New Study Results Further Reinforce that the Corus® CAD Test Helps Primary Care Clinicians Make Effective Referral Decisions for Patients with Suspected Obstructive Coronary Artery Disease

- Patients with a Low Corus CAD Score had 94% Reduced Odds of Referral to a Cardiologist -

- REGISTRY I Study Results Add to the Established Evidence Base Supporting the Clinical Utility of the Corus CAD Gene Expression Test in Real-World Clinical Practice -

PALO ALTO, Calif. – [May 05, 2014] – CardioDx, Inc., a molecular diagnostics company specializing in cardiovascular genomics, today announced the publication of the REGISTRY I study, which examined the assessment of non-acute chest pain and related symptoms that may be suggestive of obstructive coronary artery disease (CAD) in the primary care setting with the Corus® CAD blood-based gene expression test. The study, published online in the *American Journal of Medical Quality* in May 2014, found a strong association between cardiac referral rates by low (≤15) and elevated (>15) Corus CAD score groups, with only 6% (10/167) of the low Corus CAD score patients versus 70% (122/175) of the elevated Corus CAD score patients being referred for further cardiac evaluation (P < .0001). 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. With a 96% negative predictive value and 89% sensitivity, 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.

Joseph Ladapo, M.D., Ph.D., Assistant Professor of Medicine, Department of Population Health and Medicine, NYU School of Medicine and lead author on this study stated: "The challenges associated with diagnosing obstructive CAD, particularly in women, lead to many patients whose symptoms are gastrointestinal, musculoskeletal, or psychosomatic in origin receiving cardiovascular tests that expose them to unnecessary radiation risks. These tests drive up healthcare costs. An accurate and safe first-line diagnostic test is needed, as only 10%[1-4] of patients with non-acute chest pain presenting to primary care clinicians have a cardiac etiology for their symptoms."

The REGISTRY I study, which was conducted in collaboration with Humana Comprehensive Health Insights, measured the impact of Corus CAD testing on primary care referral decisions among 342 patients in seven community-based primary care practices based on each patient's individualized gene expression score. Approximately 49% of patients had a low Corus CAD score, allowing their primary care providers to focus on other causes for their symptoms. Each 10-point decrease in a patient's Corus CAD score was associated with a 14-fold decreased odds of referral for further cardiac evaluation or testing (P < .0001). In addition, patients with a low Corus CAD score had a 94% reduced odds of referral relative to patients with an elevated Corus CAD score (P < .0001).

“These findings demonstrate that Corus CAD can help drive clinically appropriate and more efficient decisions about diagnostic testing and referral to a cardiologist among patients presenting with non-acute typical and atypical symptoms suggestive of obstructive CAD, thus allowing clinicians to determine which patients can safely be managed in the primary care setting,” said Dr. Ladapo.

“The REGISTRY I study evaluated the clinical utility of Corus CAD among real-world patients cared for by internal medicine doctors, family medicine physicians, and nurse practitioners. Corus CAD’s performance in this study illustrates the practical benefits of advancing precision medicine in primary care for the assessment for coronary artery disease,” added Mark Monane, MD, Chief Medical Officer of CardioDx. “Because it is easy to learn and simple to administer, Corus CAD fits seamlessly into the diagnostic workup of patients with non-acute symptoms suggestive of obstructive CAD, providing clinicians with timely, accurate information needed to make better decisions on diagnosis and management early in the care pathway.”

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.[5] CAD can cause a narrowing or lead to a blockage of the coronary arteries (vessels that supply the heart with blood, oxygen, and nutrients), reducing, or even stopping, 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 in the vessel walls.

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. 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 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.[6,7] 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 55,000 Corus CAD test results have been commercially delivered to clinicians. Corus CAD is a covered benefit for the estimated 49 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, Calif.

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 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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For media inquiries, please contact Mai Duong of Lazar Partners, +1-646-871-8492, mduong@lazarpartners.com.

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