3D Vessel Reconstruction Technology to Aid Physicians in Stent Placement

St. Jude Medical

St. Jude Medical, Inc. (NYSE:STJ [1]) has announced U.S. Food and Drug Administration (FDA) approval and launch of its ILUMIEN™ OPTIS™ PCI Optimization™ System, a new technology designed to provide physicians with a comprehensive disease assessment tool for treating patients with coronary artery disease (CAD). The system will be on display for the first time in the U.S. during the 2013 Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium.

The ILUMIEN platform helps physicians better understand which arteries should be

treated and how best to treat them. It works by integrating both Fractional Flow Reserve (FFR) technology to measure blood flow blockage inside the coronary arteries and intravascular Optical Coherence Tomography (OCT) imaging technology. There are currently more than 1,200 published articles with clinical evidence supporting St. Jude Medical's FFR and OCT technologies.

The ILUMIEN OPTIS system is the next generation of the ILUMIEN™ System and has several first-of-its kind enhancements, including automated measurements and stent [2] planning software tools. The OCT imaging technology provides a real-time, three-dimensional (3-D) reconstruction of the patient's vessel, making it easier for physicians to visualize the area they are treating. The new system offers twice the resolution of the earlier generation, which allows for better microscopic examination of disease inside the artery to assist with stent placement. St. Jude Medical is the only company to have these tools available in an integrated platform.

"The ILUMIEN OPTIS is an advancement that offers an eye-opening perspective of the coronary arteries, providing me with a more complete understanding about the extent of the patient's disease," said Dr. Matthew J. Price, Director of the Cardiac Catheterization Laboratory at Scripps Green Hospital/Scripps Clinic in La Jolla, California. "The high-definition, three-dimensional format and the new stent placement tools allow me to create a treatment plan tailored for each patient's unique vasculature – and to confirm that I get the best possible stent result. That makes my life easier and helps the patient, too."

The OCT technology in the new ILUMIEN OPTIS system uses the Dragonfly™ Duo Imaging Catheter [3] to capture near-infrared light images and measures important vessel characteristics otherwise invisible or difficult to assess with older imaging technology. The catheter offers faster, longer pull-backs, which allows the physician to assess more of the patient's artery in less time.

The wireless PressureWire™ Aeris™ [4] technology that is integrated into the platform measures pressure differences in blood flow within the coronary arteries leading to the heart, and determines the severity of any narrowings or blockages. Knowing which specific blockages are causing the patient's blood flow to be ineffective helps guide the interventional cardiologist to determine which lesions warrant stenting, resulting in improved patient outcomes and reduced health care costs.

The FFR and OCT measurements captured by the ILUMIEN OPTIS system allow physicians to more easily differentiate different types of plaque build-up and determine if the narrowed arteries are causing a restriction in blood flow (ischemia), ultimately assisting in stent placement. The automated stent planning tools provide immediate information for assessment and real-time analysis, which may streamline workflow and help physicians diagnose their patients more quickly.

"The advancements in the ILUMIEN OPTIS system continue to build on St. Jude Medical's leadership in providing innovative products that reduce health care costs and improve outcomes for patients battling coronary artery disease. This next-generation system is a scientific advancement that delivers critical information to

physicians about the location and severity of disease within the coronary arteries, potentially resulting in better medical decision-making and overall cost-effective treatment," said Frank J. Callaghan, president of the St. Jude Medical Cardiovascular and Ablation Technologies Division.

The benefits of St. Jude Medical's PressureWire FFR Measurement technology have been supported in a number of clinical trials, including the landmark FAME [5] and FAME 2 [6] studies. Results from the original FAME trial found that instances of major adverse cardiovascular events (MACE) were significantly reduced in patients whose treatment was guided by the company's PressureWire rather than by angiography alone. The FAME 2 study revealed that stenting guided by the St. Jude Medical PressureWire to address significant blood flow blockages along with medical treatment is better than medical treatment alone. Specifically, instances of hospital re-admission because of an urgent revascularization were reduced by 86 percent when the PressureWire was used. These results add to the growing body of evidence demonstrating improved patient outcomes and cost-savings with PressureWire-guided stenting.

Attendees can visit St. Jude Medical at booth 617 at TCT during exhibition hours on Oct. 29, 30 and 31. TCT is the annual scientific symposium of the Cardiovascular Research Foundation. TCT gathers leading medical researchers and clinicians from around the world to present and discuss the latest developments in the field.

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