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Contact: Gina Jung
ACIST Medical Systems
Direct: 952 995 9306
info@acistmedical.com

Enrollment in the ACIST-FFR Multi-Center Study Has Begun

First patient enrolled at Stanford University on Nov. 14

EDEN PRAIRIE, Minn. Nov. 16, 2015 – William Fearon, MD, Professor of Cardiovascular Medicine at Stanford University (Palo Alto, CA) enrolled the first patient in the ACIST-sponsored FFR Study — Assessment of Catheter-based Interrogation and Standard Techniques for Fractional Flow Reserve (FFR) measurement on Nov. 14.

The purpose of the study is to further the clinical understanding of FFR technologies, evaluating measurement accuracy, incidence of drift and device success in 240 patients at 12 U.S. sites. Co-Principal Investigators are Drs. Matthew Price (Scripps Clinic, La Jolla, CA) and William Fearon (Stanford Hospital, Palo Alto, CA). The ACIST-FFR Study data results, along with the ACCESS-NZ Trial results (used for both FDA clearance and CE Mark approval), will further demonstrate Navvus' FFR clinical utility in everyday practice.

“As with all new technologies, it is important to understand the impact the technology can have on clinical practice and patient care,” stated Dr. Fearon. “Multi-center studies like the ACIST-FFR Study are valuable as they provide data to allow us to assess technologies and their usefulness in helping to improve patient outcomes.”

FFR is a fast-growing market within interventional cardiology. Published data and literature continues to support the use of FFR as a part of a clinical decision-making arsenal available to physicians to help optimize patient outcomes. Continued interest and increased utilization of FFR has led to new product offerings in the marketplace.

In 2014, ACIST Medical Systems, Inc. (Eden Prairie, MN) launched the ACIST RXi® Rapid Exchange FFR System and Navvus® Rapid Exchange FFR Microcatheter. Unlike traditional pressure wires, this rapid exchange FFR technology allows physicians to use their 0.014” guide wire of choice throughout the procedure, addressing challenges of pressure wires, including, accessibility in challenging anatomies, maintaining wire position, pressure-measurement drift and ease of obtaining post-intervention FFR.

“The introduction of the RXi Rapid Exchange FFR System in 2014, along with the recent launch of the ACIST HDi™ High Definition IVUS System, is another step towards the transformation of the company,” said Tom Morizio, President and COO, ACIST Medical Systems, Inc. “We built our presence by providing the first variable rate contrast injector that simplifies the delivery of contrast in the cath lab. With the addition of RXi and HDi, ACIST Medical again demonstrates its commitment to offer technologies that simplify procedures and improve patient care. The ACIST-FFR Study is our commitment to advancing science to ensure utmost safety and efficacy of our expanding product portfolio.”



About FFR

FFR measurement is a technique used in cardiology to determine the effect of narrowing, or stenosis, in the coronary arteries on blood flow. It allows for a more effective assessment of coronary lesions than when only using angiography, the gold-standard imaging technique. By identifying which stenoses are causing ischemia by significantly restricting the blood flow to the heart muscle and causing the patient's symptoms, FFR can help avoid unnecessary stenting to reopen the blood vessels, leading to improved patient outcomes.^{1,2}

ACIST

ACIST Medical Systems, Inc. is a pioneering interventional and diagnostic technology company with a portfolio of advanced products, including the world's first Rapid Exchange FFR and High Definition IVUS systems. It is also a global market leader in advanced contrast imaging systems for cardiovascular angiography and radiology imaging. Through these products, ACIST is demonstrating its commitment to bringing unique and innovative technologies that simplify cardiovascular procedures and empower clinicians to treat patients with superior care. As part of the Bracco Group, ACIST benefits from the resources of a multinational conglomerate with broad expertise in cath lab technology and a dedication to continuous advancement. Headquartered in Eden Prairie, Minnesota, USA, ACIST has worldwide presence with over 300 direct employees and facilities in Silicon Valley, Maastricht, Shanghai and Tokyo.

To learn more about ACIST, visit www.acist.com.

Bracco Group

Bracco has headquarters in Milan, Italy, and was founded in 1927. It is active in the healthcare sector through Bracco Imaging (diagnostic imaging), Pharma (prescription and over the counter drugs), ACIST Medical Systems and HLT (cardiology) and the Centro Diagnostico Italiano diagnostic clinic. It has around 3,300 employees and annual total consolidated revenues of over 1.2 billion Euro. Bracco operates in more than 90 countries worldwide.

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¹ Tonino PA et al. New Engl J Med 2009;360:213-24

² De Bruyne B et al. New Engl J Med 2012;367:991-1001