the test score. The study found that each 10-point decrease in the Corus CAD score was associated with a 13-fold decrease in the likelihood of referral for further cardiac testing ($P < 0.001$). Furthermore, the observed rate of referrals in low-scoring patients (≤ 15) was 5 percent, 94 percent lower than the referral rate seen in elevated-score patients (> 15) ($P < 0.001$). The results of this study suggest that real-world use of Corus CAD in primary care practices early in the assessment of obstructive CAD may help optimize patient care and reduce unnecessary cardiac testing.

“The accurate diagnosis of women with symptoms suggestive of obstructive CAD is a challenge we frequently encounter in the primary care setting because women are more likely to present with atypical, non-specific symptoms such as weakness, nausea, shortness of breath or abdominal pain or discomfort,” said Joseph Ladapo, M.D., Ph.D., Assistant Professor of Medicine, Department of Population Health and Medicine, NYU School of Medicine. “These types of symptoms may be attributable to a variety of conditions such as anxiety, stress, musculoskeletal disorders, gastroesophageal reflux disease or CAD. Our study of a real-world registry found that a sex-specific, blood-based gene expression test may help clinicians quickly and accurately eliminate obstructive CAD as the cause of their patients’ symptoms early in the stream of care, thereby allowing them to investigate other origins of patients’ symptoms.”

A second study presented at the meeting focused on the potential economic savings of using Corus CAD early in the stream of care to evaluate patients with suspected CAD. The study, **“Use of a Personalized Medicine, Blood-Based Gene Expression Score Was Associated with Lower Diagnostic Testing Costs in Women Presenting to Cardiologists with Symptoms Suggestive of Obstructive Coronary Artery Disease: An Economic Analysis of the IMPACT-CARD (Investigation of a Molecular**

Personalized Coronary Gene Expression Test on Cardiology Practice Pattern) Trial,” was led by John McPherson, M.D., Vice Chair for Education, Department of Medicine at Vanderbilt University Medical Center.

The study included 57 female patients, without known CAD, presenting with non-acute chest pain and atypical symptoms suggestive of obstructive CAD. A change in cardiac diagnostic testing strategy was noted in 34 women (60 percent) post-Corus CAD testing ($P<0.001$). When per-procedure costs were applied to the study results, a 22 percent savings in cardiac diagnostic testing costs was realized. Cardiac test utilization in the 57 women showed a pattern of decreased testing costs post-Corus CAD scores versus the matched control group (\$2,504 versus \$1,960 per patient), yielding a \$544 per patient cost-savings in cardiac diagnostic testing.

“Corus CAD offers clinicians a valuable tool in the assessment of patients presenting with typical or atypical symptoms suggestive of obstructive CAD,” said Mark Monane, M.D., Chief Medical Officer, CardioDx. “Common patient symptoms such as non-acute chest pain generate approximately 8,000 outpatient visits a day, and 9 out of 10 of these patients do not have stable CAD as the cause of their presenting symptoms. With personalized genomic diagnostics like the Corus CAD test, we now have the technology to provide sex-specific assessment of obstructive CAD, which may help optimize and personalize care for both women and men, and, as a result, may reduce unnecessary cardiac testing and costs to the healthcare system.”

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 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, 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 www.cardiodx.com.

Forward-Looking Statements

This press release may contain forward-looking statements, including statements regarding the safety and efficacy of 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.