St. Jude Medical, Inc.
Global Headquarters
One St. Jude Medical Drive
St. Paul, MN 55117-9913 USA
Tel 651 756 2000
www.sjm.com

News Release

CONTACTS:

J.C. Weigelt
Investor Relations
Tel 651 756 4347
jweigelt@sjm.com

Denise Landry
Media Relations
Tel 972 309 8085
dlandry@sjm.com

St. Jude Medical Announces European Regulatory Approval of First Implanted Neurostimulation Device to Treat Chronic Migraine

CE Mark approval expands treatment options for patients suffering from the pain and disability associated with intractable chronic migraine

ST. PAUL, Minn. – Sept. 7, 2011 – St. Jude Medical, Inc. (NYSE:STJ), a global medical device company, today announced it has received the industry's first and only regulatory approval for the use of an implanted neurostimulation device for patients with intractable chronic migraine. The company received European CE Mark approval for its Genesis™ neurostimulation system for peripheral nerve stimulation (PNS) of the occipital nerves for the management of the pain and disability associated with intractable chronic migraine. This type of migraine is defined as headache lasting at least four hours per day for 15 or more days per month, causing at least moderate disability, and not responding to three or more preventive drugs.

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 the neurostimulator which produces the pulses of stimulation.

"As a professor and practicing neurologist who works with these patients on a daily basis, I see firsthand the challenges they face in trying to manage their pain and disability and how chronic migraine impacts their lives and their families," said Dr. Stephen D. Silberstein, past president, American Headache Society, director of the Jefferson Headache Center, and the principal investigator in a recent St. Jude Medical chronic migraine clinical trial. "Through my participation in this study, I have observed the life-changing potential this therapy offers chronic migraine patients."

The CE Mark approval was supported by the results of St. Jude Medical's chronic migraine study, a randomized, double-blind, controlled study that collected data from 157 patients. On average, participants enrolled in the study suffered from headache 26 days per month.

The largest clinical study to date evaluating PNS to treat chronic migraine utilized various measures including the Migraine Disability Assessment (MIDAS) questionnaire, subjective assessment scales and daily patient diaries to report headache intensity, frequency, duration and medication use. At 12 weeks, patients in the active group reported an average of seven fewer headache days a month as measured by the MIDAS questionnaire compared to only a one day per month decrease in the control group (non-stimulation group). In addition, overall disability as measured by MIDAS demonstrated that participants in the active group showed a 41% improvement after 12 weeks of stimulation, compared to a 13% improvement in the control group.

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Results at one year included:

- 65 percent of patients reported excellent or good pain relief
- 88 percent said they would recommend the procedure to someone else
- 68 percent of patients expressed that their quality of life had improved
- 67 percent were satisfied or very satisfied with the results of their procedure

Results of the major study endpoints were presented in abstract and poster format at the International Headache Congress in Berlin in June 2011. Study data will be submitted for publication in medical journals later this year and early 2012.

"This CE Mark is the first approval by a regulatory body for the use of neurostimulation to manage the debilitating symptoms of intractable chronic migraine and provides a new option for patients who have generally exhausted all other treatment options," said Chris Chavez, president of the St. Jude Medical Neuromodulation Division. "For more than six years we have worked with our investigators to develop and evaluate this life-changing therapy. We will continue to work with regulatory authorities to secure approvals in order to offer this therapy option to patients throughout the world."

About Migraine

Migraine is a neurological disorder characterized by a number of specific symptoms that can last for hours or days at a time. The severity of each migraine attack can vary widely, with typical symptoms ranging from sensitivity to light, noise and motion, to nausea and vomiting in addition to headache. In general, chronic migraine sufferers have progressed to the level where they have migraine or migraine-like symptoms on more days than they are migraine free. Estimates by the World Health Organization (WHO) indicate that 10 percent of adults worldwide suffer from migraine, and 1.7 to 4 percent of adults have headaches 15 or more days per month. In fact, migraine ranks as one of the top 20 most disabling conditions in the world, according to WHO. For more information about PNS for intractable chronic migraine, visit www.MigraineAnswers.co.uk.

Three Decades of Leading-Edge Neurostimulation Technology

For more than 30 years, the St. Jude Medical Neuromodulation Division has developed new technologies to treat chronic pain and other neurological disorders. Today more than 75,000 patients in 40 countries have been implanted with St. Jude Medical neurostimulation systems. Focused on research, St. Jude Medical is developing new technologies to address a growing list of neurological disorders. Additional clinical studies are currently underway for Parkinson's disease, essential tremor, major depressive disorder, and other significant indications.

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

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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 January 1, 2011 and Quarterly Report on Form 10-Q for the fiscal quarter ended July 2, 2011. The Company does not intend to update these statements and undertakes no duty to any person to provide any such update under any circumstance.