



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

Enrollment Complete for ACIST-FFR Multi-Center Study

EDEN PRAIRIE, Minn. Jan. 11, 2017 – ACIST Medical Systems, Inc., announces that enrollment is complete for its Fractional Flow Reserve (FFR) Study – Assessment of Catheter-based Interrogation and Standard Techniques for Fractional Flow Reserve measurement. The study, which began in November 2015, included 240 patients at 12 sites across the U.S. Final results are expected to be released in mid-2017.

The purpose of this large, prospective, multi-center study is to advance the clinical understanding of FFR technologies by comparing FFR measurements obtained using the Navvus catheter to those obtained using a commercially available pressure guide wire. The Co-Principal Investigators are Drs. Matthew Price (Scripps Clinic, La Jolla, CA) and William Fearon (Stanford University, Palo Alto, CA).

“We are excited about the completion of enrollment in this important clinical trial,” said Dr. Fearon. “We look forward to analyzing the data to better understand how we can most effectively utilize this exciting technology to help our patients.”

The study is specifically evaluating measurement accuracy, incidence of drift, and device success in patients with single or multi-vessel coronary artery disease where FFR is clinically indicated. The results of the study, combined with the ACCESS-NZ Trial results, will provide important data regarding how this technology impacts patient care while demonstrating its clinical usefulness in everyday practice. ACIST FFR will also evaluate measurement accuracy in vessels as small as 2.25 mm.

“We are showing our confidence in Navvus performance by studying its use in even the smallest of vessels that might be treated. These results will add to the body of knowledge that supports the use of this device across a broad range of patients,” said Tom Morizio, President and CEO, ACIST Medical Systems.

FFR continues to be a growing market within interventional cardiology and new products are being developed that provide more technologically advanced resources aimed at improving patient outcomes.

-more-



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.

To learn more about Bracco Group, visit www.bracco.com.

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