Heartflow Receives National Reimbursement Approval in Japan

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Heartflow Analysis to be covered by Japan's health insurance system, making it more broadly available to patients with suspected coronary artery disease

REDWOOD CITY, Calif. – November 14, 2018 – Heartflow, Inc. today announced that the Japanese Ministry of Health, Labor and Welfare (MHLW) has approved the recommendation by the Central Social Insurance Medical Council (Chuikyo) to provide reimbursement for the Heartflow FFR_{CT} Analysis. The Heartflow Analysis has already received regulatory approval from the Japanese Pharmaceuticals and Medical Devices Agency (PMDA). Reimbursement will go into effect beginning December 1, 2018, enabling greater access for patients with suspected coronary artery disease (CAD).

"When a patient presents with symptoms suggesting CAD, we want to be able to quickly and effectively diagnose patients while reducing the need for unnecessary tests or invasive procedures," said Takashi Akasaka, M.D., Ph.D., Professor of Medicine, Department of Cardiovascular Medicine, Wakayama Medical University. "In clinical studies, we were able to see firsthand how the Heartflow Analysis can help to improve patient management and avoid invasive procedures in some patients. The reimbursement approval will enable more physicians and patients to obtain benefits from this ground-breaking technology."

"Adding the Heartflow Analysis to the anatomical information provided by a coronary CT angiogram enables us to better detect and treat CAD," said Hiroyoshi Yokoi, M.D., Director, Cardiovascular Center, Fukuoka Sanno Hospital and Vice Chairman, Japan Association of Cardiovascular Intervention and Therapeutics. "With the broader availability of the Heartflow Analysis, physicians in Japan will be able to more efficiently diagnose CAD while minimizing unnecessary tests or delaying care for patients."

CAD is the world's leading cause of death, and is responsible for approximately half of all heart-disease related deaths in Japan. Clinicians diagnosing someone with suspected CAD want to know as definitively as possible if the individual has a significant blockage in their coronary arteries. They also want to know the impact of that blockage on blood flow so they can determine which treatment pathway is most appropriate (e.g., medical management, stenting or coronary artery bypass grafting).

The Heartflow Analysis is a non-invasive, personalized cardiac test that applies artificial intelligence to image data taken from a standard coronary computed tomography (CT) 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 technology has been demonstrated to reduce unnecessary and 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.[1]

"The reimbursement approval in Japan is an important milestone for Heartflow as we work to make our state-of-the-art technology available to more patients around the world," said John H. Stevens, M.D., president and chief executive officer, Heartflow. "Our commercial launch will begin immediately and we look forward to giving clinicians in Japan a new tool to help them confidently diagnosis CAD and determine the optimal treatment path for patients."

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 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. Douglas PS, DeBruyne B, Pontone G., Patel MR, et al. One-year outcomes of FFR_{CT}-guided care in patients

withsuspected coronary disease: The PLATFORM Study. J Am Coll Cardiol. 2016;68(5),435-45.