HeartFlow Announces Its Novel, Non-Invasive FFRct Technology for Coronary Artery Disease Receives Positive Review from Blue Cross Blue Shield

BCBS Association’s Evidence Street Concludes HeartFlow FFRct Can Help Patients Avoid Unnecessary Invasive Procedures

REDWOOD CITY, Calif. – June 12, 2017 – HeartFlow, Inc. today announced that Blue Cross Blue Shield (BCBS) Association’s Evidence Street has issued a positive healthcare evidence review of the Company’s HeartFlow® FFRct. This non-invasive technology is the first to provide insight into both the extent of coronary artery disease (CAD) and the impact the disease has on blood flow to the heart. It combines anatomic information from a coronary CT angiogram and physiology from HeartFlow FFRct to enable clinicians to select an appropriate and personalized treatment for each patient. The Evidence Street review assessed the technical performance, diagnostic accuracy and clinical utility of HeartFlow FFRct and determined that it provides a meaningful improvement in net health outcome when used to guide the care of patients with stable chest pain who are at intermediate risk of CAD and are being considered for invasive coronary angiography.

“This marks a major milestone achievement for HeartFlow and our FFRct technology because BCBS’s Evidence Street is among the world’s most rigorous health technology assessments and has significant global reach and influence,” said John H. Stevens, M.D., chief executive officer of HeartFlow. “With BCBS insuring one in three Americans, substantially more patients with suspected CAD in the United States who are part of BCBS plans will be able to access this innovative non-invasive technology. HeartFlow FFRct also could now more rapidly become the standard of care, potentially improving clinical outcomes and saving global healthcare systems billions of dollars annually.”

Evidence Street provides healthcare technology evaluations for the BCBS Association, a national federation of 36 independent, community-based and locally operated Blue Cross and Blue Shield companies that collectively provide healthcare coverage for 105 million Americans. Evidence Street’s assessment of HeartFlow FFRct, which is summarized in a 19-page report, concluded that “CCTA (coronary CT angiogram) with a selective FFRct strategy would likely lead to changes in management that would be expected to improve health outcomes by further limiting unnecessary ICA (invasive coronary angiography) testing.”

Evidence Street joins a growing number of organizations that support the use of HeartFlow FFRct as part of the diagnostic and treatment pathway for CAD. Several payers, including Aetna, which covers more than 46 million lives, have issued positive coverage decisions. In February, the National Institute for Health and Care Excellence (NICE) of the U.K.’s National Health Service, which covers 59 million lives, issued positive guidance, recommending the technology to help determine the cause of stable chest pain in patients. NICE concluded that HeartFlow FFRct is safe, has a high level of diagnostic accuracy, and may avoid the need for invasive coronary angiography, which is associated with risks. NICE further concluded that, compared to all other tests, use of HeartFlow FFRct is the most cost-effective solution as it
avoids unnecessary invasive tests and treatment. Additionally, the American College of Cardiology (ACC) and American Heart Association (AHA) recently released updated Appropriate Use Criteria for Coronary Revascularization in Patients with Stable Ischemic Heart Disease, which include the use of HeartFlow FFRct by healthcare providers in determining the appropriateness of revascularizations in many clinical scenarios.

About HeartFlow FFRct
The HeartFlow FFRct process starts with data from a standard, non-invasive coronary CT angiogram from a patient. Leveraging deep learning, an advanced form of artificial intelligence, HeartFlow creates a personalized 3D model of the patient’s arteries. Powerful computer algorithms then solve millions of complex equations to simulate blood flow and assess the impact of blockages in the arteries. With this actionable information, the physician can determine the right course of action for the patient.

HeartFlow FFRct has received regulatory approval and is commercially available in the United States, Canada, Europe and Japan. To date, more than 10,000 patients have benefitted from this technology.

About Coronary Artery Disease
Coronary artery disease (CAD), also called coronary heart disease, is the leading cause of death for both men and women around the world. CAD develops when the arteries leading to the heart narrow, often because plaque builds up in the vessel walls. Narrowing of the arteries can reduce blood flow to the heart, causing angina (chest pain), myocardial infarction (heart attack) and death. CAD is one of the costliest medical diseases in the world today.

About HeartFlow, Inc.
HeartFlow, Inc. is a personalized medical technology company seeking to transform the way cardiovascular disease is diagnosed and treated. The company’s HeartFlow FFRct is the first available non-invasive solution that enables a physician to more accurately evaluate whether a patient has significant coronary artery disease (CAD) based on both anatomy (from coronary CT angiogram) and physiology (from HeartFlow FFRct). The solution, which leverages deep learning to create a personalized 3D model of the patient’s arteries, is well positioned to become an integral part of the standard of care for patients who are at risk for CAD because of its potential to improve clinical outcomes, improve the patient experience, and reduce the cost of care. The HeartFlow FFRct is available in the United States, Canada, Europe and Japan. For more information visit www.heartflow.com.

# # #

Media Contact:
Chris B. Ernst
HeartFlow, Inc.
cernst@heartflow.com
415-710-9445