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Infraredx Announces the First Patient Enrolled in the PROSPECT II Study on the Detection and Treatment of the Vulnerable Plaques Suspected to Cause Heart Attacks

-- Large-Scale Study in Patients with Acute Coronary Syndrome Builds on the Success of Landmark PROSPECT Study that Identified Plaques at Risk of Causing Future Coronary Events --

BURLINGTON, Mass. – June 30, 2014 – [Infraredx, Inc.](#), a medical device company committed to advancing the diagnosis of coronary artery disease and prevention of heart attacks, today announced the first patient enrolled in PROSPECT II, a multi-center, prospective study designed to assess the ability of intravascular imaging to identify non-flow obstructing vulnerable plaques. Lipid core plaque (LCP), which is suspected to be vulnerable plaque, is a type of fatty coronary artery plaque implicated in most heart attacks, and will be identified using the Infraredx TVC Imaging System™, a first-in-class dual modality intravascular imaging system. The study's first patient was enrolled by David Erlinge, MD, PhD, one of the study's principal investigators, from Lund University in Sweden.

The TVC Imaging System is the only device approved by the FDA to detect the presence of LCPs. The technology integrates near-infrared spectroscopy (NIRS) to detect LCPs, with enhanced intravascular ultrasound (IVUS) to visualize the vessel structure, and is used to guide percutaneous coronary interventions (PCI).

“There is mounting clinical evidence pointing to the role of lipid-rich plaque as the main cause of heart attacks,” said Dr. Erlinge. “The PROSPECT II study will allow us to test our hypotheses that NIRS-IVUS imaging can identify the vulnerable plaques that cause heart attacks, and that preemptive treatment of the most dangerous plaques with PCI can prevent the development of further narrowing of the coronary arteries, as well as plaque erosion and rupture.”

Infraredx will provide the primary funding for the study, with additional support from The Medicines Company and Abbott Vascular.

In 2011, the *New England Journal of Medicine* published results from the original PROSPECT study, which was the first to prospectively demonstrate that vulnerable plaques can be identified through imaging techniques months to years before adverse events occur. The PROSPECT II study, which will enroll 900 patients at 16 leading cardiac catheterization laboratories across Scandinavia, will use the TVC Imaging System to identify vulnerable plaques in the three major coronary arteries and follow patients for at least three years to detect the occurrence of coronary events. In addition, 300 patients with “bulky” plaques (detected by intravascular ultrasound), which have been shown to be at high risk for causing future adverse events in the first PROSPECT study,¹ will be randomly assigned to treatment with Abbott's Absorb™ Bioresorbable Vascular Scaffold (BVS) or optimal medical therapy. Absorb is a first-of-its-kind device which is under investigation in the US, and received CE Mark in 2011. Absorb functions similarly to a stent and is designed to open a blocked vessel and

restore blood flow, but because it is made from bioresorbable materials similar to dissolving stitches, it dissolves completely over time.¹ Absorb is called a scaffold to indicate its temporary nature. In data from international studies, regression of plaque has been observed at the site where Absorb has been implanted, a unique effect not typically seen with permanent metallic stents. Data from this sub-study, termed PROSPECT-ABSORB, will be analyzed in patients with and without a cholesterol signal at the site of the large plaque, making this the first large-scale study of the identification and preventive treatment of vulnerable plaques.

“We are proud to partner with global leaders in cardiovascular medicine and business to sponsor the PROSPECT II Absorb study,” said Donald Southard, president and CEO of Infraredx. “This study, along with other outcomes studies Infraredx is sponsoring, is designed to prove that vulnerable plaques exist and can be detected in a highly specific manner with the TVC Imaging System. We believe that positive outcomes of these studies will establish our proprietary TVC Imaging NIRS-IVUS technology as the standard of care for guiding the 3 million PCIs performed worldwide each year, and position Infraredx as a leader in what we believe will become a multi-billion dollar intravascular imaging market. Most importantly, successfully treating these vulnerable plaques will improve the quality of life for our patients and result in significant cost savings to healthcare systems worldwide.”

