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InfraRedX Announces Data Demonstrating the LipiScan™ Coronary Imaging System Detects Extensive Lipid Core Plaques Linked to a High Risk of Peri-Procedural Heart Attacks

Study Published in Circulation: Cardiovascular Interventions Shows Lesions with Large Lipid Core are Associated with 50 Percent Risk of Heart Attack in Patients Undergoing Coronary Stent Implantation

BURLINGTON, Mass. – October 18, 2011 – InfraRedX, Inc., a medical device company providing intelligent cardiovascular diagnostic imaging technologies, today announced that new data for its LipiScan™ Coronary Imaging System was published in the peer-reviewed journal *Circulation: Cardiovascular Interventions*. Near-infrared Spectroscopy (NIRS) with the LipiScan system was shown to rapidly and accurately detect extensive lipid core plaques (LCPs) that are linked to an increased risk of heart attack during or following percutaneous coronary intervention (PCI). The LipiScan system is the first and only system approved by the U.S. Food and Drug Administration to provide interventional cardiologists with a Chemogram™, a two-dimensional map of LCP, within the imaged vessel using NIRS.

“Although PCI routinely achieves excellent angiographic results, too many cases continue to suffer from peri-procedural no-reflow and myocardial infarction,” said James A. Goldstein, M.D., F.A.C.C., director of research and education, division of cardiology, Beaumont Hospital, Royal Oak, and lead author of the study. “This study utilizing InfraRedX's first-generation LipiScan system with NIR spectroscopy permitted immediate identification of large lipid core plaques known to complicate stenting and suspected to cause most heart attacks. By identifying and quantifying these dangerous plaques that are prone to embolization, the LipiScan system holds the potential to improve patient outcomes and prevent complications in cardiac procedures.”

PCI is associated with a peri-procedural heart attack in three to 15 percent of cases. In many cases, these heart attacks result from distal embolization of LCP contents. These heart attacks are detected by procedural elevations of cardiac biomarkers specific for death of heart muscle tissue. LCP is a fatty coronary artery plaque suspected to be vulnerable to rupture, to cause most heart attacks and to complicate stenting procedures either during or post-intervention. Peri-procedural heart attacks are associated with adverse long-term outcomes and in some cases cause immediate adverse events.

The published study shows that in patients with coronary artery disease, PCI of lesions with a large lipid core is associated with a 50 percent risk of heart attack during or post-procedure compared to only a 4.2 percent risk for lesions without a large lipid core. A large LCP was defined as a maximum Lipid Core Burden Index (LCBI) within a 4mm segment of ≥ 500 , which corresponds to a LCP which on average is 4mm long and occupies 180° of the vessel circumference. Sixty-two patients meeting study criteria were selected from the COLOR Registry (NCT00831116). There were no major adverse events attributed to the use of the LipiScan system.

“This important publication adds to multiple studies showing that lipid core plaques complicate stenting,” said James E. Muller, M.D., chief medical officer of InfraRedX. “We are most pleased that InfraRedX now



provides physicians with a rapid and accurate method to find lipid cores so their presence or absence can be added to a complete characterization of the vessel.”

The use of NIR spectroscopy with the LipiScan Coronary Imaging System permitted the immediate identification and quantification of LCPs whose presence could not be determined by coronary angiography. Baseline variables also correlated poorly with the presence of a large LCP, with elevation of plasma LDL levels as the only statistically significant association. Patients with a large LCP had a 12-fold increase in relative risk (95% CI 3.3 to 48, $p=0.0002$) of peri-procedural heart attacks. In contrast, plaque complexity identified on coronary angiography, a finding often considered to be an index of increased risk of a PCI-induced complication, was associated with a relative risk of only 3.5 (CI 0.91 to 14), a difference that was not statistically significant.

Results of the published study are consistent with prior findings with other intracoronary imaging methods, but the LipiScan System identified a much higher relative risk and requires no offline analysis or expert interpretation. These findings support the concept that LCPs may be prone to complications after stenting, and their detection in the catheterization lab prior to angioplasty may help guide the interventional treatment strategy. As stated in the study article, “the ability to identify stenoses with varying levels of risk of complications when stented would indicate that LCP presence or absence might play a role in determining whether or not a lesion should be treated.”

The paper titled “Detection of Lipid-core Plaques by Intra-Coronary Near-Infrared Spectroscopy Identifies High Risk of Peri-Procedural Myocardial Infarction” was published online at <http://circinterventions.ahajournals.org/content/early/2011/10/04/CIRCINTERVENTIONS.111.963264.abstract> and appears in today’s print edition of the journal.

James A. Goldstein, M.D., is a consultant for and owns equity in InfraReDx, Inc.

About the Study Methodology

Patients with stable pre-procedural cardiac biomarkers undergoing stenting were identified from the COLOR Registry, a prospective multi-center observational study of patients undergoing near-infrared (NIR) spectroscopy with the LipiScan™ Coronary Imaging System prior to PCI. The primary endpoint of the published study was the rate of peri-procedural heart attack in the groups with and without a large lipid core plaque (LCP) in the treatment zone as assessed by NIRS and expressed as maxLCBI_{4mm}. The maximum value of Lipid Core Burden Index for any of the 4 mm segments in the treated segment is calculated and used as the index of the presence or absence of a large LCP in the treated area.

About the LipiScan™ Coronary Imaging System and the LipiScan™ IVUS Coronary Imaging System

Since this study was performed using the LipiScan™ Coronary Imaging System, InfraReDx received clearance from the U.S. Food and Drug Administration (FDA) and CE Mark approval for its next-generation product, the LipiScan™ IVUS Coronary Imaging System. The system includes the world’s first and only cardiac catheter to combine intravascular ultrasound (IVUS) and near-infrared (NIR) spectroscopy to help cardiologists identify and characterize lipid core coronary plaques (LCPs). The LipiScan IVUS provides rapid and automated detection of LCPs known to complicate stenting and suspected to cause most heart attacks.



In a single catheter pullback, the LipiScan IVUS provides physicians with a traditional IVUS image that clearly displays key structural parameters of the lesion, including its location, length, degree of stenosis, and plaque burden in addition to confirming proper stent placement. At the same time, the system automatically performs spectroscopic analysis of optical data to produce a Chemogram™ map that indicates the location of lipid core plaques and quantifies the lipid core burden. Integrating and co-registering the Chemogram with IVUS provides immediate and valuable information to interventional cardiologists during the cardiac catheterization procedure. The system requires no post-processing or image manipulation.

InfraReDx recently initiated CANARY (NCT01268319), a prospective, multicenter, randomized trial designed to test the hypothesis that NIRS-guided use of an embolic protection device during percutaneous coronary intervention can reduce the rate of peri-procedural heart attack in patients identified as having large, high-risk LCPs. The study is being conducted using the company's LipiScan™ IVUS system.

About InfraReDx, Inc.

InfraReDx, Inc. is a privately funded medical device company improving patient care through the development and commercialization of intelligent imaging technologies to improve the diagnosis and treatment of coronary artery disease. InfraReDx's LipiScan™ IVUS Coronary Imaging System includes the first and only available catheter to combine both near-infrared spectroscopy (NIRS) and intravascular ultrasound (IVUS) technologies to characterize both the structure and composition of intracoronary plaques and identify lipid core plaques demonstrated to complicate stenting and suspected of causing the majority of heart attacks. Founded in 1998, InfraReDx is headquartered in Burlington, Massachusetts. For more information, visit www.infraredx.com.

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