Heartflow Builds Evidence Base Across the Heart Disease Care Continuum, From Precision Risk Stratification to CT-Guided Intervention Planning

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Three presentations at ACC reinforce Heartflow's AI-powered technology predicts MACE, drives superior lipid outcomes and results in cost-effective care

First patient enrolled in pioneering NAVIGATE-PCI Registry assessing impact of Heartflow PCI Navigator on clinical strategy, efficiency and physician confidence across 5,000 patients

MOUNTAIN VIEW, Calif., March 16, 2026 (GLOBE NEWSWIRE) -- Heartflow, Inc. (Heartflow) (Nasdaq: HTFL), the leader in AI technology for coronary artery disease (CAD), today announced new clinical evidence and a landmark registry launch that together advance the company's vision of transforming CAD management across every stage of the patient journey. At the American College of Cardiology (ACC) Annual Scientific Session, Heartflow is presenting new clinical evidence that further establishes AI-powered Heartflow Plaque Analysis as the leading tool for identifying high-risk patients earlier and guiding more effective medical management.

Simultaneously, Heartflow has enrolled the first patient in the NAVIGATE-PCI Registry, the first large-scale effort to evaluate the real-world impact of CT-guided percutaneous coronary intervention (PCI) planning on clinical strategy, procedural efficiency and physician confidence. The registry is evaluating how often treatment plans change when physicians use the AI-driven insights provided by Heartflow PCI Navigator compared to angiography alone.

"These milestones reflect tremendous progress toward Heartflow's goal of transforming coronary artery disease from the world's leading cause of death into a condition that can be detected early, diagnosed accurately, and managed for life," said Campbell Rogers, M.D., F.A.C.C., Chief Medical Officer at Heartflow. "The Heartflow Plaque Analysis data presented at ACC and the launch of the NAVIGATE-PCI Registry represent important steps in building the rigorous real-world evidence needed to support AI-driven decision-making across the full continuum of cardiovascular care. From identifying high-risk patients earlier and improving how they are managed to generating the evidence needed to guide more precise interventions when required, Heartflow is giving physicians deeper insights and greater confidence so they can deliver better outcomes for patients."

Heartflow Plaque Analysis: New Clinical Evidence for Earlier Risk Stratification and Management

Heartflow Plaque Analysis will be featured in three ACC 2026 presentations, covering long-term validation of risk stratification, real-world comparative effectiveness in lipid management, and economic sustainability. Collectively, these data reinforce Plaque Analysis as a personalized, clinically actionable and cost-effective solution for CAD management.

AI-Based Coronary Plaque Analysis and Adverse Cardiovascular Events: The Mass General Brigham CCTA Registry (Poster 1082-09, March 29, 10:06 a.m. CDT)
This cohort, based on a large-scale registry tracking over 15,000 patients, with up to 16 years of follow-up, demonstrated that Plaque Analysis is a powerful predictor of major adverse cardiovascular events (MACE), even after accounting for traditional risk factors and the severity of coronary stenosis. The findings reveal that patients with extensive plaque volume face a fourfold higher risk of such events. This robust, real-world data solidifies Heartflow Plaque Staging as the most powerful CTA-based independent predictor for personalized risk stratification, enabling clinicians to identify high-risk individuals beyond conventional metrics.

"Stenosis has long been our primary lens for evaluating coronary risk, but it tells an incomplete story, as this registry demonstrates. With over 15,000 patients and 16 years of follow-up, we now have compelling real-world evidence that total plaque volume independently drives adverse events, regardless of risk factors or the presence of anatomical stenosis," said Ron Blankstein, M.D., Director of Cardiac Computed Tomography at Brigham and Women's Hospital, and Professor of Medicine and Radiology at Harvard Medical School. "These findings catalyze a meaningful shift in how we approach risk stratification by more accurately identifying patients who might otherwise have been characterized as having lower risk based on conventional assessment and optimizing management based on their actual disease burden."

Comparative Effectiveness of Coronary Computed Tomographic Angiography With or Without AI-Plaque Analysis and Stress Testing on Lipid Lowering After One Year: A Primary Analysis of the DECIDE Registry (Poster 1469-058, March 29, 12:30 p.m. CDT)
This analysis, involving nearly 3,800 patients, compared patient management guided by CCTA with Plaque Analysis versus traditional stress-test-guided care over a one-year follow-up. A significantly higher portion of patients whose care was informed by Plaque Analysis initiated lipid-lowering therapy and achieved guideline-recommended LDL goals (<70 mg/dL). These findings

demonstrate that Heartflow's AI-powered insights optimize medical management, pushing beyond conventional diagnostic pathways for more precise and effective treatment outcomes, regardless of traditional risk factors.

The primary endpoint data from the landmark DECIDE Registry, the largest prospective registry evaluating the clinical impact of Heartflow Plaque Analysis on medical management decisions, were recently published in JACC Cardiovascular Imaging.

Budget Impact Analysis of AI-Guided Coronary Plaque Analysis vs. Usual Care from a US Payer Perspective (Poster 1468-019, March 29, 12:30 p.m. CDT)
This study demonstrated that Plaque Analysis is not only clinically impactful, but also economically sustainable. The analysis revealed that cost-effectiveness and parity with usual care are achieved in under two years with total population savings of $140 million, as incremental testing costs to prevent a single MACE fall significantly below the actual cost of treating a MACE. This research reinforces prevention as a critical value-based care strategy, highlighting how Heartflow's technology delivers substantial long-term savings and improved patient outcomes for both payers and healthcare systems.

