Heartflow Unveils Landmark DECIDE Registry Data Demonstrating Impact of Heartflow Plaque Analysis on Coronary Artery Disease Medical Management

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More than 50% of patients saw treatment changes following Heartflow Plaque Analysis – driving promising LDL cholesterol improvements and individualized care

MONTREAL, July 17, 2025 (GLOBE NEWSWIRE) -- Heartflow, Inc., the leader in AI technology for coronary artery disease (CAD), today announced new data for its AI-enabled Heartflow Plaque Analysis, including final primary endpoint data from the DECIDE Registry. Data from the DECIDE Registry showed Heartflow Plaque Analysis led to medical management change in over half of patients beyond coronary computed tomography angiography (CCTA) alone, regardless of traditional risk factors or CCTA findings. The DECIDE Registry is the largest prospective study of its kind, enrolling approximately 20,000 patients at over 30 sites across the United States.

Data will be presented this week at the Society of Cardiovascular Computed Tomography (SCCT) 2025 Annual Scientific Meeting from a cohort of 972 patients across 15 sites by Sarah Rinehart, M.D., F.A.C.C., F.S.C.C.T., medical director of cardiovascular imaging, Charleston, WV, and co-lead principal investigator of the registry. DECIDE Registry investigator Cian McCarthy, MB, BCH, BAO, SM, is the first-place recipient of the *2025 SCCT Clinical Trials and Registries Award*, which will be presented at the opening session of SCCT 2025 on Friday, July 18, followed by a presentation of the study results.

For DECIDE Registry patients, management changes informed by Heartflow Plaque Analysis with Plaque Staging* led to an average LDL cholesterol decrease of 18.7mg/dL, which is associated with an estimated 15% decrease in risk of a cardiac event. Additionally, 30% of patients with a calcified plaque volume of zero had a change in management.[1,2] These findings suggest Heartflow Plaque Analysis can deliver clinically meaningful impact by helping clinicians identify which patients require changes to their treatment plans.

“These data confirm what we’re seeing in clinical practice — Heartflow Plaque Analysis provides individualized insights that go beyond what a traditional analysis of a patient’s risk factors or CCTA alone can show,” said Dr. Rinehart. “By quantifying plaque burden and characterizing higher-risk non-calcified plaque types, Heartflow’s technology empowers physicians to personalize care and intervene earlier, which can change the trajectory of a patient’s coronary health.”

Traditional risk factors such as age, smoking, hypertension, and family history are useful for population-level CAD predictions but lack precision at the individual level. Similarly, while CCTA is effective in detecting calcified plaque, it often underreports non-calcified and low-attenuation plaque, which leaves many high-risk patients incorrectly classified. Heartflow Plaque Analysis addresses this critical gap by quantifying all plaque types and supporting informed decision-making for clinicians.

As part of the DECIDE Registry, Heartflow’s recently introduced Plaque Staging* framework is being used prospectively to help translate these advanced insights into simplified, actionable treatment plans. The Heartflow Plaque Staging framework, which was developed by expert consensus and clinically validated using outcomes data from the FISH&CHIPS Study,[3] stratifies patients into one of four risk-based stages — mild, moderate, severe, or extensive — based on AI-quantified plaque volume and composition[4] With data from over 2,800 patients, Heartflow Plaque Staging is the leading tool for risk stratification based on AI-quantitative coronary plaque assessment.

The FISH&CHIPS Study data showed higher coronary plaque-based stages, measured by Heartflow Plaque Analysis, were associated with up to five times higher risk of cardiovascular event rates at 3.3 years. The data were presented at the British Society of Cardiovascular Imaging Annual Scientific Meeting in April 2025.

“The results from the DECIDE Registry clearly show how Heartflow Plaque Analysis can meaningfully change CAD care, with more than half of patients seeing their treatment plans altered after Heartflow Plaque Analysis,” said Campbell Rogers, M.D., F.A.C.C., Chief Medical Officer of Heartflow. “We expect that tools like Plaque Staging will enhance the impact Heartflow Plaque Analysis is already making by providing a clearer framework for personalized patient care.”

**Heartflow Plaque Analysis is an FDA-cleared device. Heartflow Plaque Staging is an investigational-only framework, and its safety and effectiveness have not been reviewed by the FDA.*

About the DECIDE Registry
The DECIDE Registry is the largest prospective study of its kind, collecting real-world data from multiple sites investigating how Heartflow’s AI-enabled Plaque Analysis informs medical management plans compared to CCTA alone for patients with suspected CAD. Approximately 20,000 patients will be enrolled at over 30 sites across the United States. The primary endpoint for this

registry highlights changes in medical management after Heartflow Plaque Analysis. Clinical outcomes and biomarkers are the secondary endpoints. Safety endpoints include MACE (major adverse cardiovascular events), such as myocardial infarction and urgent hospitalization leading to revascularization.

About Heartflow, Inc.
Heartflow is advancing coronary care by transforming coronary artery disease into a screenable, diagnosable, and manageable condition. Heartflow One is the only complete, non-invasive, precision coronary care platform providing patient insights throughout the guideline-directed CCTA pathway. The AI-driven platform — including Roadmap™ Analysis, FFR_{CT} Analysis and Plaque Analysis — is supported by the ACC/AHA Chest Pain Guideline and backed by more than 600 peer-reviewed publications. Heartflow has helped clinicians manage over 400,000 patients worldwide. Discover how we're shaping the future of cardiovascular care at www.heartflow.com.

Media Contact
Elliot Levy
elevy@heartflow.com

Investor Contact
Nick Laudico
nlaudico@heartflow.com

[1] DECIDE Registry. Rinehart, et al., Presented at SCCT July 2025.

[2] Collins et al. Lancet 2016. DOI: 10.1016/S0140-6736(16)31357-5

[3] Fairbairn, et al. AI-Enabled CCTA Plaque Quantification and the Prediction of Cardiovascular Outcomes. Heart 2025.

[4] Rinehart, et al. Guiding Automated Implementation Strategies for Patients With Atherosclerotic Plaque on Coronary Computed Tomographic Angiography. JACC: Cardiovascular Imaging. 2025. https://doi.org/10.1016/j.jcmg.2025.03.019.