



Media Contact:

Nicole Osmer

nicole@nicoleosmer.com

(650) 454-0504

Tryton Announces Positive Data from Three European Registries
Results Show Low MACE and TLR Rates, No Late Stent Thrombosis;
Session at EuroPCR Highlights Stent System as Potential Treatment
for Left Main Disease

PARIS – Fri., May 20, 2011– Tryton Medical, Inc., the leading developer of stents designed to definitively treat bifurcation lesions, today announced positive results in three “real world” European registries of the company’s Tryton Side Branch Stent™ System for the treatment of atherosclerotic lesions in the side branch at the site of a bifurcation.

Six-month results of the E-Tryton 150 and E-Tryton Benelux registries from 300 patients demonstrated a low (6.1 percent) rate of major adverse cardiac events (MACE) and a low (3.0 percent) rate of target lesion revascularization (TLR), with no occurrence of late stent thrombosis at six months. The device also demonstrated a high rate of procedural and technical success.

“The results of these two registries give us data that helps us better understand how the Tryton Side Branch Stent System performs in real-world practice,” said Pieter R. Stella, M.D., Ph.D., director of the Heart Catheterization Laboratories and Clinical Cardiovascular Research at the University Medical Centre in Utrecht, the Netherlands, who presented the results at EuroPCR 2011 today. “The stent system’s promising safety profile and very good MACE and TLR rates consistently demonstrate reliable clinical outcomes for difficult-to-treat bifurcation lesions.”

A total of 302 consecutive patients were enrolled in the E-Tryton 150 and E-Tryton Benelux studies at 15 centers in The Netherlands, Belgium, Luxemburg, Ireland, Poland, Latvia, France and Spain. The primary endpoint of the studies is the overall rate of major adverse cardiac events (MACE) at six months following the procedure. MACE is defined as cardiac death, myocardial infarction and target lesion revascularization (main and/or side branch).

In addition, on Wednesday, May 18 at EuroPCR, Dr. Desale Solomon Asgedom of the Beaumont hospital in Dublin, Ireland, reported on the third registry of clinical experience at his center with patients treated with the Tryton Side Branch Stent. With a mean follow up of 17.8 months, data from 169 patients demonstrated a TLR rate of 2.3 percent and no late stent thrombosis.

TRYTON MEDICAL, INC.

1000 Park Forty Plaza, Suite 325

Durham, NC 27713

PHONE 919/226.1490

FAX 919/226.1497

info@trytonmedical.com

trytonmedical.com

“These favorable findings, which demonstrate TLR rates in line with DES-like results, continue to build the growing body of clinical evidence for the Tryton Side Branch Stent System,” said Rick Anderson, board member of Tryton and managing director of PTV Sciences. “We are pleased with this positive clinical data and we look forward to additional results from the randomized pivotal trial of the device, which is currently enrolling patients in the United States.”

Also on Wednesday, May 18, the company hosted a “How Should I Treat” session, chaired by Thierry Lefèvre, head of the Interventional Cardiology Department and Research at the Institut Cardiovasculaire Paris Sud at Institut Hospitalier Jacques Cartier in Massy, France, that focused on case presentations and bifurcation treatment. Participants of the session discussed an investigator-sponsored left main study of the Tryton Side Branch Stent for the treatment of left main disease. Until recently, left main disease has been treated with bypass surgery. (The Tryton Side Branch Stent System has not been studied extensively for the treatment of left main 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. Bifurcation lesions account for as many as one-third of all coronary lesions.¹

About the Tryton Side Branch Stent

The Tryton Side Branch Stent System is designed to offer a dedicated strategy for treating atherosclerotic lesions in the side branch at the site of a bifurcation. 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 approval in Europe and is commercially available in 21 countries throughout Europe and the Middle East. It is approved in the United States for investigational use only.

Tryton announced the availability in Europe of larger-size diameters of the Tryton Side Branch Stent System on May 18, 2011.

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/