

St. Jude Medical Receives European CE Mark Approval of Eon Mini Neurostimulator, the World's Smallest Rechargeable Device to Treat Chronic Migraine

The Associated Press

ST. PAUL, Minn.--(BUSINESS WIRE)--Sep 20, 2012--St. Jude Medical, Inc. (NYSE:STJ), a global medical device company, today announced it has received European CE Mark approval of its Eon™ family of neurostimulators for patients with intractable chronic migraine. Unveiled at the European Headache and Migraine Trust International Congress in London, this approval includes the Eon Mini™ neurostimulator, which is the world's smallest rechargeable neurostimulator with the longest-lasting battery in its class, and the Eon and Eon C™ neurostimulators. Preceding the Eon family approvals, the company received European CE Mark for its Genesis™ neurostimulation system, the industry's first regulatory approval for an implanted neurostimulation device to treat patients with intractable chronic migraine.

"Intractable chronic migraine is one of the most difficult-to-treat headache disorders," said Professor Gennaro Bussone, M.D., head of the Neurological Department at Istituto Besta in Milan Italy. "By definition, people living with this condition are spending half their month living with debilitating headaches. This therapy expands our options in helping manage patients who suffer with disabling chronic migraine symptoms." The Eon and Genesis systems deliver peripheral nerve stimulation (PNS) of the occipital nerves to manage 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 in 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.

Prior to receiving these approvals, St. Jude Medical conducted a large scale double-blind, randomized, controlled clinical study evaluating PNS to treat the pain and disability associated with chronic migraine. After 12 weeks of stimulation, patients reported an average of six fewer headache days a month. After one year of stimulation, 65 percent of patients reported excellent or good pain relief and 89 percent said they would recommend the procedure to someone else. Study data were presented at the International Headache Congress in 2011 and have been accepted for publication.

"Neurostimulation technology represents an exciting new approach to treat intractable chronic migraine," said Eric S. Fain, M.D., president of the St. Jude

Medical Implantable Electronic Systems Division. “We are proud to be able to offer this potentially life-changing therapy for patients who suffer with this debilitating condition and so desperately need a more effective treatment option.” Eon Mini Neurostimulator Approximately the size of a man’s watch, the rechargeable Eon Mini neurostimulator has a thin 10-mm profile and weighs 29 grams (approximately 1.0 oz). Its small size allows for a smaller incision, which gives physicians increased flexibility in selecting the implant location and is intended to make the site less visible and more comfortable for patients.

Eon Neurostimulator Featuring a rechargeable battery, the Eon neurostimulator is designed to provide stimulation over a long period of time, making it a good choice for patients who require high-power stimulation settings and need to use the system for a large percentage of the day. The Eon device can provide sustainable therapy and maintain a reasonable recharge interval for 10 years, potentially resulting in fewer battery replacement surgeries.

Eon C Neurostimulator The Eon C neurostimulator provides a convenient option for patients who prefer or require the simplicity of a non-rechargeable medical device. The device features the greatest battery capacity of any primary cell neurostimulator.

St. Jude Medical’s neurostimulators are the only fully implantable neurostimulation devices approved in Europe for the management of the pain and disability associated with intractable chronic migraine. They are also approved in many countries for the management of chronic pain of the trunk and limbs.

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. In terms of monetary cost, it has been estimated that migraine headache is one of the most expensive neurological disorders. According to the the total annual cost attributed to migraine amounts to €111 billion in the EU. For more information about PNS for intractable chronic migraine, visit www.MigraineAnswers.co.uk.

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

St. Jude Medical Receives European CE Mark Approval of Eon Mini Neurostim

Published on Medical Design Technology (<http://www.mdtmag.com>)

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.

Photos/Multimedia Gallery Available: <http://www.businesswire.com/cgi-bin/mmg.cgi?eid=50411389&lang=en>

CONTACT: St. Jude Medical, Inc.

J.C. Weigelt, 651-756-4347 Investor Relations jweigelt@sjm.com or Denise Landry, 972-309-8085 Media Relations dlandry@sjm.com KEYWORD: UNITED KINGDOM UNITED STATES EUROPE NORTH AMERICA MINNESOTA INDUSTRY KEYWORD: HEALTH MEDICAL DEVICES RESEARCH SCIENCE MANAGED CARE SOURCE: St. Jude Medical, Inc. Copyright Business Wire 2012 PUB: 09/20/2012 04:01 PM/DISC: 09/20/2012 04:01 PM <http://www.businesswire.com/news/home/20120920006368/>

Source URL (retrieved on 01/28/2015 - 4:27pm):

http://www.mdtmag.com/news/2012/09/st-jude-medical-receives-european-ce-mark-approval-eon-mini-neurostimulator-world%E2%80%99s-smallest-rechargeable-device-treat-chronic-migraine?qt-video_of_the_day=0