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Strategy

Completing the picture

By Aaron Bouchie
Senior Writer

By teaming up to promote each other's tests for coronary artery disease, **CardioDx Inc.** and **General Electric Co.**'s GE Healthcare unit believe they can provide more complete answers to physicians and patients than is possible with either test alone.

If they're right, CardioDx should benefit from GE Healthcare's marketing muscle, as well as imaging solutions for instances when its molecular diagnostics do not give clear answers. Meanwhile, GE Healthcare gets access to emerging technologies and could see increased use of its tests if earlier use of molecular diagnostics yields additional imaging.

No single test can diagnose coronary artery disease (CAD), and there are various tests that physicians can use to inform their decision. Diagnosing CAD begins with the ascertainment of risk factors like cholesterol and triglycerides, as well as co-morbidities like smoking, diabetes and hypertension.

Physicians then perform a number of tests, beginning with noninvasive tests like electrocardiograms and stress tests, followed by invasive procedures like angiography and transesophageal echocardiograms.

But a study of 398,978 patients undergoing angiography published in March in the *New England Journal of Medicine* showed that only 37.6% had obstructive CAD and 39.2% had no CAD, even though most had a positive result from noninvasive testing prior to catheterization. The authors concluded that better strategies for CAD risk stratification are needed.

"The primary reason we partnered with CardioDx is that in certain care areas and disease states, we believe there will be an increase in opportunities to bring together disparate areas of diagnostic information that exist today," Michael Jones, EVP of business development for GE Healthcare, told BioCentury.

"Diagnostics are done very much in a siloed approach. Especially when there is a difficult decision to be made, we want to give physicians the tools to make a more definitive clinical decision," Jones added. "This is about the integration of information, not the integration of technologies."

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>
> **Michael Jones, GE Healthcare**

While the partners are still finalizing details of their relationship, the deal will likely include CardioDx's Corus CAD, a CLIA-certified blood-based test launched last year that measures expression levels of 23 genes to predict the likelihood that a patient has obstructive CAD.

The test provides a score of 0-40, which correlates with likelihood of obstructive CAD. For example, a score of 7 correlates to a 13% likelihood, a score of 27 is roughly a 50% likelihood, and a maximum score of 40 equates to about a 75% chance of obstructive CAD.

In the validation phase of CardioDx's PREDICT study in 596 non-diabetic patients with stable chest pain and no previously diagnosed myocardial infarction (MI) or revascularization, Corus CAD had 85% sensitivity and 83% negative predictive value.

Corus CAD is most valuable to physicians to rule out obstructive CAD, rather than to diagnose it, according to CardioDx President and CEO David Levison.

Jones suggested a likely scenario is that physicians could use

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Corus CAD early on to try to rule out the need to subject a patient to an expensive, invasive angiograph or a stress test.

Corus CAD costs $1,195, while a myocardial perfusion imaging (MPI) stress test costs about $600 and angiography costs $3,000-$5,000, according to CardioDx.

GE Healthcare sells computed tomography (CT) machines for performing angiographies, as well as radiopharmaceutical imaging agents for use in diagnosing CAD.

Jones acknowledged that use of Corus CAD will likely reduce the use of imaging in some patients who might have otherwise been tested with GE Healthcare's products. But he added that Corus CAD could result in earlier use of imaging, for example if a patient who does not exhibit traditional risk factors is identified as high risk by the molecular diagnostic.

"So there is an element of justifying those imaging modalities," Jones said.

Levison noted that another test helps when an initial test is inconclusive.

"No single diagnostic can answer all of the questions a physician might have. So an imaging test might come back equivocal, and in those cases the Corus CAD test could give an incremental benefit. And vice versa: our test might not give a definitive answer and push a physician to give an imaging test," he said.

Details of the deal remain to be worked out. The companies will likely co-market and co-promote each other's products but continue to book sales of their own products. They also may co-develop other tests in CardioDx's pipeline.

The PREDICT trial is still enrolling patients who are undergoing invasive angiography to obtain samples for future product development. The company also is enrolling patients who are undergoing MPI in the COMPASS trial, with data expected in early 2011.

CardioDx also began the DISCERN trial about two years ago to identify and validate markers for distinguishing patients at increased risk for arrhythmias. Levison said he is not sure when data will be released. A third test, to identify patients at increased risk for heart failure, is further behind in development.

Concurrent with the deal, the GE Healthymagination Fund invested $5 million in CardioDx as part of a series D round. Levison said the company has also raised $5 million from an undisclosed VC, and hopes to raise at least $10 million more before closing the round in the next few months.

This is the first investment by the GE fund, which has $250 million to invest in diagnostics, health IT and tools companies. Jones, who also is director of the fund, said it is looking to invest in technologies that can help improve healthcare quality while lowering costs.

COMPANIES AND INSTITUTIONS MENTIONED

CardioDx Inc., Palo Alto, Calif.

General Electric Co. (NYSE:GE), Fairfield, Conn.