Tryton Medical Enrolls First U.S. Patient in the EXTENDED ACCESS Registry

Extended Access Registry designed to confirm results from Pivotal IDE Trial

Durham, N.C. – September 10, 2014 – Tryton Medical, Inc., the leading developer of stents designed to treat bifurcation lesions, announced that the first patient in the United States has been enrolled in the Extended Access Registry, a single arm study of its Tryton Side Branch Stent. The Tryton registry is designed to confirm the results from its Pivotal IDE Trial and is expected to enroll 133 patients from Europe and the United States. The first patient in the U.S. was enrolled by Jeffrey W. Moses, M.D., Director Cardiovascular Interventions New York Presbyterian Hospital/Columbia University Medical Center & Professor of Medicine Columbia University College of Physician and Surgeons.

The Tryton Extended Access Registry builds on the results of the TRYTON IDE Study, which showed the benefit of the Tryton Side Branch Stent in a post-hoc analysis of the intended population, complex bifurcation lesions involving significant side branches. The Tryton Extended Access Registry is designed to confirm these findings. Results from this registry together with the results from the Pivotal IDE Trial will be submitted to the US Food and Drug Administration for pre-market (PMA) approval.

"We are pleased to provide the U.S. 'kick off' case for the Tryon Extended Access Registry which is now up and running in the US and Europe. The case involved a complex LAD-Diagonal bifurcation, which went smoothly with a great angiographic result", commented Jeffrey W. Moses, M.D., principal investigator at Columbia University. "This case underscores how Tryton brings predictability to the treatment of complex bifurcations. We look for this study to confirm results of the IDE trial, demonstrating utility of Tryton in the treatment of complex bifurcation lesions involving significant side branches."

"Tryton Medical is excited to reach this next milestone on our pathway to U.S. approval," said Shawn P. McCarthy, President & CEO of Tryton Medical. "We remain on track to be the first and only approved stent for coronary bifurcations in the U.S."

The Tryton Side Branch Stent is commercially available in multiple countries within Europe, Middle East & Africa, is investigational in the US, and is not available in Japan. 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. 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 Tryton Side Branch Stent has now been used to treat more than 10,000 patients worldwide.

About Tryton Medical, Inc.

Tryton Medical, Inc., located in Durham, N.C., is the 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) to develop stents for the definitive treatment of bifurcation lesions. For more information please visit www.trytonmedical.com and follow the company on Twitter at @TrytonMedical1.

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