HeartFlow Initiates PRECISE Randomized Clinical Trial

New trial of more than 2,000 patients will evaluate a precision-testing pathway for coronary artery disease including non-invasive coronary CTA + the HeartFlow Analysis as compared to the conventional pathway for diagnosis

REDWOOD CITY, Calif. – December 6, 2018 – HeartFlow, Inc. today announced the start of the Prospective Randomized Trial of the Optimal Evaluation of Cardiac Symptoms and Revascularization (PRECISE) trial. The first patient was enrolled by Michael C. Turner, M.D., at Imperial Health Cardiovascular Specialists in Lake Charles, LA.

The PRECISE trial is designed to compare the usual approach of diagnosing and evaluating patients with stable chest pain using a stress test and/or invasive cardiac catheterization to a new Precision Evaluation Strategy using risk-based testing and coronary computed tomography angiography (CTA) scans. The PRECISE trial will evaluate whether the new approach can improve the accuracy, outcomes, efficiency, and cost of diagnosing and caring for patients with suspected coronary artery disease (CAD). The trial will enroll more than 2,000 patients from approximately 100 centers around the world.

“The impact of coronary artery disease is enormous. It remains the #1 cause of death worldwide. Yet, current testing options for suspected heart disease are imperfect, leading to inaccurate diagnoses and the need for additional, often invasive, testing,” said Pamela Douglas, M.D., the Ursula Geller Professor for Research in Cardiovascular Disease, Duke University School of Medicine and study chair of the PRECISE trial. “With the PRECISE trial, we aim to help clinicians diagnose patients with suspected CAD more efficiently by identifying patients who can be managed medically versus those who require further invasive assessment, while reducing the number, risks and costs of unnecessary tests and procedures.”

In the PRECISE trial, patients will be randomized to either the Usual Care or Precision Evaluation Strategy arm. Patients in the Precision Evaluation Strategy arm will be assessed using the PROMISE Risk Score and placed in either a low/no risk group or the intermediate/high risk group. Patients in the low/no risk group will be treated with medications and lifestyle modifications. All patients in the intermediate/ high risk group will undergo a CTA. When additional information is needed, a HeartFlow FFRct Analysis will be conducted.

“The HeartFlow Analysis provides physicians with a more complete picture and actionable information than any other non-invasive test, and can play an important role in helping physicians diagnose patients with suspected CAD,” said Campbell Rogers, M.D., Chief Medical Officer, HeartFlow. “Our company is rooted in scientific evidence and the PRECISE trial is the latest example of the company’s ongoing commitment to bringing the very best clinically useful research to our physicians and patients.”

The HeartFlow Analysis is a non-invasive, personalized cardiac test that applies artificial intelligence to image data taken from a standard CTA scan to create a digital 3D model of the patient's arteries. It then applies advanced algorithms to solve millions of complex equations to assess the impact any blockages have on blood flow to the heart. 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 has higher diagnostic performance, providing better functional evaluation of CAD, than other non-invasive tests[1]. The HeartFlow technology has been demonstrated to reduce unnecessary invasive diagnostic coronary angiography procedures, which can be associated with bleeding, stroke, major blood vessel damage and other serious complications. It also significantly reduces healthcare costs for hospitals.[2]

To date, clinicians around the world have used the HeartFlow Analysis for more than 25,000 patients to aid in the diagnosis of heart disease.

About HeartFlow, Inc.
HeartFlow, Inc. is a medical technology company redefining the way heart disease is diagnosed and treated. Our non-invasive HeartFlow FFRct 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 FFRct 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. PACIFIC FFRct Substudy. Presented at EuroPCR 2018.
[2] Douglas PS, DeBruyne B, Pontone G., Patel MR, et al. One-year outcomes of FFRCT-guided care in patients with suspected coronary disease: The PLATFORM Study. *J Am Coll Cardiol*. 2016;68(5),435-45.