“This important outcomes study results from the convergence of progress in multiple areas, including the success of the original PROSPECT Study, the development of the combined NIRS-IVUS imaging system, the new STEMI findings, the excellent outcomes data that can be obtained with the use of the Scandinavian registers, and the availability of new therapies such as Abbott’s Absorb,” said James Muller, M.D., co-founder and chief medical officer of Infraredx. “We also appreciate the strong interest of leading clinical investigators, and are pleased to join with the interventional cardiologists and the patients who will participate in this study to test the hypothesis that vulnerable plaques can be proactively detected and treated leading to positive outcomes for patients.”

The PROSPECT II study was prompted by promising new data on the ability of the TVC Imaging System to detect large vulnerable plaques precisely at the coronary artery sites at which an ST-segment elevation myocardial infarction (STEMI) occurred causing a dangerous type of heart attack.

PROSPECT II is an investigator-initiated study led by co-principal investigators Gregg W. Stone, M.D., professor of medicine, Columbia University Medical Center and co-director, Medical Research & Education Division at the Cardiovascular Research Foundation in New York; and David Erlinge, M.D., Ph.D., director of the Department of Cardiology, Lund University, Skane University Hospital in Lund, Sweden. The Cardiovascular Research Foundation (CRF) will oversee the study and provide angiographic and intravascular imaging data core lab analysis and biostatistical analysis. The Uppsala Clinical Research Center will organize and coordinate the clinical management of the trial, including patient recruitment, monitoring and data collection. Patients will be recruited through the Swedish and Norwegian Coronary Angiography and Angioplasty Register (SWEDEHEART) and the corresponding register in Denmark.

“The success of PROSPECT II would be a major step toward the goal of prospective identification and eventual treatment of the vulnerable plaques causing unanticipated coronary events,” said Dr. Stone. “Thrombosis of vulnerable plaque is the leading cause of cardiac death, myocardial infarction and heart failure, which are debilitating and costly conditions. We look forward to implementing this groundbreaking study, which has the potential to change how we approach patients with coronary artery disease.”

About Heart Disease

According to the Centers for Disease Control, heart disease is the leading cause of death for both men and women in the U.S., and 720,000 Americans experience a heart attack each year.²

Coronary artery disease is caused by the build-up of cholesterol, known as plaque, and other materials inside the walls of the coronary arteries. Over time, the accumulation of plaque can gradually reduce blood supply to the heart, leading to chest pain during exertion. In addition, the plaques may also rupture which can lead to a blood clot that causes a heart attack or sudden death.

About The TVC Imaging System™

The TVC Imaging System™ is a first-in-class intravascular imaging system that holds the potential to revolutionize the management of coronary artery disease by providing information that is critical for evaluating vessel structure and composition. The TVC Imaging System helps interventional cardiologists identify which patients are prone to complications during stenting. The device also enables cardiologists to predict peri-procedural heart attacks by assessing not only the degree of stenosis, but also the presence and extent of lipid-core plaques (LCP).

As the only multimodality imaging system to combine both intravascular ultrasound (IVUS) and near-infrared spectroscopy (NIRS), the TVC Imaging System provides clear and relevant information about vessel structure, in real time. The TVC Imaging System is the only system available in both the U.S. and Europe for the detection of LCPs. NIRS measurements have been made in over 9,000 patients in over 100 hospitals worldwide.

About Infraredx, Inc.

Infraredx, Inc. was founded in 1998 by James Muller, MD on the premise that vulnerable plaque plays a key role in the cause of heart attacks. Infraredx is a privately-funded medical device company dedicated to help provide practitioners with specific information to enhance timely clinical decision-making in the treatment of coronary artery disease. The company has committed over \$40 million to clinical research aimed at identifying vulnerable plaque and its role in coronary artery disease, improving the safety and efficacy of coronary stenting, and ultimately serving as part of a strategy to prevent initial coronary events.

Through its TVC Imaging System™, Infraredx is changing the way coronary artery disease is diagnosed and treated. The TVC Imaging System is the only intravascular imaging system that enables true vessel characterization through simultaneous structural and compositional imaging data obtained in a single pullback. Infraredx is headquartered in Burlington, Mass. For more information, visit www.infraredx.com.

References

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2. Go AS, Mozaffarian, D, et al. 2014 update: a report from the American Heart Association. Circulation 2014: 128. As listed on the Centers for Disease Control (CDC), Heart Disease Facts.

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