



Multi-Center, Community-Based Patient Registry Interim Results Presented at the AHA Scientific Sessions Support the Clinical Utility of the Corus® CAD Test in the Assessment of Obstructive Coronary Artery Disease

Interim Results from the PRESET Registry Reinforce the Established Clinical Evidence Base Supporting the Adoption of the Corus CAD Test in the Primary Care Setting

REDWOOD CITY, Calif. – November 10, 2015 – CardioDx, Inc., a molecular diagnostics company specializing in [cardiovascular genomics](#), announced today results from a multi-center, community-based patient registry called the PRESET Registry which found that patients with symptoms of obstructive coronary artery disease (CAD)* and who had low [Corus® CAD test](#) scores had an 82% decreased odds of referral for further cardiac evaluation versus patients with elevated Corus CAD test scores.¹ The Corus CAD test is a blood-based test that integrates age, sex, and gene expression levels into a single score indicating the current likelihood of a significant narrowing or blockage of the coronary arteries. The data was presented at American Heart Association Scientific Sessions 2015 in Orlando, Fl. on November 7-11, 2015.

“Challenges associated with diagnosing obstructive CAD in symptomatic patients can lead to repeat and unnecessary tests and procedures,” said Joseph A. Ladapo, M.D., Ph.D., Assistant Professor of Medicine, Department of Population Health and Medicine, NYU School of Medicine and lead author of the study. “The PRESET Registry analysis reinforces the benefits of implementing the age/sex/gene expression score (ASGES) test in the primary care setting for patients and clinicians. With the ASGES test, clinicians are able to safely and efficiently rule-out low-risk patients suspected of having CAD.”

The registry study, “Primary Endpoint Results from a Community-Based Registry Evaluating the Use of a Blood-Based Age/Sex/Gene Expression Test in Patients Presenting with Symptoms Suggestive of Obstructive Coronary Artery Disease: the PRESET Registry (A Registry to Evaluate Patterns of Care Associated with the Use of Corus CAD in Real World Clinical Care Settings),” evaluated 718 stable, non-acute and non-diabetic adult patients without a history of obstructive CAD from 21 primary care practices from September 2012 to August 2014.

The interim results of the primary efficacy endpoint demonstrated that the use of the Corus CAD test in the primary care setting was associated with a clinically relevant and statistically significant impact on medical decision making in patients presenting with typical or atypical symptoms suggestive of obstructive CAD. The median test score was 18 (range: 1-40), and 310 of the 718 (43%) patients had low scores (≤ 15). In a 30-day follow up, 27 of 310 (9%) patients with low Corus CAD scores were referred for further cardiac evaluation (OR 0.18, $p < 0.0001$). Follow-up at 30 days after the Corus CAD test revealed a low rate of major adverse cardiovascular events: 2 events were reported among low score patients, both deemed unrelated to study intervention, and longer-term follow-up is pending.

“With approximately \$5.9 billion spent annually on non-invasive and invasive cardiac testing among non-diabetic patients in the U.S. we are faced with the challenge to better and more confidently diagnose patients presenting with symptoms suggestive of obstructive CAD,” said Mark Monane, M.D., FACP, Chief Medical Officer of CardioDx. “The large number of community-based office practices included in



the PRESET registry helps to address the generalizability of the study findings. The results of the primary endpoint showing a low rate of further cardiac referral reinforce results from previous studies showing the clinical utility of Corus CAD on clinical decision making.”

About Obstructive Coronary Artery Disease

Coronary artery disease (CAD) is a very common heart condition in the United States. One in seven deaths among Americans is caused by CAD.² 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 the first and only commercially available blood test that can safely and conveniently help primary care clinicians and cardiologists assess whether or not a stable non-diabetic patient's symptoms may be due to obstructive coronary artery disease. The test incorporates age, sex and gene expression measurements into a single score that indicates the likelihood of obstructive CAD. Clinicians use the Corus CAD score, along with other clinical information, to determine whether further cardiac testing is necessary, which can help patients avoid unnecessary exposure to radiation associated with medical imaging testing, as well as possible reactions to imaging dyes and/or potential complications from invasive cardiac tests requiring catheterization. The test involves a routine blood draw that is conveniently administered in the clinician's office. The Corus CAD test is the only sex-specific test for the evaluation of obstructive CAD because it accounts for cardiovascular differences between men and women.

The test has been clinically validated in independent male and female patient cohorts, including two prospective, multicenter U.S. studies, PREDICT and COMPASS.^{3,4} In the COMPASS study, the Corus CAD test outperformed myocardial perfusion imaging (MPI) as a diagnostic tool to exclude obstructive CAD by demonstrating a higher negative predictive value (96% vs. 88%, $p < 0.001$) than MPI for assessing the presence of obstructive CAD.⁵ To date, over 100,000 Corus CAD test results have been provided to clinicians. CardioDx processes all Corus CAD test samples at its CLIA-certified and CAP-accredited clinical laboratory in Redwood City, California.

The Corus CAD test has 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 10 Medical Breakthroughs.

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, CardioDx is committed to expanding patient access and improving healthcare quality and efficiency through the commercialization of genomic technologies. Please visit www.cardiodx.com for additional information.



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* Obstructive CAD is defined as at least one atherosclerotic plaque causing $\geq 50\%$ luminal diameter stenosis in a major coronary artery (≥ 1.5 mm lumen diameter) as determined by invasive quantitative coronary angiography (QCA) or coronary computed tomography angiography (CTA) (≥ 2.0 mm).

¹ Ladapo JA, Budoff M, Ross L, et al. Primary Endpoint Results from a Community-Based Registry Evaluating the Use of a Blood-Based Age/Sex/Gene Expression Test in Patients Presenting with Symptoms Suggestive of Obstructive Coronary Artery Disease: the PRESET Registry (A Registry to Evaluate Patterns of Care Associated with the Use of Corus[®] CAD in Real World Clinical Care Settings). *Circ Cardiovasc Qual Outcomes*. 2015;8:A142.

² Mozaffarian D, Benjamin EJ, Go AS, et al. On Behalf of the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart Disease and Stroke Statistics – 2015 Update: A Report from the American Heart Association. *Circulation*. 2015;131(4):e29-e322.

³ 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.

⁴ 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(2):154-162.

⁵ The COMPASS study demonstrated that the Corus CAD algorithm has an NPV of 96% at the pre-specified threshold of 15 in a population of men and women referred to MPI.