

# Infraredx Highlights Value of IVUS + NIRS for Detecting Lipid Core Plaque at the American College of Cardiology 67<sup>th</sup> Annual Scientific Session

Presentation Bolsters Company's Upcoming Studies in IVUS + NIRS Imaging Including its Highly-Anticipated PROSPECT II and Lipid-Rich Plaque Study Findings

**BURLINGTON, Mass., March 11, 2018** -- Infraredx, Inc., a pioneer in intravascular imaging for mapping coronary artery disease, today presented a poster at the American College of Cardiology (ACC) 67<sup>th</sup> Annual Scientific Session supporting the value of combination intravascular ultrasound (IVUS) and near-infrared spectroscopy (NIRS) imaging technology to identify lipid core plaque (LCP), an underlying cause of serious cardiac events. In the poster presentation, IVUS +NIRS demonstrated efficiencies in locating LCP within arteries, indicating the technology may be a better predictor of major adverse cardiac events (MACE) than the current methodology standard set forth by the ground-breaking PROSPECT study.

"This analysis validates the use of dual-modality IVUS + NIRS catheters to clearly pinpoint LCP with increased efficiency compared to IVUS alone," said Jason Bottiglieri, president and CEO, Infraredx. "Unlike other imaging technologies, NIRS can readily distinguish areas of stable plaque from potentially dangerous LCP, which may enable cardiologists to more accurately predict and ultimately prevent serious heart attacks."

At ACC, Infraredx will present Poster #241: A Correlative Study of NIRS Lipid Core Burden Index Versus Histological Plaque Disease Arc in Human Coronary Autopsy Specimens (Sunday, March 11, 2018, 1:30-4:30 p.m. ET, Poster Hall A/B).

### **Study Methodology and Results**

- The PROSPECT Study, widely regarded as the most important study in discovering the role of vulnerable plaque in serious cardiac events, found in a substudy that the plaque disease arc via transverse IVUS was an additional independent predictor of non-culprit lesion of MACE. However, the area under the curve (AUC) parameter that was observed in the study was low (0.64) and the methodology only included use of gray-scale IVUS.
- In its commitment to advancing this important research, Infraredx utilized a similar disease arc concept in an IVUS + NIRS autopsy study to reveal the benefits and limitations of the disease arc concept. Since underlying pathological truths can be known in an autopsy study, the degree to which disease arc finds lipid core plaques could be studied, as well as novel methods incorporating the unique IVUS + NIRS chemogram map of vessel lipid core could also be explored.
- The study concluded that quickly locating areas of LCP with NIRS, and then assessing the disease arc on IVUS cross-sections of interest may be more targeted than use of the IVUS disease arc alone. It also may be more clinically efficient due to the automated and immediate generation of the NIRS chemogram.



"PROSPECT demonstrated that vulnerable plaques can be detected with IVUS technology, but with only modest predictive ability," said Gregg Stone, M.D., Columbia University Medical Center and New York-Presbyterian Hospital. "As demonstrated in this study, NIRS offers the potential to further discriminate plaques, which are likely to be particularly high-risk such as those with high lipid content, a hypothesis that is being tested in ongoing PROSPECT II and LRP studies."

#### Infraredx Presence Across ACC

Additional presentations at ACC 2018 leverage data from Infraredx's COLOR registry. The COLOR Registry was an observational study of lipid core plaque in the coronary arteries, its association with patient presentation and diagnosis, and its effects on procedural success of percutaneous coronary intervention (PCI).

#### Presentations include:

- Poster #268: Relationship Between Underlying Plaque Morphology Evaluated by Near-Infrared Spectroscopy and the Degree of Coronary Artery Stenosis: The COLOR Registry (Saturday, March 10, 2018, 9:30 a.m.-12:30 p.m. ET, Poster Hall A/B)
- Poster #277: Clinical Predictors of Culprit Lesion Lipid Quantified by Near Infrared Spectroscopy: Insights from the COLOR Registry (Saturday, March 10, 2018, 9:30 a.m.-12:30 p.m. ET, Poster Hall A/B)
- Poster #272: Angiographic Predictors of Lipid Rich Plaque Detected by Near-Infrared Spectroscopy: The COLOR Registry (Sunday, March 11, 2018, 9:30 a.m.-12:30 p.m. ET, Poster Hall A/B)

In addition to the data presented at ACC, Infraredx continues to fund landmark studies in this field of research including PROSPECT II and PROSPECT ABSORB, and will announce the highly-anticipated results from its Lipid-Rich Plaque (LRP) Study later this year. The LRP Study is a prospective, multi-center study designed to identify a correlation between LCP, as detected by Infraredx's Makoto<sup>TM</sup> Intravascular Imaging System and Dualpro<sup>TM</sup> IVUS+NIRS catheter, and the occurrence of major adverse cardiac events within two years.

## About Infraredx, Inc.

Infraredx, Inc., a Nipro company, is advancing the diagnosis and management of coronary artery disease by providing cardiologists with the most precise imaging tools required to predict and ultimately prevent heart attacks. Its Makoto<sup>TM</sup> Intravascular Imaging System, with accompanying Dualpro<sup>TM</sup> IVUS+NIRS catheter, is the only technology on the market that is FDA-cleared for the detection of lipid core plaque (LCP). LCP, understood to be vulnerable plaque, is well-documented in studies as the cause of most serious heart attacks. Infraredx is dedicated to advancing this important field of research and conducting landmark clinical trials to transform how we view and treat heart disease. For more information, please visit www.infraredx.com.



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