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

Tryton Announces Enrollment of First U.S. Patient in Pivotal Study of Side Branch Stent

Study Is the First Randomized Multi-Center Bifurcation Trial in the United States

Durham, N.C. – Jan. 26, 2011– Tryton Medical, Inc., the leading developer of stents designed to definitively treat bifurcation lesions, today announced that the first U.S. patient has been enrolled in the pivotal trial to evaluate the Tryton Side Branch Stent System™ for the treatment of coronary artery disease.

Thomas M. Broderick, M.D., F.A.C.C., of The Christ Hospital Heart and Vascular Center in Cincinnati, Ohio enrolled the first U.S. patient in the study.

"Bifurcation lesions are a serious challenge facing U.S. physicians and many patients with coronary artery disease," said Dean J. Kereiakes, M.D., F.A.C.C., medical director of The Christ Hospital Heart and Vascular Center, and site Principal Investigator. "The Tryton Stent System offers an innovative solution for these difficult cases. We are extremely pleased to have enrolled the first U.S. patient in this important study and we are encouraged by the overall performance of the device."

"Initiating this first and only randomized, multi-center bifurcation trial in the United States is a major milestone, and brings us one step closer to providing the Tryton Stent System to physicians and patients in the United States" said J. Greg Davis, president and CEO of Tryton Medical. "The Tryton Stent has been very positively received in Europe, where it has been commercially available for more than a year, and this trial is an important next step in our evolution."

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.

"There is a significant need for alternative solutions for treating bifurcation disease, a persistent and challenging problem for interventional cardiologists that occurs frequently – in about two out of ten cases," said Dr. Leon. "Data from previous studies of the Tryton solution have been encouraging, and I look forward to results from this trial."

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

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.

The randomized, controlled study will compare the use of the Tryton stent in the side branch in conjunction with a standard drug eluting stent in the main vessel vs. the use of angioplasty in the side branch with a standard drug eluting stent in the main vessel for the treatment of complex bifurcation disease. The study will enroll 704 patients at up to 75 centers in North America and Europe. 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.

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.

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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