Results of the PROSPECT II Natural History Study Demonstrate High-Risk Plaques Identified by NIRS+IVUS Imaging are Linked to Future Coronary Events

PROSPECT ABSORB, a randomized substudy, showed treatment of high risk plaques with BVS is safe and associated with favorable long-term clinical outcomes compared to GDMT alone

BEDFORD, Mass., October 14, 2020 -- Infraredx, a Nipro Company, a pioneer in intravascular imaging for mapping coronary artery disease, announced positive results from the PROSPECT II and PROSPECT ABSORB studies, presented today as a late-breaking clinical trial at TCT Connect, the 32nd annual scientific symposium of the Cardiovascular Research Foundation. The PROSPECT II study demonstrated the ability of near-infrared spectroscopy (NIRS) imaging plus intravascular ultrasound (IVUS) to identify coronary plaques responsible for future coronary events. The randomized substudy PROSPECT ABSORB, which was simultaneously published in the *Journal of the American College of Cardiology (JACC),* showed treatment of high-risk vulnerable plaques with a bioresorbable vascular scaffold (BVS) was safe and substantially associated with favorable long-term clinical outcomes compared to guideline-directed medical therapy (GDMT) alone.

Several autopsy studies have found that lipid core plaque (LCP) is the underlying cause of most coronary deaths, and ruptured lipid cores are thought to cause most major adverse coronary events (MACE) *in vivo*. The recent prospective Lipid-Rich Plaque (LRP) study, published September 27, 2019, in *The Lancet,* found correlation between untreated NIRS-detected LCP and future events. The PROSPECT II study aimed to further demonstrate that non-obstructive LCP detected by NIRS is prone to cause future non-culprit lesion-related events.

The investigator-initiated, multicenter, prospective study enrolled 898 patients from 16 sites across Sweden, Denmark and Norway. Patients with recent myocardial infarction (MI) were enrolled after successful intervention of all flow-limiting culprit lesions. Infraredx's NIRS+IVUS imaging system was utilized to perform imaging of all three coronary arteries. The system utilizes NIRS to detect LCP and automatically displays a color-coded map, called a chemogram. The chemogram allows for the straightforward display of the presence of LCP in yellow and absence in red. In PROSPECT II, untreated non-culprit lesions were identified by IVUS and lipid content was assessed by NIRS.

A total of 3,629 untreated non-culprit lesions were characterized. Study results showed that adverse cardiac events occurred in 14.4 percent of patients during median follow-up of 3.7 years, with 8.0 percent from untreated non-culprit lesions with average baseline diameter stenosis of 46.9 percent. The presence of high LCP was an independent predictor of patient-level non-culprit events and lesion-specific events. Data showed a 2.3-fold and 7.8-fold higher likelihood for patient-level and lesion-level risks, respectively. Study authors concluded lipid-rich plaques as detected by NIRS identified angiographically mild, non-flow-limiting lesions responsible for future coronary events.

"An important finding was that lesions responsible for most of the future cardiac events were caused by plaques not identified by angiography and pressure wires, the methods in widespread use today. Instead, lesions that were both lipid rich and had high plaque burden as detected by NIRS+IVUS denoted those plaques that were at highest risk for future adverse outcomes," said David Erlinge, MD, PhD, from Lund University, Sweden, who was co-chairman of the study.

The PROSPECT ABSORB substudy randomized 182 patients to BVS and GDMT (93 patients) or GDMT-alone (89 patients). The study evaluated whether a BVS could safely enlarge luminal dimensions in high-risk, angiographically non-obstructive lesions with site-determined IVUS plaque burden ≥65 percent. Angiographic follow-up at 25-months was completed, and median clinical follow-up was 4.1 years. Study results found follow-up minimum lumen area (MLA) in BVS-treated lesions to be 6.9±2.6 mm^2 and 3.0±1.0 mm^2 in GDMT alone-treated lesions, a difference of 3.9 mm^2. Randomized lesion-related MACE during a median follow-up of 4.1 years occurred in 4.3 percent of the BVS-treated patients versus 10.7 percent of the GDMT-alone treated patients. Study authors concluded that PCI of angiographically mild lesions with large plaque burden was safe in enlarging the MLA and was associated with favorable long-term clinical outcomes compared with GDMT alone.

"This study, the first randomized trial of interventional treatment of non-flow-limiting vulnerable plaques, suggests that prophylactic plaque passivation with a scaffold or stent can safely convert an angiographically mild high-risk plaque into a more stable lesion. As these lesions are not being treated today, a large-scale trial is warranted to determine whether PCI of vulnerable plaques can improve clinical outcomes in these high-risk patients," said Gregg W. Stone, MD, of the Zena and Michael A. Wiener Cardiovascular Institute, Icahn School of Medicine at Mount Sinai Hospital in New York, and co-chairman of PROSPECT II and PROSPECT ABSORB.

"The positive results of these late-breaking studies add to the already growing body of research validating that NIRS+IVUS imaging can safely detect patients and plaques at risk for future adverse events. We will continue to offer the best tools available to continue the fight against cardiovascular disease," noted Nozomu Fujita, President and CEO, Infraredx, a Nipro Company.

In April 2019, the U.S. Food and Drug Administration (FDA), based on results of the landmark LRP Study, expanded the indications for use of Infraredx's Makoto™ Intravascular Imaging System, and its accompanying Dualpro™ IVUS+NIRS Catheter, to include the identification of patients and coronary plaques at an increased risk for MACE.

Uppsala Clinical Research Center at Uppsala University Hospital in Sweden, was responsible for study clinical operations, data management, and clinical event classification, and the Cardiovascular Research Foundation in New York, was responsible for core laboratory analysis, biostatistics and data analysis.

The study was supported by Abbott Vascular, Infraredx, a Nipro Company, and the Medicines Company, now a Novartis Company.

About Infraredx, a Nipro Company

Infraredx, 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. 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 about the Makoto™ Imaging System or the OKAY II Y-Connector please visit www.infraredx.com and connect with Infraredx on Twitter and LinkedIn.

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