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May 18, 2011

CardioDx to Use $60M Funding Round to Make Clinical Utility Case for Corus CAD

CARDIODX HAS RAISED $60 MILLION in equity financing that it will invest in expanding reimbursement for its Corus CAD genetic test for coronary artery disease.

Corus CAD is a gene expression test that cardiologists can use in addition to other medical information to assess whether non-diabetic patients' medical symptoms are due to obstructive CAD.

CardioDx runs the test, which gauges the expression of mRNA by 23 genes via real-time PCR, at its CLIA-certified laboratory in Palo Alto, Calif. The expression of each gene is measured and interpreted through the company's Corus CAD software, and the patient's genetic test results are sent in a report to the doctor.

A spokesperson for CardioDx told *PGx Reporter* that the company will use the funding to complete additional studies that demonstrate the clinical utility of Corus CAD, continue to educate primary care physicians and cardiologists as to how the test can be used in the care of their patients, and reach out to payors to help them understand the circumstances under which they should pay for the test.

Specifically, CardioDx may use the money to "collaborate on registry-type studies with the payors," the spokesperson said.

Obstructive CAD, at the minimum, can cause chest pain, but it can also lead to a heart attack or death. In its discussions with payors, CardioDx likely asserts that tools such as Corus CAD could save healthcare dollars by diagnosing such a condition early and therefore avoiding more serious complications.

In addition, published studies indicate that current methods for identifying which patients should undergo elective invasive coronary angiography to diagnose coronary artery disease do not always accurately assess a patient's risk for the condition. The gold standard for diagnosing obstructive CAD is catheter-based coronary angiography, which is performed with other methods that expose patients to radiation and contrast agents. CardioDx and the developers of Corus CAD believe that the genetic test offers advantages over other CAD diagnostics because it only requires patients to give a blood sample.

"With a simple blood draw, CardioDx's Corus CAD test provides actionable information regarding the diagnosis of cardiovascular disease that helps physicians make better decisions, helps patients avoid unnecessary procedures and radiation exposure, and helps payors address a major expense category," said Patrick Enright, managing director of Longitude Capital and CardioDx board member, in a statement.

CardioDx CEO David Levison estimated that doctors have so far used Corus CAD to gauge obstructive CAD in more than 13,000 patients. The company estimates that approximately 120 health plans have reimbursed the Corus CAD test to date.

"We are working with those plans to help them better understand how Corus CAD can improve patient care and reduce unnecessary medical procedures," the CardioDx spokesperson said. "It is our goal to gain reimbursement

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coverage of Corus CAD for a large majority of the insured population in the US."

On its website, CardioDx offers to file all insurance claims and appeals on the patients' behalf to help make the economic and clinical utility case to payors. Additionally, the company has a financial assistance program for those who are deemed eligible for aid.

In April, CardioDx presented data at the American College of Cardiology annual meeting demonstrating that Corus CAD could help physicians diagnose obstructive coronary stenosis while adding independent information to coronary calcium scoring in patients undergoing CT angiography. In this study, the company reported a more than 95 percent negative predictive value for Corus CAD.

This study presented at ACC analyzed data from the multi-center, prospective Personalized Risk Evaluation and Diagnosis In the Coronary Tree, or PREDICT trial, which was originally published in October 2010 in the *Annals of Internal Medicine*. In PREDICT researchers led by CardioDx Chief Scientific Officer Steven Rosenberg investigated whether Corus CAD can help doctors more accurately assess obstructive CAD as measured by quantitative coronary angiography. The ACC study expanded on these initial findings to show that the test can gauge obstructive CAD as measured by coronary CT angiography.

Corus CAD yields a score between 0 and 40. The higher scores correspond to a higher likelihood of obstructive CAD and a higher maximum percentage of stenosis in the patient tested.

In PREDICT researchers found that the gene expression algorithm score used to diagnose obstructive CAD improved patient reclassification as to whether or not they have the condition by 20 percent relative to Diamond–Forrester score and 16 percent relative to an expanded clinical model. Corus CAD provided a reclassification improvement of 21 percent over myocardial perfusion imaging, which according to the study authors is the most prevalent noninvasive test. The authors noted, however, that these results may have been exaggerated since the patient cohort included those referred for angiography.

"Our test provides a statistically significant but modest improvement in classification of patient CAD status compared with clinical factors or noninvasive imaging," Rosenberg et al. concluded. "Further studies are needed to define the performance characteristics and clinical utility in populations with a lower pretest probability."

In addition to using its newly raised funds to support reimbursement efforts for Corus CAD, CardioDx will also funnel some of the money toward developing other genomic diagnostics for cardiovascular conditions, the spokesperson said.

Founded in 2004, CardioDx specializes in developing genomic tests for coronary artery disease, cardiac arrhythmias, and heart failure. The company is currently running a prospective clinical trial, called Diagnostic Investigation of Sudden Cardiac Event Risk, or DISCERN, in which researchers are studying genomic factors involved in ventricular arrhythmia and sudden cardiac death.

Participating in the latest funding round were Longitude Capital, JP Morgan, Acadia Woods Partners, Artiman Ventures, and RU-COM's venture arm Bright Capital, as well as previous investors. The company has raised more than $100 million in financing to date.