HeartFlow Announces JAMA Publication and Presentation of Landmark Data Showing High Diagnostic Performance for Non-Invasive Fractional Flow Reserve (FFRCT) Technology

The Associated Press

REDWOOD CITY, Calif. & MUNICH--(BUSINESS WIRE)--Aug 26, 2012--HeartFlow, Inc. announced today that data from the company's landmark prospective, international Determination of Fractional Flow Reserve by Anatomic Computed Tomographic Angiography (DeFACTO) study was presented today by principal investigator James K. Min, M.D., director of Cardiac Imaging Research at the Department of Medicine, Imaging and Biomedical Sciences at Cedars-Sinai Medical Center in Los Angeles, in a hotline session at the European Society of Cardiology (ESC) meeting in Munich, and simultaneously published in The Journal of the American Medical Association. The study results demonstrate that, when compared to standard coronary CT angiography (CT) alone, HeartFlow's computed fractional flow reserve (FFR CT) coupled with coronary CT angiography provides a more accurate determination of which patients' arterial blockages require invasive evaluation.

The study assessed the ability of FFR CT to identify flow-restricting lesions versus CT alone, by comparing the results to invasive fractional flow reserve (FFR), which is recognized by the European Society of Cardiology as the gold standard for determining which arterial blockages require treatment. 1,2 FFR CT provided a nearly 20 percent improvement in the ability to identify flow-restricting arterial blockages over the use of CT alone using an area under the curve (AUC or Receiver Operating Characteristics) analysis (AUC 0.81 vs. 0.68, p=0.0002). AUC is a robust measure of diagnostic test reliability and accuracy. The per-patient sensitivity and specificity of FFR CT were also higher than CT alone.

The improvement in diagnostic performance was even greater in arterial blockages of intermediate severity. In this set of patients, there was more than a two-fold increase in test sensitivity, from 37 to 82 percent, with no loss of specificity. In these patients, the AUC improved from 0.53 for CT alone to 0.80 for FFR CT (p=0.0002).

"One of the central challenges in taking care of patients with coronary artery disease is knowing which patients need further invasive evaluation for determining the need for coronary revascularization. The results of the DeFACTO trial clearly demonstrate that when added to coronary CT angiographic findings, FFR CT provides essential physiologic information as to which specific arterial blockages truly restrict blood flow to the heart and heighten patient risk. This is an exciting step forward for cardiology that could significantly improve how we guide patients towards the most effective and efficient care," said Dr. Min. "Further, our findings suggest that FFR CT could be particularly useful for evaluating patients with arterial

blockages of an intermediate severity, which often are the most difficult to assess non-invasively. This is a large group of patients that is unfortunately often prone to frequent misdiagnosis." "We are very pleased with the results of DeFACTO, which suggest that FFR CT coupled with CT could be poised to become the new standard for non-invasive cardiac testing. It offers the promise of a single standardized test to determine whether patients have coronary artery disease that needs further evaluation or therapy," said John H. Stevens, M.D., chairman and CEO of HeartFlow. "This technology holds the potential to substantially improve the ability of physicians to accurately determine which patients need and do not need coronary angiography and intervention, resulting in better patient outcomes and reduced costs." DeFACTO enrolled 252 stable patients with suspected coronary artery disease (CAD) at 17 centers in five countries. All patients underwent CT, invasive coronary angiography (ICA), invasive FFR and subsequent FFR CT analysis. This study evaluated the first-generation of HeartFlow's software technology and there will likely be continued improvement in accuracy in the future. These results also expand upon the findings of the DISCOVER-FLOW study published in the Journal of the American College of Cardiology in November 2011. 3–5 Recent analysis of the potential positive impact of FFR CT on healthcare costs and patient outcomes was presented by Mark A. Hlatky, M.D., professor of Health Policy and Research at Stanford University, California, USA at the Society for Cardiovascular Computed Tomography (SCCT) meeting in Baltimore, Maryland, USA. In his presentation, Dr. Hlatky noted that a strategy of using CCTA with FFR CT to guide selection of patients for invasive evaluation and PCI "might reduce costs and improve clinical outcomes compared to current treatment pathways." The simulation model presented at SCCT showed per-patient savings of more than $3,000 when compared to the conventional angiography based treatment strategy. 6 HeartFlow technology is designed to provide physicians non-invasively computed FFR (FFR CT) values at every point along the coronary tree. Until now, FFR measurements could only be measured invasively during coronary angiography with a pressure-sensing guidewire.

Studies have shown that treatment guided by invasively measured FFR has better clinical outcomes, including a 34 percent reduced risk of death or major cardiac event, and significantly lower healthcare costs. 7–10 Other currently available non-invasive diagnostic tests, such as CT, provide anatomic information but do not provide lesion-specific data, and therefore have marginal diagnostic accuracy compared to the invasive FFR gold standard. 11–13 Each year, more than 15 million Americans seek care for symptoms of heart disease. A study published in March 2010 in The New England Journal of Medicine found that in nearly 400,000 patients with suspected coronary artery disease undergoing elective invasive angiographic procedures, 62 percent had no obstructive coronary artery blockage. 14 The authors of the study noted that current modalities for identifying which patients should undergo elective invasive coronary angiography to diagnose coronary artery disease have limitations, and that better methods are needed for patient risk stratification.

About HeartFlow's FFR CT Technology HeartFlow's technology is a web-based service that enables the determination of non-invasive fractional flow reserve (FFR CT). Utilizing the latest breakthroughs in CT medical imaging and computational

science, the company's technology creates patient-specific 3D computational models of the aorta, heart, and coronary artery tree. Using a high-powered supercomputer, proprietary blood flow equations are applied to the 3D data which allows calculation of point specific FFR CT measurements throughout the coronary tree. 3–5 To view a simulation of coronary blood flow using HeartFlow technology, visit www.heartflow.com.

About HeartFlow, Inc. HeartFlow, Inc., based in Redwood City, Calif., is pioneering technology designed to help physicians noninvasively diagnose coronary artery disease, improve patient outcomes and reduce health care costs. For more information visit www.heartflow.com.

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CONTACT: for HeartFlow, Inc.

Nicole Osmer, 650-454-0504 nicole@nicoleosmer.com KEYWORD: UNITED STATES EUROPE NORTH AMERICA CALIFORNIA GERMANY INDUSTRY KEYWORD: TECHNOLOGY HARDWARE HEALTH BIOTECHNOLOGY CARDIOLOGY MEDICAL DEVICES SOURCE: HeartFlow, Inc. Copyright Business Wire 2012 PUB: 08/26/2012 02:00 AM/DISC: 08/26/2012 02:00 AM
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