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**IVUS Cohort Recruitment Complete in Landmark Tryton IDE Study**  
*More Than 175 Patients Enrolled in Multi-National Pivotal Trial*

**Durham, N.C.** – Oct. 26, 2011 – Tryton Medical, Inc., the leading developer of stents designed to definitively treat bifurcation lesions, today announced completion of patient enrollment in the intravascular ultrasound (IVUS) cohort of the randomized, controlled Tryton IDE Study evaluating the TRYTON Side Branch Stent for the treatment of bifurcation disease. Results of the multi-national Tryton IDE Study will be submitted to the U.S. Food and Drug Administration (FDA) for approval to market the device in the United States.

“The Tryton IDE Study is the first randomized clinical trial of this magnitude to evaluate a dedicated bifurcation stent, and will no doubt make an important contribution to our understanding of PCI-stenting of bifurcation lesions,” said Martin B. Leon, M.D., professor of Medicine and director of the Center for Interventional Vascular Therapy at Columbia University Medical Center, who serves as principal investigator of the study. “IVUS cohort completion is an important recruitment milestone for the Tryton IDE Study, demonstrating the dedication of the superb team of investigators.”

“Tryton Medical is proud of our role in this landmark study,” said Shawn McCarthy, president and CEO of Tryton Medical. “The Tryton IDE Study is the capstone of our clinical program, which includes a growing body of clinical data from more than 700 patients in European registries and investigator-initiated trials that show target lesion revascularization rates consistently below 4% at greater than six month follow-up. These studies complement our experience in approximately 3,500 implants, demonstrating Tryton’s routine use in clinical practice.”

More than 175 patients have been enrolled to date in the Tryton IDE study. The randomized trial 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.

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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 as assessed in an angiographic subgroup. The study will enroll 704 patients at up to 75 centers in North America, Europe and Israel. Approximately 400 patients will undergo angiographic follow up at nine months.

#### **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.<sup>1</sup> In patients undergoing PCI-stenting, approximately one-third has 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 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. The Tryton Side Branch Stent System, approved for sale in Europe, is designed to offer a dedicated strategy for treating these challenging cases. Privately held, Tryton is backed by Arnerich Massena & Associates, Spray Ventures, PTV Sciences, and RiverVest Ventures. For more information please visit [www.trytonmedical.com](http://www.trytonmedical.com).

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<sup>1</sup> Scot Garg, et al. EuroIntervention 2011;6: 928-935. Available online at [http://www.pcronline.com/eurointervention/34th\\_issue/162/](http://www.pcronline.com/eurointervention/34th_issue/162/)