

Data Presented at ACC 2013 Confirms Use of Corus@ CAD in Women with Suspected Obstructive Coronary Artery Disease Influences Patient Management Decisions

The Associated Press

CardioDx, Inc., a pioneer in the field of cardiovascular genomic diagnostics, today announced results of a prospective study that evaluated how Corus@ CAD, a blood-based gene expression test, influenced cardiologists' patient management decisions in women with suspected obstructive coronary artery disease (CAD). Based on the IMPACT (Investigation of a Molecular Personalized Coronary Gene Expression Test on Cardiology Practice Pattern) Trial, the analysis was presented in a poster session by John A. McPherson, MD, FACC, FACP, Associate Professor of Medicine, Vanderbilt University School of Medicine, titled, "Improved Diagnostic Work-up of Patients Presenting to the Cardiologist with Symptoms of Suspected Obstructive Coronary Artery Disease: Gender Specific Results from the IMPACT Trial" (#1154-73), at the American College of Cardiology 62nd Annual Scientific Session on Saturday, March 9 at 3:45-4:30 PM.

Results of the analysis demonstrated that Corus CAD was associated with a clinically relevant and statistically significant change in cardiologists' diagnostic test strategy for women with suspected obstructive CAD. Following the use of Corus CAD, a change in diagnostic testing (e.g., an increase or decrease in the use of myocardial perfusion imaging (MPI), computed tomography angiography (CTA) and/or cardiac catheterization) was noted in 60 percent of female patients ($p < 0.001$). Among the patients whose management changed, 91 percent had decreased testing. Among the female patients with decreased testing, 94 percent had low Corus CAD scores. At six months follow up, no adverse cardiovascular events were observed.

"Personalized medicine is becoming an increasingly valuable diagnostic tool to aid clinician decision-making," said Dr. McPherson. "The IMPACT Trial showed that there is significant potential for personalized medicine to be integrated into real-world clinical practice as more than an aid, but a guide for clinicians to more accurately identify which patients need further diagnostic evaluation, helping many patients avoid unnecessary invasive testing or exposure to imaging agent intolerance and related risks to radiation exposure." The investigators evaluated data from 57 stable female patients presenting with atypical, typical and non-cardiac chest pain and related symptoms without a history of CAD who were referred to cardiologists at Vanderbilt University Medical Center. The cardiologists' patient management decisions were assessed before and after the Corus CAD score was known for each patient. Corus CAD measured the peripheral blood cell expression levels of 23 genes to determine the likelihood of obstructive CAD.

CardioDx recently announced the publication of the COMPASS (Coronary Obstruction Detection by Molecular Personalized Gene Expression) study in *Circulation: Cardiovascular Genetics*, a journal of the American Heart Association[1]. Results of the prospective, multi-center U.S. study showed that Corus CAD outperformed traditional stress testing with MPI, demonstrating high accuracy with both a higher sensitivity (89 percent vs. 27 percent, $p < 0.001$) and higher negative predictive value (96 percent vs. 88 percent, $p < 0.001$) than MPI for assessing obstructive CAD. Moreover, the presence of breast tissue and fatty tissue may produce false-positive test results when using MPI in women. Side effects such as radiation exposure and contrast agent allergies resulting from MPI can be harmful for women. The use of MPI increases with age, and radiation exposure during one test is equivalent to 39 mammograms.

"All tests are not created equal and women need to be their own health advocates as current methods for evaluating CAD do not account for the critical biological differences in men and women," said Alexandra Lansky, M.D., Associate Professor of Medicine and Director of the Cardiovascular Research Center at Yale University School of Medicine.

"Diagnosing heart disease in women is historically more difficult as they may present with symptoms that are more varied, nonspecific and atypical compared to those presented by men. Traditional stress tests for obstructive CAD are also not as sensitive in women, which adversely affects the accuracy of test results. Using Corus CAD earlier in the screening process may optimize diagnostic performance and help to reduce unnecessary health care expenditures related to diagnostics." About Obstructive Coronary Artery Disease Coronary artery disease is a very common heart condition in the United States. One in five 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 Corus CAD

With a simple blood draw, Corus CAD 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 coronary artery disease, enabling many patients to avoid unnecessary invasive procedures and exposure to imaging-related radiation risks or imaging agent intolerance. The test has been clinically validated in multiple independent patient cohorts, including two prospective, multicenter U.S. studies, PREDICT and COMPASS. Additionally, a retrospective, multicenter chart review study and the prospective IMPACT trial at Vanderbilt University 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 been used commercially by clinicians in more than 35,000 patients and is a covered benefit for more than 40 million Medicare enrollees in the U.S.

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.

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.

[1] <http://circgenetics.ahajournals.org/content/early/2013/02/15/CIRCGENETICS.112.964015.abstract>

[2] Lloyd-Jones D, Adams R, Carnethon M, et al. Heart Disease and Stroke Statistics--2009 Update: A Report From The American Heart Association Statistics Committee and Stroke Statistics Subcommittee.

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