Results of St. Jude Medical's RESPECT Trial Published in The New England Journal of Medicine

The Associated Press

ST. PAUL, Minn.--(BUSINESS WIRE)--Mar 20, 2013--St. Jude Medical, Inc. (NYSE:STJ), a global medical device company, today announced publication of results from its landmark RESPECT trial in The New England Journal of Medicine. The study results show that device closure using the AMPLATZER™ PFO Occluder is superior to antiplatelet medications or warfarin in preventing recurrent cryptogenic stroke (a stroke from an unknown cause) in patients with a common heart defect called a patent foramen ovale (PFO), as measured in the prespecified per-protocol and as-treated patient cohorts of the trial. Patients in the study had a 51 to 73 percent risk reduction in recurrent strokes when evaluated across prespecified measures.

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. Studies show that nearly half of all people who suffer a cryptogenic stroke also have a PFO.

“The results of this landmark study are clinically important as we continue to search for solutions for young and middle-aged patients with a long-life expectancy, who are at risk of having a second stroke. The RESPECT trial data shows device closure with the AMPLATZER PFO Occluder, in carefully selected patients, is quite safe, effective in closing the PFO, and lowers the risk of recurrent stroke in two of the three patient cohorts,” said Dr. John D. Carroll, director of the Cardiac and Vascular Center and Interventional Cardiology at the University of Colorado Hospital and lead author of the journal article. “The reduction in stroke achieved in the PFO-closure group exceeds that of several well-established pharmacologic treatments for the prevention of secondary strokes.” Conducted over the course of eight years at 69 medical centers in the U.S. and Canada, the RESPECT study followed 980 participants who had suffered a cryptogenic stroke that was confirmed by stroke neurologists using routine imaging technologies. The average age of the patients in this trial was 46-years old. The trial was a prospective, controlled, randomized (1:1) study in which patients were randomly assigned to either the device group or the medical group. The primary efficacy endpoint was defined as the composite rate of recurrent nonfatal stroke, fatal ischemic stroke or death after randomization. Enrollment was stopped once 25 events occurred, all of which were non-fatal recurrent stroke, as measured across all patients in the study.

Patients in the device group underwent a procedure in which their PFO was closed with the Amplatzer PFO Occluder followed by six months of medication therapy. In the medical group, four standard-of-care medical therapy regimens were used throughout the study: aspirin, warfarin, clopidogrel and aspirin combined with

extended release dipyridamole.

Analyses were conducted on the intent-to-treat population, which included all patients according to the group to which they were randomly assigned, though some patients in the device group did not receive the randomized treatment. A difference in the dropout rate between the medical therapy group and the device group challenged the validity of the primary intent-to-treat raw count analysis, which did not meet statistical significance. Using the same intent-to-treat cohort in a time-to-event analysis demonstrated a risk reduction of greater than 50 percent, which trended towards statistical superiority with a p-value of 0.08.

The study protocol also prespecified that if dropout rates differed significantly between the medication and device groups that analyses of two additional cohorts would be evaluated. These included: Per-protocol cohort – patients who received the randomly assigned treatment and adhered to the protocol-mandated medical treatment As-treated cohort – patients who received and adhered to a protocol-approved treatment and were classified according to the treatment they actually received Device closure was superior to medications alone in these two prespecified analyses with a low rate of associated risks. There were no statistically significant differences in the incidence of any serious adverse event between the two groups.

“The analysis of the data from patients in the per-protocol group and the as-treated group provide compelling evidence that PFO closure with the AMPLATZER PFO Occluder is superior to medical management from both clinical and statistical perspectives,” said Frank J. Callaghan, president of the St. Jude Medical Cardiovascular and Ablation Technologies Division. “The totality of evidence from this study, including the strong performance and safety profile of the device, demonstrates the compelling clinical benefits of closure versus medical management in reducing the likelihood of recurrent stroke in this patient population.” According to the World Health Organization (WHO) an estimated 15 million people worldwide suffer from stroke each year. Of these, 5 million die and another 5 million are left permanently disabled, placing a burden on families and communities. It is estimated that 87 percent of all strokes are ischemic strokes, which occur when blood clots block the blood vessels to the brain. Up to 40 percent of ischemic strokes are classified as cryptogenic, which means the cause of the stroke is unknown.

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 sjm.com.

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