First first patient enrolled in PROSPECT II clinical trial

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The Cardiovascular Research Foundation (CRF) and Uppsala Clinical Research (UCR) announced enrollment of the first patient in the PROSPECT II (Providing Regional Observations to Study Predictors of Events in the Coronary Tree II) trial. David Erlinge, MD, PhD performed the first procedure at Skane University Hospital in Lund, Sweden.

PROSPECT II is an investigator initiated multicenter, prospective registry study which will assess the ability of intracoronary near infrared spectroscopy (NIRS) to identify non-flow obstructing vulnerable plaques which subsequently lead to coronary events. The PROSPECT ABSORB sub study is an investigator initiated multicenter, randomized trial, which for the first time will evaluate the ability of a bioresorbable scaffold to safely increase luminal dimensions of vulnerable plaque.

The PROSPECT II study will enroll 900 patients with acute coronary syndrome (ACS) and will be led by Gregg W. Stone MD, Professor of Medicine at Columbia University Medical Center in New York, and Dr. Erlinge, Professor and Director of the Department of Cardiology, Lund University, Skane University Hospital in Lund, Sweden. Patient enrollment is expected to be completed in approximately one year and the study will be conducted in approximately 16 sites in Scandinavia.

Each patient will be examined with intravascular ultrasound (IVUS) and NIRS in all three coronary arteries. In the PROSPECT ABSORB sub study, 300 patients with a plaque at high risk of causing future coronary

events, as shown in the original PROSPECT study (plaque burden ≥70%), will be randomized to treatment with the Absorb™ Bioresorbable Vascular Scaffold (BVS; Abbott) plus guideline directed medical therapy (GDMT) or GDMT alone, with each patient undergoing angiography and IVUS/NIRS after two years. All 900 patients will be measured at baseline and then followed in the registry for up to 15 years to detect the occurrence of coronary events, with the primary endpoint at 2 years. The integrated PROSPECT II and PROSPECT ABSORB study program is being funded by grants from InfraReDx, The Medicines Company, and Abbott. Uppsala Clinical Research Center (UCR) will have the operational responsibility and be the sponsor of the study. The study will be conducted in academic partnership with the CRF Clinical Trials Center (CTC).

"We are very excited that the PROSPECT II trial is officially underway with the enrollment of this first patient," said Ori Ben-Yehuda, MD, Executive Director of the CTC. "Data from this trial will provide unique insights into plaque vulnerability and may lead to new approaches in preventing myocardial infarctions."

Data from the original PROSPECT trial demonstrated for the first time prospectively that vulnerable plaques that are most likely to cause sudden unexpected adverse cardiac events can be identified through imaging techniques, months to years before the adverse events occur. These study findings were published in the January 20, 2011 issue of the *New England Journal of Medicine*.

"Using the NIRS imaging technology to detect lipid rich plaque (LRP) has been an eye-opener for us. We can see in vivo that nearly all patients with a ST-elevation myocardial infarction (STEMI) exhibit a LRP at the culprit site. In PROSPECT II we will determine the importance of LRP prospectively so that in the future, we can hopefully identify and treat the vulnerable plaque before the infarction happens," said David Erlinge,

MD, PhD, Professor and Director of the Department of Cardiology, Lund University, Skane University Hospital in Lund, Sweden.

"Findings from the original PROSPECT study have helped physicians identify those lesions that are at especially high risk of causing future adverse cardiovascular events, using a combination of imaging modalities based on IVUS," said Gregg W. Stone, MD. Dr. Stone is Professor of Medicine at Columbia University College of Physicians and Surgeons, Director of Cardiovascular Research and Education at the Center for Interventional Vascular Therapy at NewYork-Presbyterian Hospital/Columbia University Medical Center and Co-Director of the Medical Research and Education Division at CRF.

"NIRS has been well validated for detecting lipid, which is at the core of most vulnerable plaques. PROSPECT II will determine the ability of NIRS to identify these high risk lesions in an adequately powered prospective study. And PROSPECT ABSORB will, for the first time, test the feasibility of an interventional approach in preventing future major adverse cardiovascular events arising from plaques which appear angiographically innocuous (and are thus not currently stented), but are in fact the source of future acute coronary syndromes. This is truly a groundbreaking investigation," said Dr. Stone.

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