CardioDx Announces Results of Study Demonstrating the Benefits of the Corus CAD Gene Expression Test Use in an African American Patient Population

- Patients with Low Corus CAD Scores Had a 95% Decreased Rate of Referral for Advanced Cardiac Testing Versus Patients with Elevated Corus CAD Scores -

REDWOOD CITY, Calif. – [October 20, 2014] – CardioDx, Inc., a molecular diagnostics company specializing in cardiovascular genomics, today announced the presentation of the study, "The Use of a Gene Expression Score Showed Clinical Utility in Evaluating African Americans Presenting with Symptoms Suggestive of Obstructive Coronary Artery Disease in a Primary Care Practice," at the 36th Annual North American Meeting of the Society for Medical Decision Making, taking place from Oct. 18-22 in Miami.

The study evaluated the clinical utility of the Corus® CAD blood-based gene expression test in the assessment of 518 African American patients presenting with symptoms suggestive of obstructive coronary artery disease (CAD) in a primary care setting. The results demonstrate the impact of Corus CAD score on clinician decision-making: Patients with low-Corus CAD scores (≤15) had a 95% decreased rate of referral for advanced cardiac testing compared to patients with elevated (>15) Corus CAD scores (8/214 vs. 227/304). By ruling out obstructive CAD early in the work-up, the Corus CAD test was able to help clinicians avoid unnecessary referrals to cardiology or advanced cardiac testing when their patient's symptoms are due to non-cardiac causes.

Corus CAD is the first and only commercially available blood-based test incorporating age, sex, and gene expression measurements that provides a current-state assessment of obstructive CAD in non-diabetic patients presenting with non-acute typical or atypical symptoms. The results of the gene expression measurements are combined with the patient's age and sex in an algorithm that delivers a score representing the likelihood of obstructive CAD. With a 96% negative predictive value, Corus CAD can help clinicians accurately rule out obstructive CAD as the source of their patients' symptoms, so that they may investigate other non-cardiac causes.

"These results show that Corus CAD can be a powerful decision-making tool for clinicians guiding their African American patients through the diagnostic pathway for suspected obstructive CAD," says lead author Morris Brown, M.D., of Providence Medical Group in Dayton, Ohio. "Given the heterogeneity in clinical manifestations of suspected obstructive CAD amongst different ethnic populations in the U.S., a convenient and accurate blood test like Corus CAD that is effective across a spectrum of patients provides tremendous clinical value, particularly when it allows us to avoid costly and potentially harmful cardiac tests for patients who don't need them."

Video case study of a Corus CAD patient from Dr. Brown's practice available at CardioDx.com

Of the 518 patients enrolled in the study, 41% (n=214) had a low Corus CAD score, demonstrating that the test has high relevance to clinical practice for ruling out obstructive CAD in a significant number of patients in everyday practice. The authors concluded that Corus CAD improved care for those patients with a low score by avoiding unnecessary, and potentially invasive, advanced diagnostic testing. "This study adds an important new layer to the evidence base supporting Corus CAD's clinical utility," said Mark Monane, M.D., Chief Medical Officer of CardioDx, referring to the IMPACT-PCP, IMPACT-Cardiology, and Registry I studies "The results are also consistent with the positive feedback we've been receiving from the primary care clinicians using the test in everyday clinical practice. Clinicians in the community-setting are adopting Corus CAD because it allows them to simplify and streamline their diagnostic workups for suspected obstructive CAD."

About Obstructive Coronary Artery Disease

Coronary artery disease (CAD) 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 the Corus CAD Test

Corus CAD is a blood test that can safely and conveniently help primary care clinicians and cardiologists assess whether or not a stable non-diabetic patient's symptoms are due to obstructive CAD. This enables many patients to avoid unnecessary noninvasive and invasive cardiac procedures and exposure to imaging-related radiation risks, reactions from imaging dyes 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 evaluation 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 myocardial perfusion imaging (MPI) as a diagnostic test to exclude obstructive CAD by 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 75,000 Corus CAD test results have been commercially delivered to clinicians. In the U.S. alone, an estimated 49 million Medicare beneficiaries have access to the Corus CAD test as a covered benefit in addition to another 22 million covered lives with Aetna and Coventry Health. CardioDx processes all Corus CAD test samples at its CLIA-certified and CAP-accredited clinical laboratory in Redwood City, 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 expression of genes 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 and efficacy 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.