Data from St. Jude Medical RESPECT Trial for PFO Closure Highlighted at International Stroke Conference 2013

The Associated Press

ST. PAUL, Minn.--(BUSINESS WIRE)--Feb 8, 2013--St. Jude Medical, Inc. (NYSE:STJ), a global medical device company, today announced the presentation of additional data from its landmark RESPECT trial at the American Stroke Association's International Stroke Conference 2013 in Honolulu. The RESPECT trial evaluated whether closing an opening in the heart, called a patent foramen ovale or PFO, with the AMPLATZER ™ PFO Occluder lowered the patient's risk of having another stroke.

"Data from the RESPECT trial indicates that patients with a device were less likely to suffer stroke, had smaller strokes, and were less likely to have the type of stroke linked to paradoxical embolism," said Dr. Jeffrey L. Saver, director of the UCLA Stroke Center and professor of Neurology at the David Geffen School of Medicine. "Indications of preventing strokes on the surface of the brain and large strokes provide additional evidence of a genuine biological effect of closure with the AMPLATZER PFO Occluder in preventing recurrent cerebral infarcts due to a blood clot crossing through the PFO." An ischemic stroke occurs when a blood clot blocks a vessel, interrupting blood flow to an area of the brain (the other type of stroke is hemorrhagic, which occurs when a blood vessel in the brain ruptures). When a blood clot blocks a vessel, brain cells begin to die and brain damage can occur. The origin of the blood clot can impact where it becomes lodged in the brain, thereby creating strokes in different areas. A paradoxical embolism occurs when a blood clot travels from the right side of the heart to the left side of the heart, often through a PFO, and can then travel directly to the brain, causing an ischemic stroke. Statistics from the World Health Organization show an estimated 15 million strokes occur worldwide each year, of which approximately 80 percent are ischemic.

The purpose of analyzing these additional data from the RESPECT trial was to determine if patients in the device and medical therapy group suffered different types of recurrent strokes, and to identify the potential origin of the strokes. The results confirm that patients with a device in place were less likely to suffer another stroke and patients in the medical group experienced larger strokes. PFO closure with the AMPLATZER PFO Occluder demonstrates clinical evidence of risk reduction and is an important option for the prevention of recurrent stroke in carefully selected patients over conventional medical management alone.

"The overall trial demonstrates that PFO closure with the AMPLATZER PFO Occluder for these relatively young, otherwise healthy patients substantially reduces their risks of suffering another stroke," said Frank J. Callaghan, president of the St. Jude Medical Cardiovascular and Ablation Technologies Division.

About PFO and the RESPECT Trial 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 the 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.

Visit the St. Jude Medical website for more information.

The was a prospective, randomized (1:1), event driven-study designed to determine if PFO closure with the AMPLATZER PFO Occluder plus medical management was superior over medical management alone in the prevention of recurrent cryptogenic (unknown cause) stroke. The study enrolled 980 patients across 69 centers in the U.S. and Canada. Enrollment in the trial stopped once 25 primary events occurred, all of which were recurrent, non-fatal strokes. Of the 25 strokes, nine were in patients randomized to the device group. It’s important to note that three of the nine strokes in the device group occurred in patients who didn’t have a device in place.

Prior to participating in the trial, all patients, ages 18 – 60 (average age was 46 years), suffered a stroke confirmed by MRI imaging, which was ruled cryptogenic. 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. 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).

The primary efficacy endpoint in the RESPECT trial was defined as a composite rate of non-fatal stroke, post-randomization (<45 days) death or fatal ischemic stroke. Four protocol-specified analyses were applied to the primary efficacy endpoint data to statistically test whether device treatment was superior to medical management.

The trial’s original primary endpoint was a 75 percent reduction in the risk of recurrent ischemic stroke in the Intent-To-Treat (ITT) population driven by a raw count distribution of stroke events between the device and medical groups. This was determined to be invalid because of a difference in the number of patients lost to follow-up in each arm of the trial. Of the three valid protocol-specified analyses, the Intent-to-Treat Kaplan-Meier analysis demonstrated risk reduction that did not reach statistical significance, while the other two analyses (Per-Protocol and As-Treated) demonstrated clinically impactful and statistically significant benefits of PFO closure compared to medical management.

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.

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