# CardioDx Announces Participation in Landmark NHLBI Trial of Strategies for Assessment of Stable Patients With Symptoms of Coronary Artery Disease

The Associated Press

PALO ALTO, Calif.--(BUSINESS WIRE)--Nov 27, 2012--CardioDx, Inc., a pioneer in the field of cardiovascular genomic diagnostics, today announced participation in the Prospective Multicenter Imaging Study for Evaluation of Chest Pain (PROMISE), the first large randomized trial using clinical outcomes to compare alternative diagnostic strategies for assessment of patients with new stable symptoms suggestive of coronary artery disease (CAD).

Sponsored by Duke University in collaboration with the National Heart Lung and Blood Institute (NHLBI), PROMISE will test comparative effectiveness of anatomical versus functional noninvasive diagnostic tests for the assessment of stable symptomatic patients with possible CAD. Patients with suspected CAD are randomized in equal proportions to receive an initial anatomic imaging strategy using coronary computed tomography angiography (64-slice or greater) versus a functional testing strategy using a site-chosen stress test, including exercise ECG, stress echocardiography, or myocardial perfusion imaging (MPI). The study is expected to enroll 10,000 patients already referred for a nonemergent, noninvasive diagnostic test for CAD at approximately 200 sites in North America.

“As many as five million patients with chest pain undergo noninvasive tests each year to determine if the cause is coronary artery disease, but these tests aren’t perfect. The PROMISE study will compare anatomic and functional types of tests to discern which might be better at guiding the treatment of patients with suspected heart disease,” said PROMISE principal investigator Pamela S. Douglas, M.D., the Ursula Geller Professor for Research in Cardiovascular Diseases at Duke University, Director of the Duke Clinical Research Imaging Program and Senior Fellow in Clinical Health Policy, Duke Center for Clinical Health Policy Research.

As part of the trial, a genomic archive of samples is being obtained, including genetic material (DNA), genomic material (RNA) and plasma. CardioDx will purify and isolate DNA and RNA using proprietary methods. In addition, the company’s blood-based gene expression test, Corus CAD, will be used to evaluate blood samples from an estimated 2,500 to 3,000 nondiabetic patients enrolled in the trial, with the goal of evaluating the ability of the test to predict major clinical cardiovascular events. Dr. William Kraus, Director of Clinical Research at the Duke Center for Living, is leading the collaboration with CardioDx.

“We are thrilled to participate in the landmark PROMISE trial in a collaboration with Duke University that will allow us to evaluate the use of Corus CAD as an aid in the

prognosis of clinical events. This study will allow us to build on the results of the Corus CAD test as an aid in the assessment of CAD, as demonstrated in the PREDICT and COMPASS validation studies," said David Levison, president and CEO of CardioDx. "The findings of PROMISE also will help us determine the potential for developing a new test specifically focused on prognosis for CAD patients, which could involve the use of next-generation sequencing technologies to identify expression of genes predictive of future events." The PROMISE trial will follow patients for up to four years or until the study ends, with a primary endpoint of major adverse cardiac events and secondary endpoints related to procedural costs and safety. The first patient was enrolled in the study in July 2010.

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 nondiabetic patient's symptoms are due to obstructive coronary artery disease (CAD), 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 31,000 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 nondiabetic stable patients who present with typical or atypical symptoms suggestive of CAD, with no known history of CAD, have no prior myocardial infarction (MI) or revascularization procedure, and 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.

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