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

Study to Enroll 704 Patients At Up To 75 Centers in North America and Europe

**Durham, N.C.** – Dec. 20, 2010 – Tryton Medical, Inc., the leading developer of stents designed to definitively treat bifurcation lesions, today announced that the first patient has been enrolled in the pivotal trial to evaluate the Tryton Side Branch Stent System<sup>™</sup> for the treatment of coronary artery disease.

Indulis Kumsars, M.D., chief of the catheterization laboratory at Pauls Stradins Clinical University Hospital in Riga, Latvia, enrolled the first patient.

"Our team is very excited and happy to participate in this first substantial randomized trial of the Tryton bifurcation device. We look forward to gaining a better understanding of the role of a dedicated bifurcation stent in the optimal treatment of these lesions," said Dr. Kumsars.

"The enrollment of the first patient in the study is yet another milestone for Tryton in what has been a very exciting year for the company," said J. Greg Davis, president and CEO of Tryton Medical. "We have gained significant momentum in 2010 – from launching our innovative product across Europe and the Middle East to a successful fundraising event. We look forward to rapid enrollment in the pivotal study and growing product adoption internationally in 2011."

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

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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.

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.

## 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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