Late-Breaking Data Reinforces How the Heartflow Analysis Can Help Physicians Precisely Stratify Heart Disease Patients and Deliver More Personalized Care

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One-year results from ADVANCE trial demonstrate how the Heartflow Analysis can help identify lower-risk patients who can safely avoid invasive testing

NEW ORLEANS, March 17, 2019 – Late-breaking results presented and published today confirm that the Heartflow® FFR_{CT} Analysis enables physicians to efficiently identify which patients despite symptoms suggestive of coronary artery disease (CAD) have a low risk of adverse cardiovascular events and can safely avoid invasive testing out to one year. These results from the ADVANCE trial were presented as a late breaking trial during the American College of Cardiology's (ACC) 68 th Annual Scientific Session and simultaneously published in the *Journal of the American College of Cardiology (JACC): Cardiovascular Imaging*.

In the ADVANCE study of more than 5,000 patients, clinicians used FFR_{CT} values from the Heartflow Analysis to help determine patients' risk of adverse cardiovascular events and decide upon management plans. The vast majority of the patients who had a negative Heartflow Analysis received medical therapy and did not receive invasive testing or treatment. At one-year, patients in this group had a significantly low rate (0.2%) of cardiovascular death or heart attack (myocardial infarction). In comparison, the rate of cardiovascular death or heart attack was four times higher in patients with a positive Heartflow Analysis, many of whom required invasive management. These results demonstrate that patients identified as lower risk for adverse events may be safely treated with medications alone and avoid invasive management. Importantly, these patients had low rates of revascularization (stenting or bypass surgery) through 90 days and negligible need for revascularization thereafter.

"These findings provide reassurance regarding the safety of patient management utilizing a FFR_{CT}-guided decision pathway, particularly in lower-risk patients who did not undergo an invasive evaluation," said Manesh Patel, MD, FACC, Chief, Division of Cardiology, Department of Medicine, Duke University School of Medicine, Duke University Health System. "By adding the Heartflow FFR_{CT} to our available resources for diagnosing stable coronary disease, we are able to provide patients with better care as we efficiently evaluate risk in patients getting a coronary CTA, more precisely stratify patients and improve efficiency in the cath lab."

The Heartflow Analysis is a non-invasive, cardiac test for stable symptomatic patients with CAD, the leading cause of death worldwide. Starting with a standard coronary computed tomography angiogram (CTA), the Heartflow Analysis creates a digital, personalized 3D model of the heart and provides FFR_{CT} values along the coronary arteries. This information helps physicians evaluate the impact a blockage may be having on blood flow and determine the best treatment for each patient. A positive FFR_{CT} value (≤0.80) indicates that a coronary blockage is impeding blood flow to the heart muscle to a degree which may warrant invasive management.

In the ADVANCE Registry, patients from the United States, Japan, Europe and Canada underwent a coronary CTA, and when additional information was needed, a Heartflow Analysis was ordered. The added information contained in the Heartflow Analysis led physicians to reconsider and change management plans for two-thirds of their patients. Some who were originally scheduled to receive a coronary stent or bypass operation were safely able to avoid the procedure and be treated with medications alone, while others who would have received medications were redirected to stenting or bypass surgery.

"The one-year results from ADVANCE are largely unchanged from the previously-presented 90-day results, which reinforces the durable utility of using coronary CTA as a front-line diagnostic test and incorporating the Heartflow Analysis in a real-world patient population," said Campbell Rogers, MD, FACC, chief medical officer, Heartflow. "By providing functional information, the Heartflow Analysis is able to complement the anatomical information provided by a coronary CTA and enable the physician to have a more complete picture of the patient's heart health, and thus provide more personalized care for the patient."

About the Heartflow FFR_{CT} Analysis

Data from a patient's non-invasive coronary CTA are securely uploaded from the hospital's system to Heartflow's software application running in the AWS cloud. Heartflow leverages deep learning and highly trained analysts to create a personalized, digital 3D model of the patient's coronary arteries. The Heartflow Analysis then uses powerful computer algorithms to solve millions of complex equations to simulate blood flow and assess the impact of blockages on coronary blood flow. The Heartflow Analysis is provided via a secure online interface to offer actionable information to enable clinicians to determine the optimal

course of treatment.

The Heartflow Analysis offers the highest diagnostic performance available from a non-invasive test.[1] To date, clinicians around the world have used the Heartflow Analysis for more than 30,000 patients to aid in the diagnosis of heart disease.

About Heartflow, Inc.

Heartflow, Inc. is a medical technology company uniquely positioned at the intersection of advanced artificial intelligence and healthcare to transform how heart disease is diagnosed and treated. Our non-invasive Heartflow FFR_{CT} Analysis leverages deep learning to create a personalized 3D model of the heart. By using this model, clinicians can better evaluate the impact a blockage has on blood flow and determine the best treatment for patients. Our technology is reflective of our Silicon Valley roots and incorporates decades of scientific evidence with the latest advances in artificial intelligence. The Heartflow FFR_{CT} Analysis is commercially available in the United States, Canada, Europe and Japan. For more information, visit www.Heartflow.com.

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1. Driessen, R., et al. Comparison of Coronary Computed Tomography Angiography, Fractional Flow Reserve, and Perfusion Imaging for Ischemia Diagnosis. J Am Coll Cardiol. 2019;73(2),161-73.