Heartflow also invites ACC.26 meeting attendees to join its other programs, including an educational dinner, innovation session, snack-n-learn sessions, and more. See the full schedule at heartflow.com/ACC26.

Heartflow PCI Navigator: NAVIGATE-PCI Registry to Advance CT-Guided Intervention Planning
Powered by Heartflow PCI Navigator, the company's AI-driven pre-procedural planning platform, the NAVIGATE-PCI Registry is underway to investigate how integrating patient-specific insights into coronary anatomy, physiology and plaque can shape clinical strategy, enhance procedural efficiency and bolster physician confidence in the cath lab. This comes as interventional cardiologists increasingly seek advanced tools to optimize PCI procedures.

“AI-powered technology is rapidly evolving, now offering interventional cardiologists the opportunity to start planning percutaneous coronary interventions before we enter the cath lab, from any computer, anywhere,” said Ziad Ali, M.D., D.Phil., Director of the DeMatteis Cardiovascular Institute at St. Francis Hospital & Heart Center, and Co-Principal Investigator of the NAVIGATE-PCI Study. “CT-guided PCI planning allows us to anticipate lesion complexity, select devices more intelligently, and enter the cath lab with a clear procedural strategy.”

NAVIGATE-PCI represents the first large-scale effort to evaluate the clinical implications of CT-guided PCI planning. The study will examine how comprehensive pre-procedural insights can enhance PCI procedures to improve cath lab efficiency and outcomes for patients.

“NAVIGATE-PCI will generate evidence on how pre-procedural insights influence concrete decisions across procedural planning, lesion preparation strategy and expected stent placement,” added Todd Villines, M.D., F.A.C.C., Professor of Medicine, Division of Cardiology, University of Virginia, and Co-Principal Investigator of the NAVIGATE-PCI Study. “This level of clinical clarity is what physicians and health systems need to confidently integrate this innovative capability into everyday practice.”

About Heartflow Plaque Analysis with Plaque Staging
Heartflow Plaque Analysis is the only FDA-cleared, AI-powered plaque analysis tool with a reported 95% agreement with the gold standard, intravascular ultrasound (IVUS), in a prospective, international trial using blinded core lab adjudication.[1] Heartflow Plaque Staging guides patient risk stratification based on total plaque volume, informing actionable treatment plans, simplifying decision-making and personalizing preventive treatment based on patient risk.[2,3]

About Heartflow PCI Navigator
Heartflow is expanding the Heartflow One platform with the addition of Heartflow PCI Navigator to support diagnosing, managing and guiding treatment for patients throughout the spectrum of CAD care. PCI Navigator is the only integrated, AI-driven percutaneous coronary interventions (PCI) planning tool that gives interventional cardiologists a patient-specific 3D model detailing anatomy, plaque composition, and lesion-specific physiology, all aligned to optimize potential stent placement. Heartflow introduced PCI Navigator to close the critical information gaps interventional cardiologists face before entering the cardiac catheterization lab. Commercial availability of PCI Navigator is expected in the second quarter of 2026.

About Heartflow’s Technology and Research
Heartflow’s technology is redefining precision cardiovascular care through clinically proven AI and the world’s largest coronary imaging dataset. Heartflow has been adopted by more than 1,400 institutions globally and continues to strengthen its commercial presence to make this cutting-edge solution more widely available to an increasingly diverse patient population. Backed by ACC/AHA guidelines and supported by more than 600 peer-reviewed publications, Heartflow has redefined how clinicians manage care for over 500,000 patients worldwide.[4] Key benefits include:

- Proprietary data pipeline: Built from more than 160 million annotated CTA images, Heartflow’s data foundation powers advanced AI models that deliver highly accurate, reproducible insights across diverse patient populations.
- Extensive clinical and real-world validation: Heartflow’s AI-driven solutions have been validated through clinical evidence in over 200 studies assessing over 365,000 patients. Proven in real-world practice with reproducibility and accuracy, Heartflow’s coronary CTA image acceptance rates exceed 97%.
- Seamless clinical integration via upgraded workflow: Heartflow delivers final quality-reviewed analyses instantly upon order, enabling clinicians to move from diagnosis to decision without delay.
- Quality system, global security and patient-data integrity compliance: Heartflow meets or exceeds leading international standards, including HITRUST, SOC 2 Type 2, ISO 13485, and ISO 27001.

About Heartflow, Inc.
Heartflow is transforming coronary artery disease from the world's leading cause of death into a condition that can be detected early, diagnosed accurately, and managed for life. The Heartflow One platform uses AI to turn coronary CTA images into personalized 3D models of the heart, providing clinically meaningful, actionable insights into plaque location, volume, and composition and its effect on blood flow — all without invasive procedures. Discover how we're shaping the future of cardiovascular care at heartflow.com.

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[1] Ihdayhid A, et al. Radiol Cardiothorac Imaging. 2024. doi: 10.1148/ryct.230312 and internal bridging study with ICC correlation between first generation and second generation Plaque Analysis algorithm.

[2] Rinehart, et al. JACC Imaging. 2025.

[3] Fairbairn, et al. Presented at AHA 2025.

[4] Gulati, et al. 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Guideline for the Evaluation & Diagnosis of Chest Pain. J Am Coll Cardiol.

A video accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/2c5f4a13-0d27-4d98-9886-5face77035d6