



CardioDx Announces New Data Demonstrating Use of Corus® CAD in the Primary Care Setting for Evaluation of Symptomatic Patients with Suspected CAD Influences Clinical Decision Making

- Study Presented at the Quality of Care and Outcomes Research 2013 Scientific Session -

PALO ALTO, Calif. – May 17, 2013 – CardioDx, Inc., a pioneer in the field of [cardiovascular genomic diagnostics](#), today announced results of a clinical utility study of the [Corus® CAD gene expression test](#) in the real-world primary care setting for evaluating patients with signs and symptoms suggestive of obstructive [coronary artery disease](#) (CAD). The multicenter, prospective study, “Improved Patterns for Advanced Non-Invasive Diagnostic Testing Using a Personalized Gene Expression Score Among Patients Presenting to Primary Care Clinicians with Symptoms of Suspected Obstructive Coronary Artery Disease: Results from the IMPACT-PCP (Investigation of a Molecular Personalized Coronary Gene Expression Test on Primary Care Practice Pattern) Trial,” was presented at the American Heart Association’s Quality of Care and Outcomes Research (QCOR) 2013 Scientific Sessions, taking place May 15-17, 2013 in Baltimore, MD.

“Primary care offices get approximately 10,000 visits a day from patients with symptoms of chest pain,” said Lee Herman, MD, Johns Creek Primary Care, Suwanee, GA. “Evaluation of patients with typical or atypical symptoms suggestive of CAD costs billions of dollars in annual cardiac-related diagnostic expenses in the U.S. Clearly, we need better noninvasive diagnostic tests to quickly and accurately assess patients for obstructive CAD in the primary care setting. With a high negative predictive value of 96 percent and a high sensitivity of 89 percent, Corus CAD is a convenient and reliable diagnostic test that can help primary care clinicians accurately exclude the diagnosis of obstructive CAD early in the assessment pathway, and can help identify whether or not patients need further cardiac testing.”

The study, led by Dr. Herman, showed that clinicians’ diagnostic decision making was significantly influenced by integrating Corus CAD early to assess patients for obstructive CAD. Patients presenting with typical and atypical presentations of chest pain (n=251) were enrolled in the study and evaluated by nine primary care clinicians in four practices for assessment of symptoms. The clinician’s diagnostic strategy was evaluated before and after the Corus CAD results were known.

Following Corus CAD testing, clinicians modified their diagnostic strategy in 58 percent of patients (p<0.001). Among the 127 patients with low Corus CAD scores (≤15), 60 percent (76/127) saw a reduction in testing and only 2 percent (3/127) had increased testing. Patient follow-up is ongoing, with 98 percent of patients having completed 30-day follow-up. Results of the study suggest that early use of Corus CAD in primary care practices to assess obstructive CAD influences clinical decision making.

“It is exciting to see the benefits of personalized medicine moving so rapidly from theory to clinical practice,” said Mark Monane, MD, Chief Medical Officer of CardioDx. “New advances in understanding human genomics combined with evolving research on atherosclerosis have given us a deeper understanding of how a person’s sex and biology influence their CAD evaluation. The result of this

study, combined with the IMPACT-Cardiology study, demonstrate that Corus CAD use enables customized care for each individual patient, potentially leading to improved patient outcomes, a reduction in unnecessary imaging and invasive procedures, and lower overall healthcare expenditures. CardioDx is committed to establishing more convenient and broader access to Corus CAD, which will help simplify the diagnostic strategy for symptomatic patients with suspected obstructive CAD in both primary care and cardiology practices.”

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.

About Corus CAD

Corus CAD is the only clinically validated blood-based test for the assessment of obstructive coronary artery disease. The test involves a routine blood draw conveniently administered in the clinician’s office and does not expose patients to risks of radiation or imaging agent intolerance. It is the only sex-specific test for obstructive coronary artery disease, accounting for critical biological differences between men and women.

The test has been clinically validated in multiple independent patient cohorts, including two prospective, multicenter U.S. studies, PREDICT and COMPASS.^{1,2} In the COMPASS study, Corus CAD outperformed MPI in diagnostic accuracy, sensitivity (89 percent vs. 27 percent, $p < 0.001$) and negative predictive value (96 percent vs. 88 percent, $p < 0.001$) and demonstrated excellent performance for excluding obstructive coronary artery disease relative to both invasive angiography and CTA.² Additionally, a retrospective, multicenter chart review study and the prospective IMPACT CARD trial at Vanderbilt University, the first of two prospective clinical utility studies, 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 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 non-diabetic 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.

Corus CAD has been used commercially by clinicians in more than 38,000 patients and is a covered benefit for more than 40 million Medicare enrollees in the U.S.

Forward-Looking Statements

This press release may contain forward-looking statements, including statements regarding the business strategy of CardioDx, 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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For media inquiries in the U.S., please contact Wenli Chiu of Lazar Partners, +1-646-871-8492, wchiu@lazarpartners.com.

¹Rosenberg 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.

²Thomas 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.