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Tryton Announces Investigational Device Exemption Conditional Approval from FDA to Conduct U.S. Pivotal Study of Side Branch Stent

Study to Enroll 700 Patients At Up To 75 Centers in North America and Europe

Durham, N.C. – Dec. 2, 2010 – Tryton Medical, Inc., the leading developer of stents designed to definitively treat bifurcation lesions, today announced U.S. Food and Drug Administration (FDA) conditional approval for an Investigational Device Exemption (IDE) application to initiate the pivotal trial to evaluate the Tryton Side Branch Stent System™ for the treatment of coronary artery 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.

Martin B. Leon, M.D., 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, will serve 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 highly encouraging, and I look forward to results from this important trial.”

“The conditional approval of the investigational device exemption for the Tryton stent is a significant milestone for our company," said J. Greg Davis, president and CEO of Tryton Medical. “We have seen substantial interest and adoption of the Tryton solution in Europe thus far and are excited to take the first step to bring this innovative treatment to patients and physicians in the United States.”

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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 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. Approximately 374 patients will undergo angiographic follow up at nine months. The study will also include an IVUS substudy in 96 patients with IVUS follow up at nine months. The study will enroll 700 patients at up to 75 centers in North America and Europe.

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 not approved 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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