



One of the Most Important Global Healthcare Studies of this Generation Reaches Significant Patient Enrollment Milestone

1,000 patients enrolled marks milestone in study that has potential to reveal breakthrough correlations between Lipid-Rich Plaques and occurrence of heart attacks

Burlington, Mass. – April 27, 2015 – [Infraredx, Inc.](#), an intravascular imaging company committed to advancing the diagnosis and management of coronary artery disease, today announced the enrollment of 1,000 patients in the Lipid-Rich Plaque (LRP) Study. The LRP Study is a prospective, multi-center clinical trial designed to identify a correlation between lipid-rich plaques detected by Infraredx's TVC Imaging System™ and the occurrence of a cardiac event within two years. The first-in-class dual-modality intravascular imaging system integrates near-infrared spectroscopy (NIRS) with intravascular ultrasound (IVUS) technology, allowing clinicians the ability to assess vessel structure and plaque composition. The TVC Imaging System is FDA-approved to identify lipid-core plaques that may cause heart attacks. Identification of such plaques would be a major step toward the development of percutaneous coronary intervention (PCI) as a means to prevent coronary events.

Current PCI imaging technologies are limited in the information they can provide about non-flow limiting plaques that may be dangerous. The results of TVC imaging are presented in the form of a chemogram™, an easy-to-read road map of cholesterol throughout the vessel scanned. Several prior studies in patients who have already experienced a coronary event have revealed a prominent signal detected by NIRS at the site of the culprit lesion. These studies led to the initiation of the LRP Study to test the hypothesis that a plaque with a large lipid core identified by NIRS imaging is a vulnerable plaque likely to cause a future coronary event. The goal is to prove that vulnerable plaques can be identified by NIRS and provide a target for personalized therapy to prevent coronary events.

“With 1,000 patients enrolled at forty-one investigator sites across the United States and Europe, we are excited by the rapid progress of the LRP Study,” said Ron Waksman, M.D., principal investigator of the LRP Study. “Once complete, the LRP Study data could redefine the role of intravascular imaging and lay the groundwork for changing standard protocols for managing coronary artery disease.”

“We are most grateful to the many physicians and health professionals that have contributed to the rapid enrollment of patients in this important study,” said James Muller, M.D., founder and chief medical officer of Infraredx.

For more information on the study and its enrollment sites and criteria, please visit:

<http://clinicaltrials.gov/ct2/show/NCT02033694>

About The TVC Imaging System™

The [TVC Imaging System™](#) is a first-in-class dual-modality 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 plaque composition, also known as true vessel characterization. The TVC Imaging System™ may help interventional cardiologists identify which patients are prone to complications during stenting. The device may enable cardiologists to predict the risk of peri-procedural heart attacks by assessing not only the degree of stenosis, but also the presence and extent of lipid-core plaques (LCP).



The device is the only multimodality imaging system to combine both intravascular ultrasound (IVUS) and near-infrared spectroscopy (NIRS). Through Extended Bandwidth™ IVUS technology, the Advanced TVC Imaging System™ harmonizes multiple signal frequencies, resulting in a sharp image of the complete vessel allowing for easy identification of the lumen, plaque and vessel structure. The TVC Imaging System™ is the only device specifically approved in both the U.S. and Europe for the detection of lipid-core plaques. NIRS-IVUS measurements have been made in over 15,000 patients in more than 150 hospitals worldwide.

About Infraredx, Inc.

[Infraredx, Inc.](#) is a privately-funded medical device company dedicated to helping provide practitioners with the information needed for enhanced clinical decision making in treating coronary artery disease. The company is committed to 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. Founded in 1998, Infraredx is headquartered in Burlington, Mass. For more information, visit www.infraredx.com.

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