St. Jude Medical RESPECT Trial for PFO Closure Provides Clinical Evidence of Risk Reduction in Prevention of Recurrent Cryptogenic Stroke

The Associated Press

ST. PAUL, Minn.--(BUSINESS WIRE)--Oct 25, 2012--St. Jude Medical, Inc. (NYSE:STJ), a medical device company, today announced results from its RESPECT trial, which studied the AMPLATZER™ PFO Occluder in the prevention of recurrent cryptogenic stroke. Evidence presented at a late breaking trial session during the 24 th Annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, sponsored by the Cardiovascular Research Foundation, shows that the primary analysis was not statistically significant but trended towards superiority, while additional analyses demonstrated superiority. Stroke risk reduction was observed across the totality of analyses with rates ranging from 46.6 percent - 72.7 percent.

According to the World Health Organization (WHO), an estimated 15 million strokes occur worldwide each year. In 2010, stroke cost the U.S. an estimated $53.9 billion in health care services, medications and missed days of work. Approximately 87 percent of all strokes are ischemic, which occur when blood clots block the blood vessels to the brain. Up to 40 percent of ischemic strokes are classified as cryptogenic, a stroke of unknown cause, and the prevalence of PFO is up to three times greater in this population.

Normal in a developing fetus, the foramen ovale allows oxygenated blood from the placenta to bypass the lungs. This small, flap-like opening typically closes shortly after birth. When this flap remains open, or patent, it is referred to as a PFO. A PFO can potentially allow dangerous clots to pass from the right side of the heart to the left, travel up to the brain and cause a stroke.

“The patient population affected by cryptogenic stroke tends to be relatively young and healthy. PFO closure with the AMPLATZER PFO Occluder is potentially a novel prevention strategy that may be superior to medications alone,” said Dr. John D. Carroll, director of the Cardiac and Vascular Center and Interventional Cardiology at the University of Colorado, who presented the data at TCT. “Stroke is a devastating disease and we now have compelling evidence that shows a 46 to 72 percent risk reduction in recurrent strokes, which is meaningful for this otherwise healthy patient population with a long life expectancy.” A prospective, randomized (1:1) event driven study, the RESPECT trial began in 2003 and enrolled 980 patients at 69 centers across the U.S. and Canada. All patients in the study suffered a stroke, confirmed by MRI imaging, which was ruled cryptogenic prior to participating in the trial. Participants were randomly assigned to one of two groups. One group received the AMPLATZER PFO Occluder and medical management, and the other group was treated using the current medical management standard of care alone, which consists of receiving medicine to prevent clots and potentially decrease the risk of another stroke. Enrollment was stopped once 25 primary events (stroke and all-

cause mortality) occurred. All patients were monitored at one month, six months, 12 months, 18 months, 24 months and annually thereafter. Patients enrolled in the trial will continue to be followed until a regulatory decision is made by the U.S. Food and Drug Administration (FDA).

“More than a third of these patients are likely to have another stroke over their lifetime. If we can cut that number in half, we’re making a significant difference in the lives of patients and their families,” said Dr. Jeffrey L. Saver, director of Stroke Center at UCLA and Professor of Neurology at David Geffen School of Medicine. “The totality of results from the RESPECT trial provides evidence that device therapy has clinically meaningful benefits for patients with a PFO and cryptogenic stroke who are at risk for recurrent stroke.” The RESPECT trial’s unique design assumed that both randomization and patient follow-up would be equal between the two arms for the duration of the study. During the trial, a difference in lost to follow-up between the two arms was observed and therefore, the raw count analysis (the intended primary endpoint analysis) was unduly biased. As a result, AGA Medical (now St. Jude Medical) disclosed to the FDA this unequal bias while still blinded to the primary endpoint data and reiterated that final analysis would include three additional, protocol-specified analyses.

The protocol-specified analyses performed on the data included the raw count analysis and three Kaplan Meier (time-to-event) analyses, the results of which are summarized below.

Intent-to-Treat (ITT) – Raw Count analyses Patients were counted to the arm they were randomized to, regardless of receiving treatment. This assumes a similar study population was maintained in each arm, but because the populations are different, this analysis is no longer valid. 46.6 percent risk reduction of stroke in favor of device (p = 0.131) Intent-to-Treat – Kaplan Meier (KM) analyses A KM analysis adjusts for any drop out differential between study arms to more accurately compare the two outcomes over time. Patients were included based on the arm they were randomized to, regardless of receiving treatment. 50.8 percent risk reduction of stroke in favor of device (p = 0.089) Per Protocol (PP) analyses Patients were analyzed according to whether the study treatment protocol was followed, e.g. inclusion / exclusion criteria, medical management protocol, etc. 63.4 percent risk reduction of stroke in favor of device (p = 0.034) As Treated (AT) analyses Patients were analyzed as to whether they actually received the treatment, e.g. device vs. medical therapy only. 72.7 percent risk reduction of stroke in favor of device (p = 0.007) “We are pleased with the results of the RESPECT trial and remain confident in the safety and performance of the AMPLATZER PFO Occluder and the strength of our clinical trial design,” said Frank J. Callaghan, president of the St. Jude Medical Cardiovascular and Ablation Technologies Division. “St. Jude Medical is committed to providing the clinical research needed to help physicians improve care for their patients.” About TCT The Cardiovascular Research Foundation (CRF) is an independent, academically focused nonprofit organization dedicated to improving the survival and quality of life for people with cardiovascular disease through research and education. Since its inception in 1991, CRF has played a major role in realizing dramatic improvements in the lives of countless numbers of patients by establishing the safe use of new

technologies, drugs and therapies in interventional cardiovascular medicine.

Transcatheter Cardiovascular Therapeutics (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.

About St. Jude Medical St. Jude Medical develops medical technology and services that focus on putting more control into the hands of those who treat cardiac, neurological and chronic pain patients worldwide. The company is dedicated to advancing the practice of medicine by reducing risk wherever possible and contributing to successful outcomes for every patient. St. Jude Medical is headquartered in St. Paul, Minn. and has four major focus areas that include: cardiac rhythm management, atrial fibrillation, cardiovascular and neuromodulation. For more information, please visit www.sjm.com.

Forward-Looking Statements This news release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties. Such forward-looking statements include the expectations, plans and prospects for the Company, including potential clinical successes, anticipated regulatory approvals and future product launches, and projected revenues, margins, earnings and market shares. The statements made by the Company are based upon management’s current expectations and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks and uncertainties include market conditions and other factors beyond the Company’s control and the risk factors and other cautionary statements described in the Company’s filings with the SEC, including those described in the Risk Factors and Cautionary Statements sections of the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2011 and Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2012. The Company does not intend to update these statements and undertakes no duty to any person to provide any such update under any circumstance.

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