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Tryton Announces Successful Live Case Transmission at TCT Conference in San Francisco

Data Presentations Highlight Consistently Positive Clinical Results

San Francisco and Durham, N.C. – Nov. 10, 2011 – Tryton Medical, Inc., the leading developer of stents designed to definitively treat bifurcation lesions, today announced the transmission of a live satellite feed of a clinical case using the Tryton stent to an audience of several hundred interventional cardiologists at the annual Transcatheter Cardiovascular Therapeutics (TCT) 2011 Conference in San Francisco.

The procedure was performed at New York-Presbyterian Hospital/Columbia University Medical Center by Varinder P. Singh, M.D. The patient was enrolled as part of the Tryton IDE Study, a multi-national randomized trial that compares the Tryton stent in the side branch artery vs. the use of balloon angioplasty in the side branch artery, with both arms of the trial utilizing a standard drug eluting stent in the main vessel.

“This case demonstrates how the Tryton stent provides a straightforward way to secure the side branch and achieve superb angiographic results,” said Dr. Singh. “We are excited to participate in this landmark trial.”

“This has been an incredible week for Tryton,” said Shawn P. McCarthy, president and CEO of Tryton Medical. “We are thrilled with the level of enthusiasm and support we are hearing from physicians here at TCT. It’s clear that a definitive solution for bifurcation disease is an important unmet need, as demonstrated by the considerable interest in Tryton data presented this week, culminating in yesterday’s successful Tryton IDE live case transmission.”

In addition to the live case, a number of presentations confirmed the consistent clinical results of the Tryton stent:

- A standing-room-only clinical symposium featured a comprehensive overview of Tryton clinical evidence with a number of leading clinicians. Thierry Lefèvre, M.D., of the Institut Hospitalier Jacques Cartier in Massy, France, who co-chaired the event, highlighted the positive target lesion revascularization (TLR) rates for the Tryton stent, consistently below 4% at greater than six month follow-up.
- Eulogio Garcia, M.D., of the Hospital Clinico San Carlos in Madrid, Spain, presented results of an E-Tryton Spanish registry. In a new cohort of 132 patients with six-month follow-up, the Tryton stent demonstrated a TLR rate of 3.8% and a 0.8% rate of myocardial infarction.

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- Michael Norell, M.D., of the Heart and Lung Centre–The Royal Wolverhampton NHS Trust, presented single-center clinical experience results from 71 patients treated with the Tryton stent with an average 15 months average follow-up, with no instances of unplanned re-admission with ischemia, myocardial infarction or death. The poster concluded that “Tryton performs predictably and successfully scaffolds the side-branch ostium. The enhanced ability to rewire the side-branch for final kissing inflation when compared with other ‘two-stent strategies’… may have contributed to our low observed clinical event rate,”
- Solomon Asgedom, M.D. and Prof. David P. Foley, M.D. of the Beaumont Hospital in Dublin, Ireland, presented results of the Tryton stent in 169 patients showing a TLR rate of 2.3% in 178 lesions with18-month mean follow up.
- Michael Magro, M.D., of the Thoraxcenter, Erasmus Medical Center in Rotterdam, the Netherlands, presented a multi-center review of a Tryton left main registry, concluding that "the use of the TRYTON side branch stent for treatment of left main bifurcation disease in combination with a conventional drug eluting stent is feasible, and results in an optimal angiographic appearance."

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.[i] 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. More than 3,500 patients have been treated with the Tryton stent.

About the Randomized Tryton IDE Study

More than 175 patients have been enrolled to date in the Tryton IDE study, 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 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. Results of the study will be submitted to the U.S. Food and Drug Administration (FDA) for approval to market the device in the United States.

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.

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[i] Scot Garg, et al. EuroIntervention 2011:6: 928-935. Available online at http://www.pcronline.com/eurointervention/34th_issue/162/