CardioDx Announces Final Endpoint Results from the PRESET Registry at the AHA Scientific Sessions 2016

- Data Reinforce the Strong Evidence Base Supporting the Clinical Utility of the Corus® CAD Blood Test in Real-World Practice -

REDWOOD CITY, Calif. – November 14, 2016 – CardioDx, Inc., a molecular diagnostics company specializing in cardiovascular genomics, announced results from the final endpoint analysis of the multi-center, community-based patient registry called the PRESET Registry (NCT01677156, A Registry to Evaluate Patterns of Care Associated with the Use of Corus CAD in Real World Clinical Care Settings). This analysis showed that the age, sex, and gene expression score (ASGES) derived from the Corus CAD blood test has clinical utility in the evaluation of outpatients presenting with stable symptoms suggestive of obstructive* coronary artery disease (CAD). Clinicians referred 10% of patients with low Corus CAD test scores (predefined as scores ≤15) versus 44% of patients with elevated scores (predefined as scores >15) for further evaluation by cardiology or advanced cardiac testing (unadjusted Odds Ratio (OR) = 0.15, p<0.0001; adjusted OR after accounting for clinical covariates = 0.18, p<0.001.) Major adverse events and revascularization were noted in 3/252 (1.2%) patients with low Corus CAD scores and 14/314 (4.5%) patients with elevated Corus CAD scores (p<0.03). The data was presented at the American Heart Association Scientific Sessions 2016, which took place on November 12-16 in New Orleans, La.

The Corus CAD blood test integrates age, sex, and gene expression levels into a single score corresponding to the current likelihood of a blockage or significant narrowing in the coronary arteries. The test has previously shown clinical validity in the COMPASS study, in which 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 evaluating the presence of obstructive CAD.[1]

"The use of the age, sex, and gene expression score proved to be a valuable tool to identify a safe and effective course of care for those patients presenting with symptoms suggestive of obstructive CAD," said Joseph A. Ladapo, M.D., Ph.D., Assistant Professor of Medicine, Division of General Internal Medicine and Health Services Research, David Geffen School of Medicine at UCLA and lead author of the study. "Integrating the test into our approach for managing stable, symptomatic patients suspected of having obstructive CAD can help physicians provide effective and informative care for patients without exposing them to the risks of radiation or contrast dye associated with other, commonly used tests."

The poster presentation, 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 reported results from the PRESET Registry, which included 566 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. This final endpoint analysis evaluated both clinical decision-making and one-year safety follow-up among non-acute adult patients with typical or atypical symptoms suggestive of obstructive CAD.

"Wider use of more effective approaches for the management of patients presenting with stable symptoms of coronary artery disease have been needed for some time," said Mark Monane, M.D., FACP, Chief Medical Officer of CardioDx. "The large number of community-based practices included in the PRESET Registry helped demonstrate the generalizability of Corus CAD in this setting. The final endpoint analysis with one-year follow-up post Corus CAD testing reinforces the fact that patients with low scores are unlikely to have major adverse cardiac events and revascularizations and thus helps to provide further confidence to clinicians for integrating Corus CAD into their primary care practices."

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.[3,1] 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.[4] To date, over 200,000 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 ≥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).

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[1] 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.

[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 – 2016 Update: A Report from the American Heart Association. *Circulation*. 2016;133(4):e38-e360.

[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] 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.