TRYTON Medical

BUILT FOR BIFURCATION

Tryton Medical Announces Completion of Patient Enrollment in Landmark Pivotal Study of Side Branch Stent

Study Is the First and Largest Randomized Multi-Center Bifurcation Trial

Durham, N.C. – Nov. 26, 2012 – Tryton Medical, Inc., the leading developer of stents designed to definitively treat bifurcation lesions, today announced the completion of enrollment in the TRYTON Pivotal IDE trial evaluating the Tryton Side Branch Stent.™

The landmark Tryton pivotal study is an international randomized trial that compares a Tryton stent in the side branch vs. conventional provisional stenting (balloon angioplasty) in the side branch, with both arms of the trial utilizing a standard drug eluting stent in the main vessel. The study, which is the first and only randomized IDE pivotal clinical trial to evaluate a dedicated bifurcation stent, has enrolled 704 patients at 67 centers in North America, Europe and Israel. The primary endpoint of the study is target vessel failure at nine months. A secondary endpoint is percent diameter stenosis at nine months in the side branch vessel.

Martin B. Leon, M.D., F.A.C.C., professor of Medicine and director of the Center for Interventional Vascular Therapy at Columbia University Medical Center, and founder and chairman emeritus of the Cardiovascular Research Foundation, serves as principal investigator of the study.

“Completion of patient recruitment is a major milestone for the Tryton IDE Pivotal Trial, which is truly a landmark study. In addition to being the first powered randomized controlled trial evaluating a dedicated side branch stent, it is the largest coronary bifurcation study ever attempted and the first one to have core angiographic (3D and planar) and IVUS sub-studies. The results of the Tryton study will directly guide the treatment of patients with complex bifurcation disease,” said Dr. Leon. “Our current inability to treat these lesions with ‘work horse’ drug eluting stents, represents an important unmet clinical need which confronts interventional cardiologists. From my travels to Europe and Israel, I have been impressed with how easily the Tryton Stent is incorporated into routine practice. We look forward to results from this trial.”

“Tryton Medical’s differentiated technology addresses the challenges of bifurcated lesions, which affect nearly a third of patients undergoing a PCI procedure. Data from more than 1,000 registry patients in Europe treated with the Tryton stent are already challenging provisional stenting, with compelling results of target lesion revascularization of four percent and thrombosis of 0.5 percent at one year," said Shawn P. McCarthy, president and CEO of Tryton Medical. “We are looking to corroborate this positive registry data in the Tryton Medical randomized controlled study. With more than 6,000 implants to date, we are leveraging our impressive data to further expand globally. We are on track to be the first and only approved stent for coronary bifurcations in the U.S.”

About Coronary Bifurcation Disease

Coronary artery disease often results in the buildup of plaque at the site of a bifurcation, where one artery branches from another. Current approaches to treating these lesions are time consuming and technically difficult. As a result, the side branch is often left unstented, leaving it vulnerable to higher rates of restenosis, the re-narrowing of the stented vessel following implantation. In patients undergoing PCI-stenting, approximately one-third have a bifurcation lesion. Left main disease, an accumulation of plaque that narrows the base of the coronary tree, is a persistent challenge in interventional cardiology, as more than 75 percent of left main lesions are bifurcation lesions.

About the Tryton Side Branch Stent
The Tryton Side Branch Stent System is built for bifurcation using proprietary Tri-zone™ technology to offer a dedicated strategy for treating bifurcation lesions. Tryton's cobalt chromium stent is deployed in the side branch artery using a standard single-wire balloon-expandable stent delivery system. A conventional drug-eluting stent is then placed in the main vessel. The stent system has received CE Mark and is commercially available throughout Europe, Russia and the Middle East. It is approved in the United States for investigational use only.

About the Randomized Tryton IDE Pivotal Study
The landmark Tryton pivotal study is a multi-national randomized trial that compares a Tryton stent in the side branch vs. the use of balloon angioplasty in the side branch, with both arms of the trial utilizing a standard drug eluting stent in the main vessel. The study, which is the first and only randomized IDE pivotal clinical trial evaluating a dedicated bifurcation stent, enrolled 704 patients at 67 centers in North America, Europe and Israel, and includes angiographic and IVUS substudies. Martin Leon, M.D. (Columbia University, New York) serves as principal investigator for the study and Patrick Serruys (Thoraxcenter, Rotterdam) is leading IVUS and three-dimensional angiographic analysis.

About Tryton Medical, Inc.
Tryton Medical, Inc., located in Durham, N.C., is a leading developer of novel stent systems for the treatment of bifurcation lesions. The company was founded in 2003 by Aaron V. Kaplan, M.D. (professor of medicine at Dartmouth Medical School/Dartmouth- Hitchcock Medical Center) and Dan Cole to develop stents for the definitive treatment of bifurcation lesions. Privately held, Tryton is backed by Arnerich Massena & Associates, Spray Ventures, PTV Sciences, and RiverVest Ventures. For more information please visit www.trytonmedical.com.

# # #

Media Contact:
Nicole Osmer
nicole@nicoleosmer.com
(650) 454-0504