St. Jude Medical's Peripheral Nerve Stimulation Study Confirms Benefit for Chronic Migraine Patients

The Associated Press

ST. PAUL, Minn.--(BUSINESS WIRE)--Oct 3, 2012--St. Jude Medical, Inc. (NYSE:STJ), a global medical device company, today announced publication of results from the first large-scale study of peripheral nerve stimulation (PNS) of the occipital nerves in patients suffering from chronic migraine. The study results, published online by Cephalalgia the journal of the International Headache Society, show a significant reduction in pain, headache days and migraine-related disability.

Conducted at 15 medical centers in the U.S., the study followed 157 participants who, on average, suffered from headache approximately 21 days per month. At 12 weeks, patients receiving PNS therapy reported an average of six fewer headache days a month.

Additional key findings at 12 weeks were as follows: 43 percent improvement in overall disability scores, as measured using the Migraine Disability Assessment questionnaire (MIDAS) 53 percent of the patients ranked their relief as excellent or good Patients reported a 42 percent improvement in pain relief “One of the primary reasons that patients seek therapy is to try to find a way to lessen the number of days they experience migraine,” said Stephen D. Silberstein, M.D., past president of the American Headache Society, director of the Jefferson Headache Center, and the principal investigator in the study. “For the millions who suffer from chronic migraine, these study results are important, as they confirm that peripheral nerve stimulation (PNS) of the occipital nerve may help improve their quality of life and lessen the number of days per month they suffer with this debilitating condition.” PNS therapy for this condition involves the delivery of mild electrical pulses to the occipital nerves that are located just beneath the skin at the back of the head. A small electrical lead or leads are placed under the skin and connected to a neurostimulator, which produces pulses of stimulation.

In this prospective, randomized, controlled study, participants were implanted with the St. Jude Medical Genesis™ neurostimulator and randomly assigned to an active or control group for 12 weeks. The active group received stimulation immediately upon implantation, while patients in the control group did not receive stimulation until after the first 12 weeks. Both the investigators and the patients were blinded to treatment.

Although statistical significance was demonstrated across most measures, it was not observed for the primary endpoint (defined as the difference in the percentage of patients in the active group versus control who achieved 50 percent or greater pain reduction at 12 weeks). However, patients in the active group were more likely than control patients to experience 30 percent or greater pain reduction, which is

considered clinically meaningful.

“When this study was initially designed, the primary endpoint was based on a reduction in pain, which at the time was the standard measurement for neurostimulation studies,” said, Dr. Mark Carlson, chief medical officer and senior vice president of research and clinical affairs for the St. Jude Medical Implantable Electronic Systems Division. “However during the course of the study, many neurologists began to recognize reduction in the number of headache days as a more significant improvement in patient quality of life than the measurement of pain reduction alone.” The most common adverse event was persistent pain and/or numbness at the implant site, followed by lead migration. The majority of adverse events were classified as mild or moderate in severity.

Preliminary data from this study was presented at the International Headache Congress (IHC) in 2011. The Genesis neurostimulation system used in this study is approved in Europe and Australia for the management of the pain and disability associated with intractable chronic migraine.

About Chronic Migraine Chronic migraine is a disabling neurological disorder that can last for hours or days at a time. The World Health Organization (WHO) estimates that 1.7 to 4 percent of adults have headache on more than 15 days per month. Compared with people who periodically experience migraine headache, individuals with chronic migraine experience significantly greater disability, economic burden, and impairments in health-related quality of life. According to the the total annual cost attributed to migraine amounts to €111 billion in the EU.

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.

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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