Heartflow Secures De Novo Clearance from the U.S. Food and Drug Administration for Breakthrough FFRCT Technology

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Highly Accurate, Non-invasive Test Has the Potential to Change the Way Coronary Artery Disease is Managed

REDWOOD CITY, Calif. – Dec. 1, 2014 – Heartflow Inc., a pioneer in personalized medical technology for cardiovascular disease, today announced that it received de novo clearance from the U.S. Food and Drug Administration for its FFR_{CT} technology. Heartflow FFR_{CT} is the first and only non-invasive imaging technology for coronary artery disease to offer insight on both the extent of the blockage, as well as whether it is impacting blood flow, two vital pieces of information physicians need to develop a treatment plan that is right for a patient.

The FFR_{CT} platform was developed by marrying non-invasive imaging with computational fluid dynamics technology to produce detailed models of a patient's cardiovascular anatomy. The technology is cleared for the evaluation of patients showing signs and symptoms of coronary artery disease, in conjunction with other clinical patient data. "FDA clearance of our FFR_{CT} technology is a significant milestone that only further reinforces our belief in its potential to transform the way coronary artery disease is managed," said John H. Stevens, M.D., chairman and CEO of Heartflow. "Research on this technology began more than 20 years ago. We have continued to develop it with the goal of helping healthcare professionals identify the most appropriate care for each patient precisely, safely, efficiently and cost-effectively. We are now are a major step closer to achieving this paramount goal."

Coronary artery disease develops when the arteries leading to the heart become diseased or damaged, often because of the build up of plaque in the vessel walls. The plaque – or lesions – can cut off vital blood flow to the heart, causing chest pain, heart attacks and death. Coronary artery disease affects an estimated 16.3 million adults and is one of the most costly medical conditions to the United States healthcare system.

Non-invasive tests are widely used as a first-line method to diagnose coronary artery disease, but studies have shown a need to improve their accuracy. A study conducted by Duke University investigators and published in the New England Journal of Medicine found that fewer than 38 percent of patients who underwent elective invasive cardiac catheterization and angiography were found to have obstructive coronary artery lesions, even though non-invasive testing had been performed on 84 percent of those patients.[1]

Heartflow's FFR_{CT} technology works by solving millions of complex equations simulating blood flow in the coronary arteries to provide mathematically computed fractional flow reserve (FFR_{CT}) values from images derived using non-invasive computed tomography (CT) angiography. Fractional flow reserve values demonstrate blood pressure differences around a lesion to determine whether it is likely to reduce blood flow to the heart. These simulated values help physicians determine the right course of action for each patient.

FDA clearance of the technology was supported by clinical data from the landmark Heartflow NXT study that demonstrated superior discriminatory ability to identify lesions that have the potential to impede blood flow when compared to coronary CT angiography alone. In the study, published in the Journal of the American College of Cardiology earlier this year, FFR_{CT} had higher diagnostic accuracy (86 percent) than coronary CT angiography (65 percent). This difference is primarily due to a significantly increased specificity with FFR_{CT} (86 percent) compared to coronary CT angiography (60 percent).[2] Invasive angiography performed with 71 percent accuracy in the study.[3]

"FFR_{CT} represents a tremendous advancement in the management of coronary artery disease," said Dr. Daniel Simon, president, Harrington Heart & Vascular Institute at University Hospitals Case Medical Center, and Herman K. Hellerstein Chair and professor of medicine at Case Western Reserve University School of Medicine. "Historically, we have been faced with either using tests we knew were not always accurate or putting a patient through an invasive procedure just to determine whether they needed another invasive procedure. For the first time, we have access to a test that is both non-invasive and highly accurate in showing us the extent of a lesion, as well as how it can hinder blood flow through the vessel. I believe FFR_{CT} has the potential to completely change the way we manage coronary artery disease globally."

About Heartflow Inc.

Heartflow Inc. is a personalized medical technology company dedicated to transforming the way cardiovascular disease is managed. Committed to improving outcomes, reducing costs and creating a better patient experience, Heartflow's goal is to provide healthcare professionals with actionable knowledge about each patient by combining best-in-class, non-invasive

healthcare imaging with advanced, computational fluid dynamics technology and the insights of big data. Heartflow's non-invasive FFR_{CT} technology helps physicians diagnose coronary artery disease and provides them with information they need to manage each patient. For more information visit www.Heartflow.com.

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1. Patel, M. et al. N Engl J Med 2010;362:886-95
2. Nørgaard, B. et al. J Am Coll Cardiol 2014;63:1145–55
3. Nørgaard, B., Transcatheter Cardiovascular Therapeutics presentation, October 2013