Landmark Study of HeartFlow’s New Non-Invasive Diagnostic Test Demonstrates High Diagnostic Performance in Patients with Suspected Coronary Artery Disease

Computed FFR\textsubscript{CT} Identifies Flow-Restricting Arterial Blockages with High Accuracy

REDWOOD CITY AND SAN FRANCISCO, Calif., October 30, 2013 – HeartFlow, Inc. today announced positive data from a study of the company’s newest-generation non-invasive computed fractional flow reserve FFR\textsubscript{CT} technology. Results from the HeartFlowNXT study demonstrate that, when compared to standard coronary CT angiography (CT) or invasive coronary angiography (ICA), FFR\textsubscript{CT} provides a more accurate determination of which arterial blockages are associated with coronary ischemia and which are not, suggesting that FFR\textsubscript{CT} may aid physicians in making decisions regarding further invasive testing or treatment.

The study’s findings were presented today in a First Report Investigation session at the 25\textsuperscript{th} Annual Transcatheter Cardiovascular Therapeutics (TCT) meeting in San Francisco.

HeartFlow’s patient-specific coronary blood flow modeling technology is a new non-invasive test that uses proprietary algorithms based on computational fluid dynamics and data from a patient’s coronary CT scan to assist physicians in the diagnosis of coronary artery disease and identification of specific flow-restricting blockages in the coronary arteries.

The prospective international HeartFlow NXT study enrolled 254 stable patients with suspected coronary artery disease (CAD) at 10 centers in seven countries. The objective of the study was to compare diagnostic performance of FFR\textsubscript{CT}, coronary CT, and ICA, to invasive FFR measurement (the current gold standard for determining flow-restricting arterial blockages). All patients underwent coronary CT, invasive coronary angiography (ICA), and invasive FFR, and then had FFR\textsubscript{CT} analysis performed using the latest generation of HeartFlow’s software technology.

The findings of the study suggest the potential to eliminate the need for risky and expensive invasive evaluation and treatment in some patients. FFR\textsubscript{CT} demonstrated superior ability to correctly identify those patients without coronary ischemia compared to coronary CT (specificity 79\% vs. 34\%). The study also showed a specificity of 79\% compared to invasive angiography of 51\%. FFR\textsubscript{CT} correctly identified patients who had coronary ischemia with a high sensitivity (86\%) and high negative predictive value (92\%). There was also a striking improvement in the ability of FFR\textsubscript{CT} to discriminate patients with and without flow-restricting arterial blockages compared to CT alone (area under the curve [AUC] on receiver operating characteristics analysis 0.82 vs. 0.63, p<0.0001). AUC is a robust measure of diagnostic test reliability and accuracy.

“Proper selection of patients for invasive diagnosis and treatment is a crucial element of taking care of people who may have coronary artery disease. These procedures entail risk and expense. This new tool will be an exciting step forward for cardiology and may significantly improve how we guide coronary artery disease patients towards effective and efficient care,”
said principal investigator Bjarne Norgaard, M.D., Ph.D., department of Cardiology, Aarhus University Hospital Skejby, Aarhus, Denmark. Dr. Norgaard presented the data today at TCT.

Studies have shown that treatment guided by invasive FFR results in better clinical outcomes, including a 34% reduced risk of death or major cardiac event, and significantly lower healthcare costs. 1-3 Currently available noninvasive diagnostic tests do not provide stenosis-specific functional data, and therefore have limited diagnostic accuracy compared to invasive FFR. 4-6

HeartFlow’s noninvasive technology is designed to provide physicians with FFR_CT values at every point along the coronary tree. 7 Traditional FFR measurements can only be obtained invasively during coronary angiography with a pressure-sensing guidewire.

“The results of HeartFlowNXT allow us to consider for the first time the real possibility of a single non-invasive standardized test which can help physicians determine the impact of patients’ coronary artery disease, offering the promise of a new standard for diagnosis of coronary artery disease,” said John H. Stevens, M.D., chairman and CEO of HeartFlow. “This technology will substantially improve the ability of physicians to accurately determine which patients need or do not need coronary angiography, potentially resulting in better patient outcomes and reduced costs.”

An analysis of the potential positive impact of FFR_CT on healthcare costs and on patient outcomes was recently published by Mark A. Hlatky, M.D., professor of Health Policy and Research at Stanford University. In his analysis, Dr. Hlatky noted that using 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 model showed potential savings of more than $3,000 per-patient when compared to the conventional angiography-based treatment strategy. 8

About HeartFlow, Inc.

Founded in 2007, HeartFlow, Inc., is a cardiovascular company based in Redwood City, Calif. A pioneer in the field of non-invasive coronary artery disease diagnosis, HeartFlow is committed to developing technology designed to help physicians noninvasively diagnose coronary artery disease and improve patient outcomes while reducing health care costs. For more information visit www.heartflow.com.

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